Recent Federal Developments
September 15, 2015

TSCA/FIFRA/IRIS/NTP/TRI

EPA Releases TSCA Assessment Documents For Flame Retardant Chemicals: On August 18, 2014, the U.S. Environmental Protection Agency (EPA) released for public comment three Problem Formulation and Initial Assessment documents and a Data Needs Assessment (DNA) document for one of four structurally similar flame retardant chemical clusters being reviewed under the Toxic Substances Control Act (TSCA) Work Plan assessment effort. 80 Fed. Reg. 49997. The goal of these assessments is to identify scenarios where further risk analysis may be necessary. The documents address the likely exposure and hazard scenarios to workers and consumers based on current production, use, and exposure information for the following flame retardant chemical clusters:

- Tetrabromobisphenol A (TBBPA), also known as Brominated Bisphenol A, cluster -- used as flame retardants in plastics/printed circuit boards for electronics.

- Chlorinated Phosphate Esters -- used as flame retardants in furniture foams and textiles.

- Cyclic Aliphatic Bromides/Hexabromocyclododecane (HBCD) cluster -- used as a flame retardant in extruded and expanded polystyrene foams (EPS/XPS), polystyrene (PS) products.

The DNA document addresses the Brominated Phthalates (TBB and TBPH) cluster of flame retardants that are used in polyurethane foam products. EPA reviewed previous assessments and identified critical gaps in toxicity, exposure, and commercial mixtures data. The DNA document is intended to guide the collection of additional data and information. Comments on the three Problem Formulation and Initial Assessment documents are due by **October 19, 2015**. Comments on the DNA document for Brominated Phthalates are due by **December 16, 2015**.

EPA Schedules Workshop On Considerations For Risk Assessment Of Biotechnology Algae: On August 25, 2015, EPA announced a public meeting on **September 30, 2015**, to receive public input and comments on EPA's data needs to support risk assessments of biotechnology products subject to oversight under TSCA that make use of genetically engineered algae and cyanobacteria. 80 Fed. Reg. 51561. The notice states that the workshop will inform an update to an EPA guidance document entitled *Points to Consider in The Preparation of TSCA Biotechnology Submissions for Microorganisms*. As reported in our August 3, 2015, memorandum, EPA Posts Information on Biotechnology Algae Project, EPA has posted a

document concerning its development of a project intended to support public dialog concerning the development and use of biotechnology. EPA has oversight responsibility for the production and use of intergeneric cyanobacteria, eukaryotic microalgae, and their products by application of genetic engineering approaches. EPA's recently posted document, *US Environmental Protection Agency Biotechnology Algae Project*, states that it is focusing its project around these biotechnology algae applications. EPA encourages all members of the public interested in participating in this workshop to register to attend, whether in-person or through the web-connect and teleconference that will also be available. Advance registration will close on **September 25, 2015**. EPA will hear oral comments at the **September 30, 2015**, workshop. Written comments are due **October 31, 2015**.

EPA Proposes Revisions To Pesticide Certification Applicator Rules: On August 24, 2015, EPA proposed changes to the existing regulations concerning the certification of applicators of restricted use pesticides (RUP). 80 Fed. Reg. 51356. The proposed changes are intended to improve the competency of certified applicators of RUPs, increase protection for noncertified applicators of RUPs operating under the direct supervision of a certified applicator through enhanced pesticide safety training and standards for supervision of noncertified applicators, and establish a minimum age requirement for certified and noncertified applicators. Comments must be received on or before **November 23, 2015**.

EPA Announces Availability Of Final Endocrine Disruptor Screening Program Test Guidelines (Series 890); Three Tier 2 Non-Mammalian Tests: On August 25, 2015, EPA announced the availability of three Office of Chemical Safety and Pollution Prevention (OCSPP) final test guidelines. 80 Fed. Reg. 51558. The new test guidelines are: Medaka Extended One-generation Reproduction Test (MEOGRT), OCSPP Test Guideline 890.2200; Larval Amphibian Growth and Development Assay (LAGDA), OCSPP Test Guideline 890.2300; and Avian Two-generation Toxicity Test in the Japanese Quail (JQTT), OCSPP Test Guideline 890.2100. The test guidelines are part of a series of test guidelines established by OCSPP for use in testing pesticides and chemical substances. The test guidelines serve as a compendium of accepted scientific methodologies and protocols that are intended to provide data to inform regulatory decisions.

