BERGESON & CAMPBELL, P.C.

Predictions and Outlook for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) 2015

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FORECAST 2015

2015 will be a very interesting year. There are two overarching considerations that will make the year more difficult to predict than merely assuming most of this year's issues will simply be extensions of past issues, with a few new initiatives sprinkled in. First, the new Republican majority in the Senate will change the dynamic between the Executive and Legislative branches. Second, the Obama Administration will begin its lame duck status as it enters the last two years of office. Corollary to the end of the Obama Administration is the jockeying for the 2016 Presidential election that also begins now. The Iowa Presidential caucus is, after all, only a little more than a year away. We can expect the year to be full of Congressional oversight hearings, candidate jockeying, and a focus on various "legacy issues" as those transitioning put effort into finishing or attaining objectives set out earlier in the Administration.

Most of the high profile fireworks, even in the chemical policy space, will not directly involve the regulation of chemicals and pesticides. High profile activities will center on climate change policies and initiatives, and attempts to hinder or foster them. At the same time, for the Office of Chemical Safety and Pollution Prevention (OCSPP), we can expect serious consideration of legislative amendments to the Toxic Substances Control Act (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

Most observers expect the recent trend of bitter partisan rancor to continue in Congress, but the presence of a Republican majority on both sides of Capitol Hill will allow for more hearings and generally more hostile oversight of U.S. Environmental Protection Agency (EPA) activities. Ironically, one exception to this presumption might be that the chances of significant TSCA legislative amendments may have actually increased due to change in party control in the Senate. The change in leadership of the Senate Environment and Public Works (EPW) Committee from Sen. Boxer (D-CA) to Sen. Inhofe (R-OK) might increase the possibility of legislation in the Senate. Sen. Boxer was critical of past attempts at bipartisan TSCA proposals, as she expressed concern with any language affecting the possible preemption of state authority, a sensitive issue in California. These concerns will remain, and the President will still have veto power over any legislation that makes it through Congress, so no successful legislation is assured. TSCA is discussed more below, but early signs of potential for compromise legislation may come early in the New Year.

Even assuming an early honeymoon period, oversight of EPA activities in the House and by the Senate is expected to be robust. Late in the year, incoming House Oversight and Government Reform Committee Chair Jason Chaffetz (R-UT) announced his decision to create a new Subcommittee to focus on the Obama Administration's policies on the environment and energy. Senate EPW Chair Inhofe's oversight is expected to be equally intense. This will extend the climate change debate, where Sen. Inhofe is on the record as opposing EPA initiatives and rulemakings. But with the Senate in Republican hands, some issues that have seen attention in the House Committees with no parallel action in the Senate may be taken up.

These would include criticism of current EPA science assessment policies, "over-regulation" generally, and some focus on the Clean Water Act (CWA) rules. "WOTUS" -- the waters of the U.S. rule -- will be scrutinized, especially as the Administration has stated it would like to issue its highly controversial rule in final in 2015.

The pesticide program will also see more scrutiny in the Senate. The new Chair of the Agriculture Committee, Sen. Pat Roberts (R-KS), is a past Chair of the Committee in both the House and the Senate, and had a leading role in enactment of the Food Quality Protection Act (FQPA). Chair Roberts' extensive experience with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and familiarity with pesticide regulatory issues might lead to more intense questioning concerning program decisions and priorities. The two most controversial issues for pesticides concern the Endangered Species Act (ESA) and restrictions on pesticide use to avoid impacts on honeybees and other pollinators. The pesticide industry is also expected to raise the issue of how EPA pesticide program decisions seem to be affected by actions outside of FIFRA. ESA is an obvious example of where some registration decisions appear to be driven more by non-FIFRA considerations than by FIFRA requirements. The continued requirement for National Pollutant Discharge Elimination System (NPDES) permits for certain pesticide applications is another example. With a Senate Republican majority, there is discussion of whether there is a possibility of legislatively relaxing the requirement for permits provided FIFRA requirements are met. The House Committee also has a new Chair, Rep. Michael Conaway (R-TX), and he also is expected to raise similar oversight issues regarding the implementation of FIFRA, ESA, NPDES, and related issues.

BUDGET

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

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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 "reign-in EPA," a popular agenda item for some of the more conservative members of Congress.

EPA has planned cuts in personnel allotments, even if budget dollars are available, to substitute contractor support for some level of permanent staffing positions. This would allow more budget flexibility in the future for insulation against future budget reductions. Under the current mix of contractor and personnel dollars, even small cuts can have disproportionate impacts on personnel ceilings and workforce planning. Retirements and budget cutbacks could lead to skills-mix personnel issues and a general loss of institutional knowledge and history.

For the pesticide industry, budget concerns and personnel reductions are already stretching 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 unforeseen ESA issues, and now the issue of pollinator protection has added to the evaluation timelines for insecticides. Deadlines for decisions in many cases have slipped and required PRIA extensions to the point where it may become a matter of Congressional concern, possibly triggering an oversight hearing.

Confirmation of EPA nominees can be expected to challenge the Obama Administration. Among the positions expected to pose challenges are Janet McCabe, the nominee to be Assistant Administrator for the Office of Air and Radiation, and Ken Kopocis, the nominee to be Assistant Administrator for the Office of Water. In addition, there are at least half a dozen senior position vacancies at EPA awaiting Senate action. Positions include the Assistant Administrator for International and Tribal Affairs, Assistant Administrator for the Office of Research and Development, Chief Financial Officer, and Assistant Administrator for Environmental Information.

PROSPECTS FOR TSCA LEGISLATION

The change in leadership of the Senate EPW Committee from Sen. Boxer to Sen. Inhofe might increase the possibility of TSCA legislation in the Senate. This is because Sen. Boxer was critical of past attempts at bipartisan TSCA proposals, based largely on her stated concerns with TSCA's preemptive effect on California programs. More importantly, however, is that late in the session, compromise drafts of TSCA amendments were circulated, drafts that reflected significant movement towards possible compromise legislation.

Specifically, in October 2014, there was circulation of a draft compromise bill attributed as a joint bill endorsed by Sen. Udall (D-NM) and then ranking member Sen. Vitter (R-LA). For a detailed description and analysis, see Bergeson & Campbell, P.C.'s (B&C®) web page, "TSCA Reform News & Information." There were some rhetorical fireworks associated with who really endorsed what text, who leaked the draft compromise, and other now irrelevant details. The text of the draft, of particular note, appeared to be a serious

attempt to accommodate the concerns of the many constituencies that at various times had criticized earlier drafts. This is noteworthy as there have been almost a dozen past bills circulated since the principal parties, including the Administration, the chemical industry, and some non-governmental organization (NGO) groups, had announced broadly consistent "principles" for reform legislation in 2009. Getting down to the particulars has been a frustrating exercise for participants and observers alike.