OECD Publishes Final OCSPP Test Guidelines

On July 28, 2015, the Organization for Economic Cooperation and Development (OECD) announced the publication of three new, final testing guidelines to aid in the development of more comprehensive data on chemicals suspected to be endocrine disruptors, as follows:

- Medaka Extended One Generation Reproduction Test (MEOGRT) (OECD Test Guideline 240)

- Test No.: The Larval Amphibian Growth and Development Assay (LAGDA) (OECD Test Guideline 241)

- Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) In Vitro Assays to Detect Chemicals with ER Binding Affinity (OECD Test Guideline 493)

The following updated or new draft guidelines were published concurrently for screening and prioritization purposes, to provide mechanistic information that can be used in a weight of evidence approach and/or to include endocrine disruptor endpoints for use in the assessment of effects of a test chemical on male and female reproductive performance:

- Reproduction/Developmental Toxicity Screening Test (OECD Test Guideline 421)

- Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD Test Guideline 422)

- Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists and Antagonists (Draft OECD Test Guideline 455)

- Mammalian Spermatogonial Chromosomal Aberration Test (OECD Test Guideline 483)

As done for the OECD 421 and 422 test methods, consideration is now being given to expanding the utility of the Prenatal Developmental Toxicity Study (OECD Test Guideline 414) to include sensitive endocrine disruptor endpoints following a proposal by Denmark in April 2015. A preliminary analysis of data from studies conducted in a research context is now underway, which will be followed by a statistical analysis to evaluate endpoints for relevance and reliability for the identification of endocrine active chemical. For detailed information regarding the request for contributions of available data from studies that examined endocrine disruptors endpoints as possible additions to the standard OECD 414 test method, please visit OECD's call for data. The deadline for data contributions is **September 25, 2015**.

Inspector General Initiates Investigation Of Antimicrobial Testing Program: EPA's Inspector General (IG) has launched an investigation into the Office of Pesticide Programs' (OPP) antimicrobial testing program. The investigation reportedly will focus on how OPP determines whether sterilants, disinfectants, and tuberculocides used in hospitals are effective, according to an August 26, 2015, letter from the IG's office. The IG's office has initiated four such investigations into the performance of an OPP program in the past 12 months. Reportedly, there

are also ongoing investigations into how OPP responds to petitions from the public; how it negotiates compliance agreements with states; and how it is working to prevent the spread of insects resistant to an insecticide commonly used in genetically modified crops.

EPA Extends Pesticide Cumulative Risk Assessment Comment Deadline: On August 28, 2015, EPA extended the comment date on its draft guidance, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*. 80 Fed. Reg. 52274. EPA's draft framework provides guidance on how EPA will screen groups of pesticides for cumulative evaluation. EPA proposes using a two-step approach, beginning with the evaluation of available toxicological information and, if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMG) and conducting cumulative risk assessments (CRA). Additionally, EPA is also seeking comments on a draft copy of the human health risk assessment where the cumulative assessment was conducted in conjunction with pending actions for abamectin. EPA has described a process that is data intensive and that requires sophisticated knowledge and modeling. EPA acknowledges that "the level of refinement provided by this approach is not necessary or even feasible for all existing pesticide classes." The policy documents for conducting the first step in the process, "developing CMGs," are still being refined. This document provides the guidance for screening information to identify candidate CMGs and does not outline how actually to conduct CRAs. Rather, this document relies on policies and principles provided in other documents found on the EPA CRA website. These additional policies and principles were developed during the conduct of five CRAs for chemical groups such as the organophosphates and carbamates. Requirements for EPA to determine and assess the risks of possible common mechanism of action among groups of similar pesticides was one of the most far-reaching new requirements imposed by the Food Quality Protection Act. Some observers expected a larger impact on pesticide use than what has occurred to date; whether EPA's new approach results in more groupings or otherwise leads to restrictions on more groups of pesticides remains to be seen. Comments on the draft guidance are due **September 28, 2015**. More information regarding EPA's assessment of pesticide cumulative risk is available online.

EPA Announces Electronic Submission For Pesticide Applications: On September 1, 2015, EPA announced the debut of a new electronic system for pesticide applications, the Pesticide Submission Portal. According to EPA, this debut is the first step in a phased approach that ultimately will allow EPA to accept all pesticide applications electronically -- a move that will help modernize the pesticide registration process, increase operational efficiencies, and reduce paper waste. EPA will continue to accept paper, CD, and DVD applications, but encourages applicants to take advantage of what EPA states is the new, more efficient option. The following types of applications will now be accepted through the Pesticide Submission Portal:

- New pesticide active ingredients;
- New pesticide products containing already-registered pesticide active ingredients;

- Amendments to registered pesticide products;
- Experimental use permits;
- Inert ingredient requests;
- Pre-application;
- Petitions for food or feed tolerance, and
- Distributor products.

The Portal is accessed through EPA's Central Data Exchange (CDX) Network and requires user registration. For registrants currently submitting CDs or DVDs using the e-Dossier downloadable tool or their own builder tools using EPA's XML guidance, they may use the Portal and forego the courier costs to send to EPA. For electronic submissions, applicants do not need to submit multiple copies of any pieces of their application, as the requirement for multiple copies of data and five copies of draft labeling only applies to paper submissions. Additional benefits of using the Portal include a status indicator that allows registrants to track the movement of their submissions and automatically generated MRID numbers. Additional information on the Portal, including a user guide and updated XML guidance, is available on EPA's Electronic Submission for Pesticide Applications page.

EPA To Host Disinfection Hierarchy Workshop And Webinar: On September 8, 2015, EPA announced that it will host a Disinfection Hierarchy Stakeholder Workshop and corresponding webinar on **October 7, 2015, from 8:30 a.m. - 5:00 p.m. (EDT)**. The "disinfection hierarchy" describes the descending order of susceptibility of classes of microorganisms to antimicrobial chemicals. Demonstrated efficacy against a representative organism would support a manufacturer's claims against more susceptible (easier to kill) organisms, potentially eliminating the need to test against, or alternatively, to submit data for each individual organism. EPA has relied on the disinfection hierarchy concept historically. For example, EPA relied on the disinfection hierarchy concept to take timely action to address the H1N1 virus in 2009, by allowing reliance on Influenza A data. More recently, EPA states that it agreed that use of a registered hospital disinfectant with a label claim for use against a non-enveloped virus was appropriate for disinfection of surfaces contaminated with the ebola virus.

EPA is considering expanding its use of disinfection hierarchy concepts for the registration of public health antimicrobial pesticides. EPA states that its goals for expanding the use of these concepts are:

1. To provide guidance to health care officials and the public on the most effective type of registered antimicrobial products on the market to combat an emerging pathogen; and

2. To increase the efficiency of, and lower the costs associated with, registering antimicrobial pesticides, while maintaining a high level of public health protection.

According to the announcement, the workshop will focus on the scientific merits of the hierarchy, and will provide a forum for stakeholders to discuss:

- The current science on which disinfection hierarchy concepts are based;
- Scientific issues that may present challenges for use of the disinfection hierarchy in registering antimicrobial pesticide products; and
- Ideas on how to address these issues.

A panel of approximately 15 stakeholders from the public sector, academia, and industry will address a series of charge questions, followed by the opportunity for audience questions or comments. The current list of panel members is available here.

EPA's OPP has developed a draft white paper on disinfection hierarchy concepts that will serve as the basis for discussion during the workshop. The draft white paper includes questions on which EPA states it is seeking input. The agenda for the workshop is available here.

More information on disinfection hierarchy is available in Bergeson & Campbell, P.C.'s (B&C®) memorandum Summary of Ninth Antimicrobial Workshop.

FDA

FDA Announces Voluntary Participation In IMDRF: On August 19, 2015, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) announced it will participate in the International Medical Device Regulators Forum's (IMDRF) Regulated Product Submission Table of Contents (RPS ToC) Pilot Program. 80 Fed. Reg. 50293. FDA is seeking volunteers submitting premarket approval (PMA) applications or premarket notifications (510(k)) to participate in this pilot program that is intended to provide an opportunity to evaluate possible harmonization of medical device regulation. The IMDRF consists of authorities from the U.S., European Union (EU), Australia, Brazil, Japan, China, and Canada. The participation in this particular pilot is open from **September 2015** to **September 2016**.

FDA Issues FSMA Final Rules: On September 10, 2015, FDA's Center for Food Safety and Applied Nutrition (CFSAN) issued the final rules for The Preventive Controls for Human Food and Preventive Controls for Animal Food. The preventive rules are part of the Food Safety Modernization Act (FSMA). The key requirements include hazard analysis, preventive controls, and oversight and management of preventive controls, including monitoring, corrective actions, and verification. The rule includes "elements of both the original and supplemental proposal, in addition to new requirements that are the outgrowth of public input received during the comment

period for both proposals." Included in the final rules are updates to current good manufacturing practices and more flexibility in the supply chain program. Compliance for some businesses will begin in **September 2016**. For more details, *see* http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

RCRA/CERCLA

EPA Proposes RCRA Rules Easing Standards For Pharmaceutical Wastes And Revising Generator Standards: EPA on August 31, 2015, proposed two rules under the Resource Conservation and Recovery Act (RCRA) that would alter fundamentally the hazardous waste regulatory program. One rule eases the standards for healthcare facilities that dispose of hazardous waste pharmaceuticals, while the other proposes some three score of revisions to the requirements for generators of hazardous waste. The rules will be published in the *Federal Register* shortly, and EPA will take public comment on them for 60 days. Both rules are less stringent than the existing hazardous waste regulations. If promulgated in final, RCRA-authorized states thus would not be required to adopt the rules. Pre-publication copies of the rules are available online. The rules are EPA's first attempts in 35 years to tailor the one-size-fits-all RCRA hazardous waste program generator requirements to specific industry sectors. The proposed hazardous waste pharmaceuticals rule is intended to reduce the burden on healthcare workers and pharmacists working in healthcare facilities by creating a specific set of regulations for hospitals, clinics, and retail stores with pharmacies and reverse distributors that generate hazardous waste. Some pharmaceuticals are regulated as hazardous waste under RCRA when discarded. Healthcare facilities that generate hazardous waste pharmaceuticals as well as associated facilities have reported difficulties complying with the RCRA Subtitle C hazardous waste regulations for a number of reasons. First, healthcare workers, whose primary focus is to provide care for patients, are not knowledgeable about the RCRA hazardous waste regulations, but are often involved in the implementation of the regulations. Second, a healthcare facility can have thousands of items in its formulary, making it difficult to ascertain which ones are hazardous wastes when disposed. Third, some active pharmaceutical ingredients are listed as acute hazardous wastes, which are regulated in small amounts. To facilitate compliance and to respond to these concerns, EPA proposes to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies, and other healthcare-related facilities face. The revisions are also intended to clarify the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals. EPA is specifically proposing to add a new Subpart P under 40 C.F.R. Part 266. This new subpart is a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. If promulgated in final, healthcare facilities that are currently small quantity generators (SQG) or large quantity generators (LQG) and all pharmaceutical reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under Subpart P of 40 C.F.R. Part 266, instead of 40 C.F.R. Part 262. That is, the proposed standards are not an optional