The October draft did not solve all problems. For example, the state preemption issue remains a large hurdle, and it will remain so for 2015. This latest draft addresses most of the significant concerns raised about deadlines, the risk standard, testing requirements and priorities, confidential business information (CBI), and other key issues.

As such, the October draft provides a new and improved template to serve as the basis for continued efforts to find a response, if not a resolution, to various complaints voiced about earlier drafts. While any new session of Congress starts with a clean slate, and any agreement from past years is non-binding, the October draft is significantly friendlier towards the various environmental group critiques of past efforts. This does not mean that all interest groups will be satisfied, and if success seems near, often new demands are made by various players for any number of different reasons. What is most promising is that if the draft language appears agreeable to the chemical industry supporters of TSCA reform, it will be a milestone in negotiations, as this draft contains numerous concessions that have been previously absent. This is what makes the new proposal so tantalizing, as it represents a significant breakthrough from previous incantations of agreeing in principle with relatively little follow-through.

LEGACY ISSUES

Just as 2015 signifies the beginning of the 2016 Presidential election race, it also begins a time for the current Administration to consider what will be part of the legacy of its time in office. For environmental matters, actions to address climate change are an explicit part of that desired legacy. Outside of the air program arena, however, each media program and its leadership will have similar desires or goals for the final two years. For OCSPP, no explicit mention has been made of such a list; one can readily speculate that in keeping with broad themes over the past six years, any list would include achievements in the areas of environmental justice, green product development, more transparent decision-making, and progress in assessing industrial chemicals.

Whatever is on this list of legacy concerns, 2015 will be an important year for securing achievements, as 2016 will likely be consumed by Presidential politics and partisan jockeying. This might lead to an emphasis, for example, on completing the worker protection standard or completing the design of any computational toxicology approach, as well as establishing precedents for ways to add protections to prevent or

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reduce bystander risk, and procedures for more public participation in decision-making. These are obviously speculations, but legacy concerns are real at this point in a two-term Administration.

THE OCSPP BRAIN DRAIN

OCSPP, along with other parts of EPA, is slated to complete a staff buyout/early retirement process in early 2015. Reportedly, OCSPP is targeting over 100 staff. We have already seen a significant exodus as experienced, talented professionals leave EPA, and more are expected. After years of speculation as to when the Office of Pollution Prevention and Toxics (OPPT) would see a significant outflow of institutional talent from among its many "retirement-eligibles," it looks like that time is nigh. Based on reports of retirement parties, OPPT is slated to lose a number of its most senior toxicologists, chemists, and others. How and whether the Office can recover from these departures is likely to be an important issue for 2015 and beyond.

PREDICTIONS FOR OPPT IN 2015

Our Predictions report for 2014 noted that "with three years to go in the Administration, OPPT needs actually to complete key actions rather than make new commitments." What can be said about the past year and the next two years in this regard? Looking at the Fall 2013 Regulatory Agenda, of the 18 items listed (many of which had been listed for years), some progress was realized; actions were taken on two items, while 13 were carried over to the Fall 2014 Regulatory Agenda as open items (with revisions in some cases), and three disappeared entirely. In one instance, EPA issued a proposed rule not reflected in the 2014 Agenda (a Significant New Use Rule (SNUR) on nonylphenols (NP) and nonylphenol ethoxylates (NPE)). In addition, three new items were added.

Perhaps action will be forthcoming in 2015 on several "long in the tooth" SNURS (including final rules on polybrominated diphenylethers (PBDE) and hexabromocyclododecane (HBCD), among others), as well as the existing chemicals nanoscale materials Section 8 reporting rule. Others to watch for include an important proposed SNUR on long chain perfluorinated chemicals; a SNUR on 2,4-toluene diisocyanate, 2,6-toluene diisocyanate, and unspecified forms of toluene diisocyanate (TDI); and several rules relating to formaldehyde emissions standards for composite wood products.

Late in the year, on December 29, 2014, EPA published a final rule adding nine benzidine-based chemical substances to the existing SNUR on benzidine-based chemical substances, and, with respect to both the newly-added and previously-listed benzidine-based chemical substances, makes inapplicable the exemption relating to persons that import or process the substances as part of an article. The final rule also includes a SNUR for di-n-pentyl phthalate (DnPP) and a SNUR for chloroalkanes, C12-13. The final rule is notable for the way that it applies to imported articles containing any of the benzidine-based chemicals. EPA has been working in selected cases to make inapplicable the 40 C.F.R. Section 721.45(f) article exemption that otherwise applies to SNURs. The first such recent final SNUR was issued in October 2013 for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances that, among other provisions, designates import of LCPFAC chemical substances as part of carpets as a significant new use. The current action on benzidine-based chemicals is broader in that it is not limited to certain articles and for this reason is precedential. Given EPA's clear interest in more broadly applying SNURs to imported articles, more on this issue can be expected in 2015. More information is available in B&C's December 19, 2014, memorandum, "TSCA -- EPA Signs Final SNURs and Signals Narrowing of Article Exemption."

Another important action not listed in the 2014 Agenda concerns EPA's next steps on chemicals used in "fracking"; this was the subject of an Advance Notice of Proposed Rulemaking (ANPR) in 2014. EPA is reportedly sorting through several thousand comments that came in at the end of September 2014.

Some important progress was made on the Chemicals Work Plan effort in 2014 when OPPT issued the program's first final risk assessments for four chemicals: two were found to present risks and were identified for further action, while for two others, after an involved public peer review process, OPPT concluded there were no concerns identified. More information is available in B&C's September 2, 2014, memorandum, "EPA Releases Final Risk Assessments for Three TSCA Work Plan Chemicals."

- OPPT also issued a 2014 update to the original 2012 Work Plan, which had the net effect of growing the list from 83 to 91 entries. More information is available in B&C's October 23, 2014, memorandum, "TSCA Work Plan for Chemical Assessments: EPA Adds and Removes Chemicals Based on New Data." While the issues associated with starting a new effort (particularly on existing chemicals under TSCA) are challenging, having issued in final a few assessments, 2015 will be a key year for OPPT to demonstrate significant progress via its Work Plan approach. According to information on OPPT's website, it is currently working on nine assessments, five of which involve multi-chemical groups, with four started in 2012, four in 2013, and one in 2014.