alternative to managing hazardous waste pharmaceuticals under 40 C.F.R. Part 262; they are mandatory standards. Under the proposal, healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals (those that are not expected to be eligible to receive manufacturer's credit) will be managed on-site, similar to how they would have been under a previous proposal for managing these wastes: the 2008 Universal Waste proposal for pharmaceutical waste (73 Fed. Reg. 73520; December 2, 2008). When shipped off-site, they must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA hazardous waste treatment, storage, and disposal facility (TSDF). Healthcare facilities will be allowed, however, to send potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors for processing manufacturers' credit. In response to comments received on the Universal Waste proposal, EPA is proposing standards to ensure the safe and secure delivery of the creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors. EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at pharmaceutical reverse distributors. Like healthcare facilities, pharmaceutical reverse distributors will not be regulated under 40 C.F.R. Part 262 as hazardous waste generators, nor will they be regulated as TSDFs. Rather, the proposal establishes a new category of hazardous waste entity, called pharmaceutical reverse distributors. The proposed standards for pharmaceutical reverse distributors are, in many respects, similar to the LQGs standards, with supplementary standards added to respond to commenters' concerns. For both healthcare facilities and reverse distributors, EPA is proposing to prohibit facilities from disposing of hazardous waste pharmaceuticals down the toilet or drain (flushed or sewered). According to EPA, the proposal is projected to prevent the flushing of more than 6,400 tons of hazardous waste pharmaceuticals annually. Further, EPA proposes that hazardous waste pharmaceuticals managed under Subpart P will not be counted toward calculating the site's generator category. Additionally, EPA is proposing a conditional exemption for hazardous waste pharmaceuticals that are also controlled substances under Drug Enforcement Administration regulations. Finally, EPA is proposing management standards for hazardous waste pharmaceutical residues remaining in containers. The second rule proposed by EPA on August 31, 2015, is the Hazardous Waste Generator Improvements Rule. This rule proposes "a much-needed update to the hazardous waste generator regulations to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed, and close important gaps in the regulations," according to EPA. Two key provisions where EPA is proposing flexibility are allowing a hazardous waste generator to avoid increased burden of a higher generator status when generating episodic waste provided the episodic waste is properly managed and allowing a conditionally exempt small quantity generator (CESQG) to send its hazardous waste to a large quantity generator under control of the same person. EPA also proposes to revise certain components of the hazardous waste generator regulatory program; address gaps in the regulations; provide greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner; reorganize the hazardous waste generator regulations to make them more user-friendly and thus improve their usability by the regulated community; and make technical corrections and

conforming changes to address inadvertent errors, remove obsolete references to programs that no longer exist, and improve the readability of the regulations. EPA states that these proposed changes are both a result of EPA's experience in implementing and evaluating the hazardous waste generator program over the last 30 years, as well as a response to concerns and issues identified by the states and regulated community. In addition to these two changes, EPA is proposing to revise about 60 provisions in the RCRA hazardous waste regulatory program applicable to generators. Many of the changes proposed by EPA alter long-entrenched regulatory requirements. EPA is proposing to revise the definition of "small quantity generator" and add definitions for the other two generator categories, as well as a definition for "central accumulation area." In addition, EPA proposes to change the name of the "conditionally exempt small quantity generator" category to "very small quantity generator" or VSQG. EPA is also proposing four changes to the hazardous waste identification regulations. First, EPA is proposing to add a new provision that would explain what generator category would apply to a generator that generates both acute and non-acute hazardous waste in the same calendar month. Second, EPA would revise the regulations at 40 C.F.R. Sections 261.5(h) and (i) and 261.3 that address the mixing of a non-hazardous waste with a hazardous waste. Third, EPA is proposing to amend 40 C.F.R. Sections 261.5(f)(3) and (g)(3) to allow CESQGs to send their hazardous waste to LQGs that are operated under control of the same person. Under this proposal, a CESQG that wants to take advantage of this provision would need to comply with the proposed requirements. Finally, EPA is proposing to amend 40 C.F.R. Section 261.6(c) to require biennial reporting for owners or operators of facilities that recycle but do not store hazardous waste before the recycling. EPA is proposing a number of changes to the regulations for generators of hazardous waste at 40 C.F.R. Part 262 to improve the understanding of the RCRA generator regulations to encourage increased compliance by the regulated community.

CAA/CWA/SDWA

Federal Judge Blocks Waters Of The United States Rule In 13 States: Stating that EPA "likely . . . has violated its Congressional grant of authority" in promulgating the Waters of the United States (WOTUS) rule, on August 27, 2015, the U.S. District Court for the Southeastern Division of North Dakota issued a memorandum opinion blocking implementation of the rule in 13 states that filed suit in the district. The court also ruled that EPA likely violated the Administrative Procedure Act (APA) in promulgating the WOTUS rule. The rule, issued by EPA and the Army Corps of Engineers on June 29, 2015 (80 Fed. Reg. 37053) took effect on August 28, 2015. But the court's ruling blocks the rule's effectiveness in North Dakota, Alaska, Arizona, Arkansas, Colorado, Idaho, Missouri, Montana, Nebraska, Nevada, South Dakota, Wyoming, and New Mexico. The court ruled that these 13 states met the conditions necessary for a preliminary injunction, including that they would likely be harmed if courts did not act and that they are likely to succeed when their underlying lawsuit against the rule is decided. EPA states that it will enforce the regulation as planned and that the court decision only impacts the 13 states that sought the injunction. Aside from these 13 states, "[i]n all other respects, the rule is effective on August 28," EPA said in a statement. EPA's interpretation appears at be at odds with other

stakeholders, many of whom believe the court's ruling holds the rule in abeyance across all states.

EPA Proposes Standards Limiting Methane Emissions From Oil And Gas Sector: EPA on August 18, 2015, issued a package of proposed actions intended to reduce methane emissions from the oil and natural gas industry, including hydraulic fracturing (fracking) operations. The proposal is a part of the Obama Administration's Climate Action Plan to cut methane emissions from the oil and gas sector by 40 to 45 percent from 2012 levels by 2025. EPA estimates that the proposed standards for new and modified sources are expected to reduce 340,000 to 400,000 short tons of methane in 2025, the equivalent of reducing 7.7 to 9 million metric tons of carbon dioxide. EPA further estimates the rule will yield net climate benefits of $120 to $150 million in 2025 and will slash 170,000 to 180,000 tons of ozone-forming volatile organic compounds (VOC) in 2025, along with 1,900 to 2,500 tons of air toxics, such as benzene, toluene, ethylbenzene, and xylene. The proposed standards are intended to complement voluntary efforts, including EPA's Methane Challenge Program, and are based on practices and technology currently used by industry. To cut methane and VOC emissions, the proposal requires the oil and natural gas industry to find and repair leaks, and capture natural gas from the completion of fracking wells, limiting emissions from new and modified pneumatic pumps, and limiting emissions from several types of equipment used at natural gas transmission compressor stations, including compressors and pneumatic controllers. As part of the proposal, EPA is updating the 2012 New Source Performance Standards (NSPS) to address methane as well as VOC emissions for sources covered in that rule. EPA's proposal would also require that industry reduce VOC and methane emissions from hydraulically fractured and refractured oil wells. In addition, the proposal would require reductions in methane and VOC emissions downstream from wells and production sites, covering equipment in the natural gas transmission segment of the industry that was not regulated in EPA's 2012 oil and natural gas rules. The rules have not yet been published in the *Federal Register*. EPA will take comment on the proposals for 60 days after they are published. Pre-publication versions of the suite of proposals and related fact sheets are available online. EPA has scheduled three public hearings on the proposal: two on **September 23** in Dallas, TX, and Denver, CO, and a third on **September 29** in Pittsburgh, PA.

NANOTECHNOLOGY

UK Report Assesses Workplace Exposure And Control Measures During The Manufacture And Handling Of Engineered Nanomaterials: The United Kingdom's (UK) Health and Safety Laboratory (HSL) of the Health and Safety Executive (HSE) prepared a report entitled *Summary of work undertaken to assess workplace exposure and control measures during the manufacture and handling of engineered nanomaterials*. The report notes that HSE and HSL attempted to identify and engage with companies that manufactured or used nanomaterials, but only four volunteered to take part in this project. The report cautions that the observations represent a limited data set, and need to be understood in this context and not overgeneralized. The objectives were to visit companies to assess exposure to airborne nanomaterials during their

manufacture, handling, and use, and to assess the effectiveness of the controls used to reduce exposure to nanomaterials. The key findings include:

- An increased understanding of some of the tasks and activities undertaken during the manufacturing, handling, or use of nanomaterials and the potential for exposure to airborne nanomaterials;
- Existing good hygiene control practices can be used to reduce exposure to airborne nanomaterials;
- An exposure monitoring strategy suited to small businesses to monitor emission of airborne nanomaterials was evaluated and found to be practical and cost effective;
- The company Control of Substances Hazardous to Health (COSHH) assessments were not specific to nanomaterials and all of the assessments reviewed could have been improved;
- An effective risk management assessment strategy could include a combination of a simple exposure monitoring approach and an occupational hygiene assessment of the process and the controls; and
- There is not enough evidence yet to propose a measurement methodology that should be used to underpin separate specific occupational exposure limits (OEL) for nanomaterials if these were to be proposed.