- The 2012 Work Plan applied a process that focused on peer reviewed risk assessments of Work Plan chemicals. In an October 23, 2014, update to the web page on Work Plan assessments, OPPT's approach seems to have shifted to a process that will give greater emphasis to the initial problem formulation step before jumping into the risk assessment. This shift may have been developed as a way to short circuit the time- and resource-expensive approach taken in the initial Work Plan assessments. This approach included external public peer reviews for two cases where both the initial and peer reviewed conclusions indicated negligible risks for the uses examined. This may well be a pragmatic way to increase throughput while conserving valuable assessment resources.

RCC INITIATIVE

On December 3, 2014, the Regulatory Cooperation Council (RCC) held a webinar concerning its consultation on chemicals management work plans. EPA, Environment Canada, and Health Canada are working together in the areas of significant new activities (SNAc)/SNURs and chemical risk assessments. Stakeholders were urged to indicate interest by December 31, 2014, in participating in one or both of the technical working groups discussed during the webinar (i.e., SNAC/SNUR and risk assessment collaboration). The initiative has an aggressive timeframe for the risk assessment Work Plan:

- Provide input on selection of common priority/priorities (**March 2015** to **June 2015**);

- Collaborate in information gathering activities, e.g., provide data on quantities and use patterns for selected common priority/priorities (**October 2015** to **October 2016**); and

- Participate in multi-stakeholder technical working group formed to contribute to exercise on collaboration on a common priority (**March 2015** to **October 2016**).

The much anticipated TSCA rulemakings on existing chemical nanoscale materials were not issued in 2014 as EPA clarified late in the year that it withdrew the combined SNUR and TSCA Section 8 draft proposed rule and has decided instead to limit the rule to recordkeeping and reporting requirements under TSCA Section 8.

Similarly, the SNAc/SNUR Work Plan timetable is demanding:

- Establish multi-stakeholder technical working group (**March 2015**);
- Web conferences with working group to share results of information gathering activities, solicit comment on baseline information (**April 2015** to **August 2015**);
- Face-to-face working group meeting to discuss potential alignment opportunities and best practices for compliance (**October 2015**);
- Web conferences to discuss proposed alignments, solutions to compliance challenges, and recommendations (**January 2016** to **May 2016**); and
- Web conferences to consult on final recommendations (**July 2016** to **November 2016**).

This process may be the best if not only venue to address stakeholder concerns with the existing TSCA implementation program.

NANOMATERIALS FORECAST

2014 saw steady growth in the number of TSCA notifications for nanoscale chemical substances consistent with prior years; EPA has reviewed a total of 160 + new chemical notifications. The much anticipated TSCA rulemakings on existing chemical nanoscale materials were not issued in 2014 as EPA clarified late in the year that it withdrew the combined SNUR and TSCA Section 8 draft proposed rule and has decided instead to limit the rule to recordkeeping and reporting requirements under TSCA Section 8. The SNUR, which would have required companies to notify EPA regarding "new uses" of existing chemical nanomaterials, will not be pursued. While no reason for the withdrawal was offered, many speculate that the Office of Management and Budget (OMB) was not comfortable with the SNUR approach. EPA's Fall 2014 Regulatory Agenda includes an item concerning the TSCA Section 8(a) rulemaking that would require reporting of certain information, including production volume, methods of manufacture and processing, exposure/release information, and available health and safety data on such nanoscale materials. OPPT hopes to issue the proposed rule in 2015.

Interestingly, other EPA program offices are now focusing more on nanoscale materials. Specifically, the Effluent Guidelines program in the Office of Water is collecting data and information on the potential industrial wastewater hazards and discharges associated with nanomaterials manufacturing and formulating.

Late in the year, a coalition of food safety advocates sued EPA in the U.S. District Court for the District of Columbia urging EPA to regulate nanosilver as a pesticide under FIFRA. The suit seeks an answer to The International Center for Technology Assessment's 2008 petition urging EPA to regulate as pesticides products containing nanoscale silver -- a widely used nanoscale material -- and to analyze its potential human health and environmental risks. In addition to urging EPA to

require FIFRA registration of products containing nanosilver, the petition urged EPA to prohibit sale of nanosilver products with unapproved claims of health benefits. The petition also asked EPA to assess human health and environmental risks of nanosilver under other laws, including the FQPA and ESA. What impact, if any, the suit will have on EPA is unclear.

The U.S. Food and Drug Administration (FDA) was the next most active federal agency in the nano area, having issued three final guidance documents and one draft guidance that it intends to provide "greater regulatory clarity for industry on the use of nanotechnology in FDA-regulated products." One of the final guidances addresses FDA's overall approach for all products that it regulates, while the two additional final guidances and the new draft guidance provide specific guidance for the areas of foods, cosmetics, and food for animals, respectively. More information on the guidances is available in B&C's June 26, 2014, memorandum, "FDA Issues Final Nanotechnology Guidances and Draft Guidance for Comment."

GREEN CHEMISTRY AND SAFER CHEMICALS AND PRODUCTS

In 2014, Jim Jones, OCSPP's Assistant Administrator, continued his push for growth and 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 more recent OPPT efforts to upgrade the DfE program, including developing a new logo and announcing new opportunities for companies to propose chemicals for addition to DfE's Safer Chemical Ingredients List (SCIL) and to be recognized via DfE's new Safer Product Labeling award. We expect these efforts to continue and to grow in 2015 and reiterate our encouragement to clients and friends to look carefully into these opportunities.

HOW ARE "SAFER AND GREENER" NEW CHEMICALS FARING THESE DAYS?

OPPT's new chemicals website discusses how the new chemicals program "supports development of safer chemical[s]...by minimizing or eliminating regulatory burdens," "strongly encourages industry efforts to prevent pollution," and goes on to encourage submission of pollution prevention (P2) information on new chemicals, which, we are assured, "EPA carefully considers...in evaluating potential risks and benefits." There is a certain tension between Jones' interest in green chemistry and the difficulties industry has encountered in recent years in attempting to introduce safer and greener new chemicals. Industry has put considerable effort into producing well-developed P2 pages with its premanufacture notification (PMN) submissions; OPPT's reaction to and appreciation of the information seems underwhelming. For example, new chemicals based on Presidential Green Chemistry Challenge award-winning technologies or that involve innovative ways to utilize waste streams have faced overly long delays before OPPT review is completed, often with the added burden of well-intentioned but commercially challenging SNUR triggers and recordkeeping requirements. In brief, OPPT's response over the past several years appears at best to have been mixed, if not more "stop" than "go." As with all things TSCA, "hope springs eternal," and there is hope that this situation can be improved over the next two years.