Companies Appeal ECHA's Decision On Silicon Dioxide: On August 19, 2015, the European Chemicals Agency (ECHA) announced appeals of its March 11, 2015, decision on substance evaluation for silicon dioxide. Case A-015-2015 was filed by Evonik Degussa GmbH and 34 others, while Case A-014-2015 was filed by Grace GmbH & Co. KG and Advanced Refining Technologies GmbH. The appellants in Case A-015-2015 challenge ECHA's decision to include silicon dioxide on the Community Rolling Action Plan (CoRAP) "due to initial grounds for concern relating to 'the substance characterisation, nanoparticles and toxicity of different forms of the substance.'" The appellants argue that none of the alleged grounds for concern are criteria for inclusion of a substance on the CoRAP, and as a result, ECHA's decision to include silicon dioxide on the CoRAP was adopted in breach of Article 44 of the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation and must be set aside. In addition, the appellants claim further that, since the decision to include the substance on the CoRAP was illegal and must be set aside, the March 11, 2015, decision lacks legal basis as only substances appearing on the CoRAP can be evaluated. In Case A-014-2015, the appellants' arguments include: "The Agency has based its decision very largely on its own classification of [synthetic amporphous silica] as a nanomaterial, a classification that the Agency is not empowered to make and that in any event is irrelevant to the toxicity of [synthetic amporphous silica]." In the March 11, 2015, decision, ECHA requires silicon dioxide registrants to provide specified data by **March 20, 2017**.

Belgium's Nanomaterials Register Now Available: Belgium's Federal Public Service (FPS) for Health, Food Chain Safety and Environment created an online portal for companies to register nanomaterials they put on the market. Nanosubstances must be registered before **January 1, 2016**. Mixtures containing such substances must be registered before **January 1, 2017**. Belgium has posted several documents to help companies determine whether they must register:

- *Who has to register?* The answer is given in a schematic way, with a decision tree for substances and a decision tree for mixtures. According to the document, the main difference between the decision trees follows from the exemption made in Article 1.8 of the Royal Decree: "The provisions of this Decree shall not apply to . . . pigments, when placed on the market in a mixture, an article or a complex object." The following products are exempt from registration: biocide; medicinal products for human or veterinary use; products intended to come into contact with foodstuff; animal feed; and technological aid or other products that may be used for processing ingredients of agricultural origin.
- *When do I have to register?* Existing substances produced in nanoparticular state that are already on the market before **January 1, 2016**, must be registered before **January 1, 2016**. Existing mixtures containing substances produced in nanoparticular state that are already on the market before **January 1, 2017**, must be registered before **January 1, 2017**. New substances produced in nanoparticular state after **January 1, 2016**, and mixtures containing such substances after **January 1, 2017**, must be registered before being placed on the market.
- *Which type of account?* Creating an account gives users access to the registration tool and allows the submission of one or more registrations.
- *Which type of registration?* A foreign supplier can submit only one type of registration, namely the inverse (of the limited) registration. A registrant or a representative can submit different types of registrations, depending on whether the registration concerns a substance or a mixture; a first registration or an annual update; a registration using a previous registration number; or a product that is used exclusively within the framework of scientific research and development or within the framework of product and process-oriented research and development.
- *Registration -- which info?* This document aims to guide users through the registration process and to provide an overview of the information that will be asked during this process.

EC Invites Scientists To Apply For Membership In SCCS And SCHEER: The European Commission (EC) invites scientists to apply for membership in its non-food scientific committees, the Scientific Committee on Consumer Safety (SCCS) and Scientific Committee on Health, Environmental and Emerging Risks (SCHEER). SCCS and SCHEER provide the EC

with "high quality and independent risk assessment and scientific advice in the areas of public health, consumer safety and environmental risks." SCCS provides opinions on questions concerning health and safety risks of non-food consumer products such as cosmetic products and their ingredients, including nanomaterials. SCHEER provides opinions on questions concerning health, environmental, and emerging risks, including potential risks associated with new technologies such as nanotechnologies. Applications are due **November 2, 2015**.

EC Scientific Committee Will Consider Safety Of Nano Titanium Dioxide In Sunscreens And Personal Care Spray Products: On September 14, 2015, the SCCS posted a request from the EC for a scientific opinion on titanium dioxide (nano) as a UV-filter in sunscreens and personal care spray products. In 2013, the SCCS issued an opinion on titanium dioxide (nano), and concluded that titanium dioxide (nano), at a concentration up to 25 percent, can be considered not to pose any risk of adverse effects in humans after application on healthy, intact, or sunburned skin. At the time, the SCCS stated that, on the basis of available information, the use of titanium dioxide nanoparticles in spray products could not be considered safe. In 2014, the SCCS issued an opinion clarifying the meaning of the term "sprayable application/products" for the nano forms of carbon black CI 77266, titanium dioxide, and zinc oxide. In the 2014 opinion, the SCCS stated that its concern was limited to spray applications that might lead to the consumer's lungs being exposed to titanium dioxide nanoparticles by inhalation. According to the request for an opinion posted on September 14, 2015, in July 2015, the EC received new data from industry to support the safe use of titanium dioxide (nano) when used as a UV-filter in sunscreens and personal care spray products at a concentration up to 5.5 percent. The request asks the SCCS:

- In light of the data provided, does the SCCS consider titanium dioxide (nano) safe when used as a UV-filter in sunscreens and personal care spray products at a concentration up to 5.5 percent; and
- Does the SCCS have any further scientific concerns regarding the use of titanium dioxide (nano) when used as a UV-filter in sunscreens and personal care spray products.