UPDATE ON SOME RECENT RULES

Recent OPPT rulemakings have presented challenging. Examples include a direct final Section 8(d) rule on a series of cadmium compounds (*see* our Regulatory Development memo and a subsequent memo when the rule was withdrawn) and a recent proposed SNUR on NP and NPEs (*see* our memo that raises concerns about the limited due diligence exhibited in the rulemaking record for OPPT's assertion that the

listed chemicals are commercially dead; we also note that several organizations in requesting an extension to the comment period also identified various additional concerns with OPPT's approach). OPPT faces many resource and other challenges in doing its work, and occasional mistakes are inevitable and understandable. With TSCA reauthorization looming, 2015 may be a year to monitor closely issues that may stem from inadequate resources to develop key rulemakings.

OFFICE OF PESTICIDE PROGRAMS (OPP) ISSUES

Two issues will dominate pesticide regulatory activity during 2015: endangered species and pollinator protection. Other issues will be important (e.g., completing the worker protection standards rule), but ESA and pollinators will take the most time, energy, and attention of registrants, regulators, and other stakeholders.

ENDANGERED SPECIES

ESA implementation issues and litigation will continue to drive registration decisions for 2015. 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 B&C's 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 most recent of which was held in October 2014. These workshops have generally been sessions where various registrants and consultants, along with some from the NGO community, contribute suggestions to EPA and the Services about ways to improve the current methods and how to incorporate recommendations made by the NAS. 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. On December 11, 2014, EPA sent to Congress the report required in the 2014 Farm Bill for a description of the approaches and actions taken to:

- Implement the recommendations of the 2013 NAS report;
- Ensure public participation and transparency as part of implementing the recommendations; and
- Minimize delays in integrating delays in registration and reregistration review requirements with species and habitat protections.

The report describes the progress made to date among the review agencies towards integrating review procedures as part of implementing the recommendations of the NAS Report. There has been progress in more closely aligning the review process of the agencies. More generally, this is seen as "small steps" towards refining the process to becoming more predictable and timely.

The issue of endangered species protection has expanded to potential legal challenges to new active ingredient registrations. In early 2014, NGO groups

Two issues will dominate pesticide regulatory activity during 2015: endangered species and pollinator protection.

threatened and eventually filed a challenge to the first new use registration of a new active ingredient (cyantraniliprole), marking the first time an ESA complaint was filed against a new pesticide. Before this, new active ingredients were 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 a new front in the legal challenges to EPA's approval of pesticides and compliance with the ESA.

POLLINATORS

OPP actions regarding the pollinator issue continue to be driven by the directives and announcements of EPA in July and August 2013. EPA required significant label changes to lessen any impact on pollinators from insecticide use, and EPA is still working its way through the label submissions made in response to those demands EPA made in 2013. State lead agencies have also asked about apparent inconsistencies between the flexibility that is perhaps available on the "bee box" labeling EPA required and other mandates of the label that may not allow much flexibility (for example, provisions intended to address an emergency or sudden pest pressure that requires application of certain affected insecticides). Future work with regard to how to impose improved labeling to enhance pollinator protections will have to address these potentially conflicting goals.

Meanwhile, on June 20, 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." The text of the Memorandum lists goals and comments on pollinator health, and focuses on creating a government-wide task force, along with directives about research into factors affecting pollinator health and suggestions for improving pollinator habitat. The role and possible impacts of pesticides on pollinators are mentioned, but are not prominent. 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.

Six months from the date of the Memorandum was December 20, 2014 -- so now, where are we? In summary, remarks by those leading the task force (staff from the U.S. Department of Agriculture (USDA) and EPA) report that the Memorandum response is now planned to be sent to the White House in draft form around the due date, the Holidays probably allowing for some schedule wiggle room. The public likely will be allowed to comment on the suggestions. That might mean a public release of the draft plan sometime in early Spring 2015, which coincidentally could dovetail with the beginning of the use season for commercial honeybee services. (The almond crop in California begins to need bees around February depending on weather, temperature, and other factors.) So for now, no public release of the strategy is expected for at least 90 days or more. Private conversations and trade press reports indicate some slowness in convening and coordinating such a large and diverse group of agencies. Some agencies appear reluctant to participate in significant ways or otherwise are not sure exactly how or what their contribution to the effort should be. That, of course, is one of the main points of the exercise.

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Another recent pollinator development came in late October. 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 evaluated. The report concluded, based on selected studies and 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. The EPA 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 criticize the report as incomplete and promise to provide information to EPA to rebut the conclusions. The comment period is still open, and it is expected that some response to these comments on this issue will be part of the Agency response to the President's Memorandum on the Pollinator Health Task Force.

WORKER PROTECTION STANDARDS

In March 2014, EPA issued a proposed rule to update the worker protection standard. The proposed rule would, among other things, increase the frequency of mandatory training to help minimize pesticide exposure, establish no-entry buffer zones around pesticide-treated fields, expand training to reduce take-home exposure of pesticide residues on worker clothing, and prohibit children under the age of 16 years old from handling the more hazardous category 1-4 pesticides. Registrants and grower groups raised concerns about the possible impact of the new requirements and especially questioned the need for some of the more extensive recordkeeping requirements and generally the need for significant revisions, as incidents and general toxicity of most pesticides has been reduced since the original rule was issued in the early 1990s. Farmworker advocates see the revisions as long overdue, and if anything, support even more stringent requirements. EPA plans to review the submitted comments and issue the final rule in 2015.

BYSTANDER EXPOSURE/"DRIFT"

The issue of pesticide "drift" -- the unintentional movement of some level of pesticide residues outside of the intended area of application -- has been a very difficult policy issue for many years. It is easy to state casually that in many circumstances some low amount of a pesticide applied to a field may move off site, due to any number of factors -- in other words: "drift happens." The issue quickly becomes one of whether the amount of off-site movement matters, which is very dependent on a number of factors, including the nature of the specific pesticide (toxicity, volatility), or the application method (aerial or ground application). As a result, EPA has had a very difficult time in addressing the drift issue, finding it an extremely difficult task to develop a "drift policy" or define generally what, if any, level of potential drift is acceptable. As EPA has struggled to define a clear policy, in October 2009 EPA received a petition submitted by NGO groups to assess possible risks from off-site movement and to impose protective buffer zones. EPA formally

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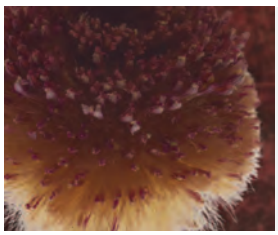

EPA guidance in these areas appears destined to become EPA's functional "drift policy" despite years of controversy and difficulty in past attempts to propose a clear and "simple" definition of acceptable off-site movement.

responded to this petition on March 31, 2014, and agreed with the petitioners that exposure to spray drift and volatilization should be assessed. EPA then published two sets of documents for public review that are intended to be used as assessment tools to evaluate the need for additional restrictions during the pesticide registration review process.

EPA guidance in these areas appears destined to become EPA's functional "drift policy" despite years of controversy and difficulty in past attempts to propose a clear and "simple" definition of acceptable off-site movement. Implementing the off-site deposition modeling and mitigating estimated bystander exposure risks will likely lead to some significantly enhanced restrictions on some currently used products and use patterns. As EPA continues to evolve core policies in this arena, and as EPA refines the pertinent exposure models, registrants may face proposals for much greater restrictions on their products as part of registration review. For a detailed analysis of EPA's spray drift pesticides, *see* http://www.lawbc.com/seminars-webinars/2014/10/.

ENDOCRINE TESTING/COMPUTATIONAL TOXICOLOGY

An endocrine testing program is a requirement of FQPA with an original deadline of 1999 for the establishment of the program. For many reasons, among them the inherent complexity of the task, EPA is only now completing its initial review of 52 chemicals (mostly pesticides) under the "Tier 1" testing program. At the same time, EPA has spent significant resources over more than ten years developing a computational toxicology program designed to allow a relatively quick and inexpensive method or battery of tests to screen and begin the assessment of the many thousands of chemical substances currently with little or no toxicological data. Together these activities are designed to evaluate the potential of endocrine effects for pesticides and chemicals and to facilitate EPA's ability to assess thousands of compounds that otherwise would take many decades to review. This set of tools will only become more important if TSCA legislation is enacted with any kind of deadlines for assessing chemicals.

The FIFRA Scientific Advisory Panel (SAP) met December 2-5, 2014, to review the use of computational toxicology and exposure tools and other available data to prioritize and screen chemicals for their ability to interact with the estrogen, androgen, or thyroid hormonal pathways. In the notice announcing the meeting, EPA noted that it is exploring faster and less expensive ways to screen chemicals and pesticides under the endocrine screening program, given that more than 10,000 unique substances have been identified for inclusion in the program.

Work on these programs will continue through 2015 as EPA intends to announce the results of its review of the Tier 1 chemicals and issue another round of candidates for Tier 1 testing. Peer review and further development of the computational toxicology approach will also continue, and it might be expected to remain on the list of things the current Administration hopes to complete before the end of the Obama presidency.

WHAT CAN WE EXPECT FROM DTSC'S SCPR IN 2015?

The California Department of Toxic Substances Control (DTSC) is moving steadily forward in its implementation of the Safer Consumer Products Regulations (SCPR). As companies currently embroiled in the DTSC process implicated by DTSC's identification of the first three draft product-chemical combinations can likely attest, the SCPR are game-changing regulations creating immediate and costly implications, regardless of the fact that DTSC has not formally proposed any of these products as Priority Products. In 2015, there are at least three developments that are likely to expand the number of companies affected by these Regulations.

First Priority Products to Be Proposed Formally

On March 13, 2014, DTSC announced its proposed list of three product-chemical combinations: (1) children's foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP); (2) paint strippers containing methylene chloride; and (3) spray polyurethane foam systems with unreacted methylene diphenyl diisocyanate (MDI). *See* B&C's March 13, 2014, memorandum, "California Announces First Draft Priority Products under Safer Consumer Products Regulations." The announcement was not the start of formal rulemaking, instead, DTSC proposed these product-chemical combinations and allowed time to receive comments and hold several public workshops.

DTSC refined and revised the scope of these initial product-chemical combinations based on comments received in writing and during the workshops. DTSC, for example, announced that it is adding the candidate chemical tris (2-chloroethyl) phosphate (TCEP) along with TDCPP in children's foam-padded sleeping products, clarified that paint strippers containing methylene chloride will not include surface cleaners, and determined that only two-part foams with unreacted MDI will be the focus for spray polyurethane foam systems. None of the comments appear to have deterred DTSC's findings that these three product-chemical combinations meet the criteria for listing as Priority Products and DTSC thus appears poised to initiate the rulemaking process to list these three Priority Products in early 2015. This process will conform to California's Administrative Procedure Act (APA) and include another 45-day public notice and comment period. The APA allows up to one year from the public notice commencing the rulemaking to the time when regulations must be issued in final.

Final Priority Product Work Plan to Be Issued

DTSC also will be moving forward in 2015 to issue the Final Priority Product Work Plan. Under the Regulations, DTSC was required by October 2014 to develop an Initial Priority Product Work Plan that describes

As companies currently embroiled in the DTSC process implicated by DTSC's identification of the first three draft product-chemical combinations can likely attest, the SCPR are game-changing regulations creating immediate and costly implications, regardless of the fact that DTSC has not formally proposed any of these products as Priority Products.

product categories it will use to evaluate and identify product-chemical combinations to be added to the Priority Products. The purpose of the Work Plan is to provide a "level of predictability to potential manufacturers, importers, retailers, and other stakeholders regarding the types of products that can be considered for evaluation over the next three years." The Initial Priority Product Work Plan identified seven product categories:

- Beauty, Personal Care and Hygiene Products;
- Building Products;
- Household/Office Furniture/Furnishings;
- Cleaning Products;
- Clothing;
- Office Machinery Consumable Products; and
- Fishing and Angling Equipment.

See B&C's September 15, 2014, memorandum, "DTSC Releases Draft Initial Priority Product Work Plan."

DTSC received nearly 350 comments that it is currently reviewing and incorporating into the final Work Plan. Once the Work Plan is issued in final, companies will need to determine if their consumer products are those identified in the Work Plan and develop a plan for analyzing and addressing those products as they may relate to future regulation.

Draft Alternative Analysis Guidance to Be Released

Another action that was expected by the end of 2014, but appears to be delayed until early 2015, is the release of DTSC's alternative analysis (AA) guidance. This guidance is intended to provide a process to evaluate Priority Products for "safer" alternatives and not regrettable substitutes. This guidance has been under development for some time now, with the latest changes being made based on input from the Green Ribbon Science Panel at its October 19-20, 2014, meeting. The guidance will be critical for companies to utilize in conducting the intensive AA required under the Regulations, and can provide important insight for all companies potentially affected by the Regulations as to DTSC's views on satisfying the elements of the AA process.