Registration Open For "Nano In Belgium" Workshop: The FPS Health, Food Chain Safety and Environment, the FPS Employment, Labor and Social Dialogue, and the FPS Economy, Small and Medium-sized Enterprises (SME), Self-Employed and Energy will hold a workshop on "Nano in Belgium" on **October 22, 2015**. The workshop will focus on nano research, and the agencies encourage representatives from Belgian research institutes, universities, and industries to participate by either posters or oral presentation. The main goal is to improve networking between scientists, industry, and regulators in Belgium, thus improving Belgian participation in nano research and regulatory developments at the European level. Participation is free, but registration is required. The deadline for registration is **September 21, 2015**.

BIOBASED/RENEWABLE PRODUCTS

BRAG Biobased Products News And Policy Report: B&C's consulting affiliate, B&C® Consortia Management, L.L.C. (BCCM), manages the Biobased and Renewable Products Advocacy Group (BRAG®). For access to a weekly summary of key legislative, regulatory, and business developments in biobased chemicals, biofuels, and industrial biotechnology, go to http://www.braginfo.org.

ECHA Issues Article 95 Biocide Suppliers List: On September 2, 2015, ECHA issued an updated **list of biocide suppliers** as required under Article 95 of the Biocidal Product Regulation (BPR). Although prior versions of the list were released previously, this list has current legal effect since Article 95 provides that, as of September 1, 2015, a biocidal product cannot be made available in EU markets unless the active ingredient supplier or product supplier is listed for the particular product type (PT) (*e.g.*, PT 5 (Drinking water), PT 19 (Repellents and attractants)) to which the biocide product belongs.

The purpose of Article 95 in creating a list of persons placing active substances in the EU market is to ensure the equal treatment of persons placing active substances on the market and to avoid "free riders." Without the requirements in Article 95, a supplier of an active substance that has not supported the approval of that substance (either through the Review Programme of the biocide directive, or as a newcomer under the BPR) could still enter the market without compensating the entity that undertook the costs and effort to have the active substance listed.

There will be continued updates and revisions made to the list as new suppliers seek inclusion. In addition, ECHA states that it received 158 applications from suppliers seeking inclusion on the list, and has created a list of pending applications that ECHA is still processing. ECHA notes: "The list of pending Article 95(1) applications should not be confused with the list of relevant substances and suppliers ("Article 95 list") and the presence of a company (per substance/PT/role) on the list of pending applications does not guarantee that the application will be successful and that the company will ultimately be included in the Article 95 list." Updates to the list also are expected for certain substances that were not within the scope of the Biocidal Products Directive (BPD) (*e.g.*, some *in situ* generated active substances, substances benefiting from derogation for food and feed in Regulation 1451/2007), and for which different BPR notification and inclusion dates apply.

Although enforcement efforts regarding the Article 95 list have not yet been tested, companies placing biocidal products in EU markets must carefully review the list to ensure that they and/or their suppliers are listed not only for the particular active ingredient and/or product at issue, but also for the product's particular PT.

There is a one year period, until **September 1, 2016**, to sell existing stocks for biocide products where the suppliers are not included on the List.

LEGISLATIVE DEVELOPMENTS

Congress Returns To A Busy Schedule: On September 8, 2015, the 114th Congress returned for its second session, facing a packed schedule. The box score for the first session mirrors the political logjam in Washington. From January 6 through August 31, the House spent 105 days in session and the Senate 115. A total of 6,273 measures were introduced. But lawmakers passed only 49 bills, less than one percent of all measures introduced.

MISCELLANEOUS

EFSA Issues Call For Data On Fipronil And Bees: On September 1, 2015, the European Food Safety Authority (EFSA) issued a call for data on the risks to bees from the insecticide, fipronil, as requested by the EC. Specifically, EFSA is calling on national authorities, research bodies, industry, and other interested organizations to submit new information related to the risk to bees from fipronil.

In 2013, the EC imposed restrictions on the use of fipronil following an EFSA assessment of the risk to bees from fipronil. The EFSA prohibited the use of fipronil as a seed treatment, except on seeds sown in greenhouses and seeds of leek, onions, shallots and brassica vegetables sown in fields and harvested before flowering. When it imposed these restrictions, the EC stated that within two years it would initiate a review of any new scientific information; this call for data is the first step of this process. Interested parties are asked to submit:

- Literature data, including grey literature and data from other relevant research activities;
- Study reports -- such as acute laboratory studies, chronic toxicity studies, residues data, and field studies -- conducted specifically to assess the risk to bees from fipronil that were not considered under the previous EFSA assessment; and
- National evaluations and/or monitoring data not considered under the previous assessment.

EFSA is asking for all information to be submitted by **January 15, 2016**. Following receipt of a separate mandate from the EC, EFSA will then review the material and offer a conclusion concerning an updated risk assessment.

EFSA is also currently gathering new information related to the risks to bees from the neonicotinoid pesticides clothianidin, imidacloprid and thiamethoxam. This data call runs until **September 30, 2015**, and is part of the EC's follow-up to the restrictions it imposed on the three substances in 2013. More information regarding EFSA's call for data on pesticides is available on B&C's Pesticide Law and Policy Blog, EFSA Issues Call for Data on the Health and Environmental Effects of Neonicotinoid Pesticides.