IS PROP 65 REFORM ANTICIPATED?

On March 7, 2014, the Office of Environmental Health Hazard Assessment (OEHHA) released a pre-regulatory proposal for a potential draft regulation amending Proposition 65 regulations. Significantly -- and likely controversially -- the proposal seeks changes to the warning requirements to require more detailed information, including the names of the chemicals covered by individual warnings, the ways that individuals are exposed to these chemicals, and how individuals can avoid or reduce their exposure to these chemicals. *See* B&C's April 1, 2014, memorandum, "Proposition 65: OEHHA Releases Pre-Regulatory Proposal for Revised Proposition 65 Warning Regulations." OEHHA received over 50 comments on its pre-regulatory proposal. OEHHA has noted that this "potential" regulation "may change substantially prior to the eventual initiation of a formal regulatory proceeding" and considering the significant concerns that were raised regarding whether the pre-regulatory proposal would in fact accomplish its goals of "improv[ing] the quality of Proposition 65 warnings while providing both flexibility and certainty for businesses," further changes are expected before any regulations are proposed formally. OEHHA initially stated its intent to propose formal regulations in early summer 2014 and adopt final regulations in early summer 2015. The regulations have not yet been proposed, but another version

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(whether a pre-regulatory proposal or a formal rule-making draft) is expected to be released. Under any circumstance, companies will be afforded additional opportunities for public input.

OEHHA also is expected in 2015 to schedule a workshop to discuss the next steps in its regulatory reform/update project. OEHHA solicited comments due by November 17, 2014 on ideas and considerations for action to improve any of the following potential regulatory areas:

- Develop alternative risk levels for chemicals in foods (25703(b));
- Update the Naturally Occurring regulation (25501);
- Update and streamline the Safe Use Determination process (25104);
- Clarify regulatory provisions on averaging exposures (25701, 25721, 25801, 25821);
- Determine chemicals to be given priority in the development or update of Safe Harbor levels;
- Identify where additional interpretive guidance is needed; and
- Clarify use of data on postnatal developmental exposures.

EUROPEAN UNION

PREPARING FOR 2018 REGISTRATIONS UNDER THE EU'S REACH REGULATION?

Activities are ramping up considerably to support 2018 registrations under the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation. Most companies by now have prioritized their substances and developed a strategy to ensure a successful registration prior to the May 31, 2018, deadline. There is much activity with identifying Lead Registrants and follow-up communications with Substance Information Exchange Forum (SIEF) members. There has been a decided uptick in appointed Lead Registrants placing initial contracts with laboratories to benefit from 2014 pricing prior to avoiding projected 2015 price increases. We anticipate that as time passes, laboratory space will be in high demand along with commensurate price increases. Later in 2015 or 2016, some registrants will begin to make available Letters of Access (LoA) to support 2018 registrations. To date, many LoAs are not available for lower volume substances. Business decisions, however, are now being made as to whether to maintain substances on the market in the EU. For companies electing to forgo the EU market, 2015 will see the implementation of market exit strategies or volume control measures. Stakeholders also will continue to remain active in 2015 in efforts to resolve cost sharing issues by providing guidance and sample agreements.

The European Chemicals Agency (ECHA) continues its evaluation of registration dossiers submitted as part of the 2013 registration deadline, providing comments on dossier quality and scientific review. Many testing proposals are being accepted, resulting in an increase of higher end studies, with updated registration dossiers and potential for increase of LoAs for joint registrants. With many updates to Lead Registration dossiers, joint registrations may be required to be updated, resulting in further review and evaluation of use patterns and supply chain communication via updated extended Safety Data Sheets (eSDS).

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ECHA is expected to remain engaged and develop approaches to tackle two main areas of improvement for registration activities: cost reductions and registration dossier quality.

ECHA UPDATE

ECHA in 2015 intends to focus on updating guidance documents that are scheduled to be completed two years prior to the 2018 registration deadline. Specifically, ECHA has indicated that its Guidance on Information Requirements and Chemical Safety Assessment will be revised in 2015-2016. We anticipate the inclusion of requirements for nanomaterials and alternative or new methods to address the required endpoints to support a registration, i.e., extended one generation reproductive toxicity study (EOGRTS) (Organization of Economic Cooperation and Development (OECD) Test Guideline number 443), within the guidance documents. A new regulation is proposed to address issues related to registration to include transparency and cost sharing within SIEFs.

ECHA continues to evaluate several alternative *in vitro* test methods to address for mammalian endpoints -- skin sensitization, skin corrosion, acute toxicity, and eye irritation. As noted, ECHA is now also updating its guidance document and the *Guidance on Information Requirements* will include additional information on new *in vitro* methods. ECHA aims to continue to develop and strengthen its regulatory science strategy via supporting capacity building to support alternative test methods and the development of new tools.

ECHA is expected to remain engaged and develop approaches to tackle two main areas of improvement for registration activities: cost reductions and registration dossier quality. To do so, ECHA is finding cost solutions to assist Small- and Medium-Sized Enterprises (SME) with the impact for preparing for the 2018 registration. Registration dossier quality is being addressed via substance sameness and ECHA is expected to revise and clarify the REACH information requirements for nanomaterials subject to registration. ECHA is continuing to update the Use Descriptor System and is reportedly developing a new version of IUCLID in 2015. These activities will offer greater clarity and consistency on reporting uses in registrations. ECHA intends to roll out a new dissemination portal in 2015. In addition, ECHA will continue to update its compliance control strategy in 2015 with emphasis being placed on informal dialogues with registrants to assist in addressing the challenges surrounding non-compliance issues.

Many downstream users (DU) remain unaware of their rights and obligations under REACH. The eSDS is to allow for the transmission of relevant information on the risk and adequate control measures needed to ensure safe use. Due to the classification, labeling, and packaging (CLP) mixtures deadlines, industry is also working on developing scientific methods to address risks of mixtures and communicating these risks via the eSDS for mixtures. Outreach in 2015 is expected to continue by Member States, who are stepping up next efforts.

SVHC UPDATE

The development of the Substances of Very High Concern (SVHC) Roadmap and its implementing plan is expected to continue in 2015. There is significant emphasis being placed on the workability and predictability of the authorization process to include

inclusion of substances on the Candidate List (Annex XIV) and the application process. Simplified procedures are being evaluated for those cases where the authorization process may be considered disproportionate to the expected benefits of protecting human health and the environment to include when substitution (Analysis of Alternatives) cannot be anticipated. Member States and industry continue to press for authorization and restriction requirements. This is particularly true for DUs that typically may not need to comply with other REACH-related requirements. Part of the SVHC Roadmap included on ECHA's website provides advance notice if a substance has been considered for regulatory risk management together with the result of the Risk Management Option Analysis (RMOA), *i.e.,* which regulatory route has been selected (such as harmonized classification and labeling, authorization, restriction). Evaluations increased in 2014 to 50 per year and are expected to increase in 2015.

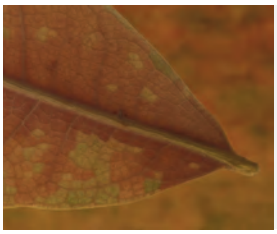
REACH ENFORCEMENT TRENDS FOR 2015

Pilot reporting activities are expected to continue in 2015 on a voluntary basis. In addition, collaboration between relevant parties, including customs authorities, is expected to increase in 2015. It is likely there will be an increase in REACH-related questions involving impacts as additional proof of REACH compliance is likely to be requested by customs authorities in 2015.

Member States have expressed interest in working cooperatively with others to effectuate joint inspections that address other legislations, *e.g.*, Biocides Product Regulation (BPR). Joint inspections would allow for an enhancement in cost efficiency. In addition, risk analysis may be used by the Member States to conduct more targeted inspections. Recently, Geert Dancet, ECHA Executive Director, expressed concern regarding the lack of notifications received for articles containing SVHCs. As a result, more emphasis is likely to be placed on monitoring articles containing SVHCs and ensuring the reporting requirements are being followed.

ENDOCRINE DISRUPTORS UPDATE

Earlier this year, the European Commission published a roadmap for defining criteria of endocrine disruptors that would be applied to EU legislations, including, but not limited to, REACH, BPR, Plant Protection Products Regulation (PPPR), and Cosmetics. As described in the roadmap, the Directorate General Health and Consumers (DG Sanco) has also opened a public consultation, the result of which will be used in the impact assessment of the different options considered. Even without the official definition and criteria accepted, there has been an increase in the number of substances selected for evaluation or identified as SVHCs in association with REACH's Authorization procedure, justified by endocrine disrupting properties as "equivalent level of concern." After a particularly heated debate as to whether a safe threshold exists, the Commission pushed back the responsibility to industry to decide on a case-by-case basis if a Derived No-Effect Level (DNEL) can be set. Further



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guidance on threshold testing is expected to be developed in 2015. This will significantly influence Authorization applications. Without a safe threshold, substances will need to follow the socio-economic dossier route rather than the adequate control dossier route. This is illustrated by the di-(2-ethylhexyl) phthalate (DEHP) listing, which was originally listed in Annex XIV due to its reproductive toxicity properties in which a safe threshold was determined. The Commission, however, recently accepted Denmark's proposal to identify DEHP as an endocrine disruptor. At the end of their review period, companies will need to demonstrate a safe threshold. If a safe threshold is not supported, the Authorization application will need to be prepared following the socio-economic route.

BIOCIDAL PRODUCTS REGULATION FORECAST

A key objective of the BPR is to cease the so-called "free-riders" syndrome that exists under the prior legislative framework. Each active substance and product supplier shall be listed on the Article 95 list as referred to by ECHA and industry. As of **September 1, 2015**, a biocidal product consisting of, containing, or generating a relevant substance, cannot be placed on the EU market if the substance supplier or product supplier is not included in the Article 95 list for the product type(s) to which the product belongs. On its website, ECHA urges companies not to underestimate the work and time necessary for data-sharing negotiations. There are significant concerns that many companies may not timely initiate activities to allow for compliance with the regulation. From an enforcement standpoint, it is not likely that ECHA will be sympathetic to non-compliance unless there are extenuating circumstances.

CLASSIFICATION, LABELLING AND PACKAGING FORECAST

From **June 1, 2015**, the Classification, Labelling and Packaging (CLP) regulation will be the only legislation to apply to the classification and labeling of both substances and mixtures. Both the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD) will be repealed. For substances, classification and labeling according to CLP must be included in the SDS. Mixtures must be classified only according to the CLP, but re-labeling and re-packaging of mixtures already placed on the market before **June 1, 2015**, will have a two-year transition period. With effect from **June 1, 2015**, requirements for SDSs will be amended to adapt the above changes, Annex II of Commission Regulation (EU) No. 453/2010.

ASIA

CHINA

IMPACT OF THE REVISED ENVIRONMENTAL PROTECTION LAW

The revised Environmental Protection Law, which took effect January 1, 2015, sets environmental protection as China's basic policy. Under the revised Law, economic and social development should be coordinated with environmental protection. It encourages studies on the impact environmental quality has on public health, urging prevention and control of pollution-related diseases. The revised Law also includes harsher punishments for environmental wrongdoing. The revised Environmental Protection Law is available online, in Chinese.

On October 17, 2014, the Ministry of Environmental Protection (MEP) released for public comment four

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According to a State Administration of Work Safety (SAWS) spokesperson, China could publish the final version of its revised Catalog of Hazardous Chemicals in early 2015.

interim measures related to the revisions to the Environmental Protection Law. The draft interim measures define the criteria for the consecutive daily fines and their duration, number, amount, implementation procedures, and the related terminology; define the criteria for seizure and detention for severe environmental pollution and contamination and their duration, implementation procedures, and the related terminology; provide implementation procedures on investigation, approval, implementation of corrective actions, reinstatement, and inspection related to the restrictions and suspension of production for severe environmental pollution and contamination; and give prescriptive guidance on disclosure scope, content, manner, and supervision of the compliance information of environmental protection regulations of enterprises and institutions. More information is available, in Chinese, in MEP's October 17, 2014, notice.

FINAL CATALOG OF CHEMICAL HAZARDOUS CHEMICALS

According to a State Administration of Work Safety (SAWS) spokesperson, China could publish the final version of its revised Catalog of Hazardous Chemicals in early 2015. The draft Catalog, which was released in September 2013, included approximately 3,000 substances, less than the almost 4,000 substances included in the current Catalog of Hazardous Chemicals. In general, listed substances are subject to Decree 591 and its subordinate regulations addressing their safe management throughout the supply chain. Listed substances would need a license to be produced, used, or imported. More information regarding the draft Catalog is available in The Acta Group's (Acta®) October 8, 2013, memorandum, "China Issues Draft Hazardous Chemicals List for Comment."

SOUTH KOREA

IMPLEMENTATION OF K-REACH

The Act for the Registration and Evaluation of Chemicals (K-REACH) went into effect on January 1, 2015. We envision 2015 to be a key year of growth and learning as chemical substance notification activities under the new regulatory framework begin. Guidance documents and many regulatory tools remain under development and are to be made available in 2015 to support new and existing chemical notification activities. Completion of the pilot project to evaluate potential challenges with joint submission activities and develop industry support measures is scheduled for **May 2015**. As noted below, the first batch of draft existing chemical substances has been identified for inclusion of evaluation under K-REACH.

As of January 1, 2015, any person who manufactures, imports, or sells new chemicals or 1 ton or more of existing chemicals annually must report the chemicals' use, quantity, and related items annually to the authority. The reporting period is by calendar year with the annual report due by June 30 of the following year. The first report due for the calendar year January 1, 2015 - December 31, 2015, is **June 30, 2016**. There is no information currently available on the report format and how the information will be submitted to the authority.

CHEMICALS INCLUDED IN THE FIRST BATCH OF EXISTING CHEMICALS SELECTED FOR REGISTRATION UNDER K-REACH

The Ministry of Environment (MOE) published a draft list of the first batch of existing chemicals selected for registration under K-REACH. The 518 chemicals on the list, which has also been made available by the Korean Chemicals Management Association (KCMA), were selected based on a number of criteria, including their designation as carcinogenic, mutagenic, or reprotoxic, and toxic to the aquatic environment in the EU. The final list is expected to be published in **June 2015**, however, revisions to the draft list are expected prior to being made final. Once the list is officially published, listed substances must be registered within three years. The next batches of existing chemicals selected for registration are expected to be announced in **2018** and **2021**. More information is available, in Korean, in MOE's announcement and in KCMA's announcement.

SMES COMPLIANCE GUIDANCE WITH K-REACH

South Korea intends to implement a number of measures to assist SMEs with their K-REACH obligations. The MOE and Ministry of Trade, Industry and Energy (MOTIE) will lead support and training programs to address the effects of registration and evaluation procedures. Between **February 2015** and **December 2017**, two additional programs will be introduced to establish effective chemical management processes and information flow:

- MOE will nominate about ten SMEs, each representing an industrial sector, and study each stage of K-REACH's registration and evaluation procedures to build a support strategy; and
- Independent consultants will provide one-on-one consulting to approximately 1,000 SMEs to help them comply with procedures such as the identification of chemicals, reporting, and registration and evaluatio

TAIWAN

We anticipate that 2015 will be a busy period given the implementation of chemical control management in Taiwan that now encompasses new chemicals and changes to regulations addressing existing chemicals. Existing chemicals are those chemicals that are present on Taiwan's Chemical Substance Inventory (TCSI). In 2014, beta testing was on-going for the web-based registration tool Chemical Information System and Tool (CHEMIST). As with other chemical management programs, only Taiwan-based entities can submit dossiers. Access to the tool is open to all entities, however. An "Agent" can be appointed by non-Taiwan-based companies to conduct notifications. In addition, documents and tools are only available in Chinese but will also be made available in English. We anticipate that English versions will be made available in 2015.

Phase 1 registrations (greater than or equal to 100 kg), also referred to as "Pre-registration" activities for all substances manufactured or imported, are to begin September 1, 2015. The competent authority is also expected to announce the list of Designated Substances for Standard Registration (phase-in) but it is unclear if this announcement will be made in 2015 or 2016.

AMENDED TOXIC CHEMICAL SUBSTANCES CONTROL ACT

As noted in our Predictions report for 2014, on December 11, 2013, President Ma Ying-jeou promulgated legislation amending the Toxic Chemical Substances Control Act (TCSCA). The amendments, which took effect December 11, 2014, revised 17 articles and created a system for the registration, evaluation, and control of chemicals. The Taiwan Environmental Pro-

tection Administration (Taiwan EPA) in December 2013 published an excerpt from its *Environmental Policy Monthly*, "Compulsory Registration of Manufactured or Imported Toxic Substances Starts from 2014," stating that it "is keen to point out" that the revisions will require manufacturers or importers of toxic chemicals to register certain information with the Taiwan EPA, including information on the circumstances of the manufacture/import of the chemicals, their physical forms, their chemical compositions, toxicities and exposures, and hazard assessments. The Taiwan EPA must complete the registration process before manufacture or import of such chemicals is permitted. Taiwan EPA published final regulations concerning the registration of new and existing chemical substances in the December 4, 2014, *Taiwan Gazette*. In addition to addressing new and existing chemical substances registration, the regulations also address information disclosure and the protection of CBI.

MINISTRY OF LABOR (MOL) IMPLEMENTATION AMENDMENTS TO THE LABOR SAFETY AND HEALTH ACT

MOL announced on July 4, 2014, that the amendments to the Labor Safety and Health Act, now renamed the Occupational Safety and Health (OSH) Act, would be implemented in two stages. During the first stage, the amended provisions of existing regulations (41 subordinate regulations) are in effect as of July 3, 2014. The second stage new schemes and measures were launched on January 1, 2015. According to MOL, the new regulatory measures effective January 1, 2015, include: a machinery, equipment, appliance, and chemical source management system; maternity protection and employment equality measures for maternity health and protection; and regular process safety assessment and supervision for high-risk business.

TAIWAN EPA AND MOL TONNAGE BANDS

Under Taiwan EPA's December 4, 2014, regulations, four tonnage bands will be used to set testing and data requirements:

- Level one is 1-10 tonnes per year;
- Level two is 10-100 tonnes per year;
- Level three is 100-1,000 tonnes per year; and
- Level four is over 1,000 tonnes per year.

The volume classification of applications for joint registration of new and existing chemical substances will be decided by the sum of the volumes declared for importation or manufacture by the joint applicants. Manufacturers or importers of 1,000 tonnes per year or more of substances will be required to submit "safe use" information, including hazard and exposure evaluation assessments. Under OSH Act Article 13, manufacturers or importers of chemical substances that are not on the inventory must submit a chemical safety assessment report to the central competent authority, and receive registration approval for the new chemical substances. Taiwan EPA revised the tonnage bands in its final rules to correspond to the tonnage bands in Appendix One of MOL's draft rules.

There are three different types of notification schedules: Standard (review time 45 working days), Simplified (review time 14 working days), and Small Quantity Registration (review time 7 working days). Each of these notification types is dependent upon the volume and data requirements' increase by volume.

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

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