OEHHA Announces Intent To List Glyphosate Under Prop 65: On September 4, 2015, the California Environmental Protection Agency's Office of Environment Health Hazard Assessment (OEHHA) announced it intends to list the chemicals identified in the table below as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). The action is being proposed pursuant to the "Labor Code" listing mechanism. OEHHA has determined that tetrachlorvinphos, parathion, malathion, and glyphosate meet the criteria for listing by this mechanism.

Chemical	CAS No.	Endpoint	References
Tetrachlorvinphos	22248-79-9	Cancer	IARC (2015a); Guyton *et al.* (2015)
Parathion	56-38-2	Cancer	IARC (2015a); Guyton *et al.* (2015)
Malathion	121-75-5	Cancer	IARC (2015a); Guyton *et al.* (2015)
Glyphosate	1071-83-6	Cancer	IARC (2015a; b); Guyton *et al.* (2015)

Health and Safety Code Section 25249.8(a) incorporates California Labor Code Section 6382(b)(1) into Proposition 65. The law requires that certain substances identified by the International Agency for Research on Cancer (IARC) be listed as known to cause cancer under Proposition 65. Labor Code Section 6382(b)(1) refers to substances identified as human or animal carcinogens by IARC. As the lead agency for the implementation of Proposition 65, OEHHA evaluates whether a chemical's listing is required by Proposition 65.

According to OEHHA, tetrachlorvinphos, parathion, malathion, and glyphosate each meet the requirements for listing as known to the state to cause cancer for purposes of Proposition 65.

IARC has published on its website a list entitled "Agents classified by the IARC Monographs, Volume 1-112" (IARC, 2015a) and the glyphosate monograph in Volume 112 of the IARC Monographs series (IARC, 2015b). IARC concludes that malathion and glyphosate are classified in Group 2A ("probably carcinogenic to humans") and that tetrachlorvinphos and parathion are classified in Group 2B ("possibly carcinogenic to humans"). IARC concludes that there is sufficient evidence of carcinogenicity in experimental animals for tetrachlorvinphos, parathion, malathion, and glyphosate (Guyton *et al.*, 2015; IARC, 2015a & b). Comments are due by **October 5, 2015**.

U.S. Department Of Health And Human Services Notice Of Proposed Rule Making: On September 8, 2015, the U.S. Department of Health and Human Services (HHS) and 15 other federal departments and agencies announced proposed revisions to the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991 (subpart A of 45 C.F.R. part 46). 80 Fed. Reg. 53931. The need for the proposed revisions is derived from the

advanced changes in the "volume and landscape of research involving human subjects." The advancement in technology and sophistication of electronic health data have grown in scale and diversification but the oversight system has remained unchanged for over two decades. The comment period for the proposed rule is open until **December 7, 2015**. For more details, *see* http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Ninth Circuit Vacates EPA's Unconditional Registration For The Neonicotinoid Pesticide Sulfoxaflor Based On Hazard To Bees: In an opinion issued on September 10, 2015, the U.S. Court of Appeals for the Ninth Circuit vacated EPA's unconditional registration for the pesticide sulfoxaflor and remanded the matter to EPA to obtain further studies and data regarding the effects of sulfoxaflor on bees and bee colonies. Sulfoxaflor is a new insecticide in the class of insecticides referred to as neonicotinoids, but its mechanism of action is distinct from other neonicotinoids. The Petitioners in this case were various trade organizations representing commercial beekeepers, as well as some individual beekeepers. The registrant Dow AgroSciences LLC (Dow) intervened in the action.

This is an unusual case because the registration of a new pesticidal active ingredient has been vacated on substantive as opposed to procedural grounds. The court's rationale reflects a lack of judicial deference to what EPA typically refers to as the scientific "weight of the evidence." While the term itself does not appear in the opinion, the court is insisting that EPA must follow its standard methodology without allowing for any deviations based on professional judgment. Although in this instance the court has supported the position of opponents of pesticide use, judicial reluctance to accept scientific "weight of the evidence" conclusions could also make it harder for EPA to impose additional restrictions when new but inconclusive evidence appears.

This case could cause EPA to be more explicit in adding procedures to its standard analytic methodologies that allow deviations from the methodology based on professional judgment. The case could also cause EPA to reconsider its recent reluctance to avoid issuing conditional registrations and its preference for unconditional registrations for new active ingredients. In any case, decisions that afford EPA less discretion to use "weight of the evidence" reasoning when basing scientific conclusions on less than conclusive data or studies could have an impact on a number of EPA practices and policies involving interpretation of scientific data. For a more detailed memorandum, please see B&C's Pesticide Law and Policy Blog®.

EPA Requests Comment On Fiscal Year 2017 - 2019 Enforcement Priorities: EPA on September 15, 2015, announced its National Enforcement Initiatives (NEI) for its Fiscal Years (FY) 2017 - 2019 and requested comment on them. 80 Fed. Reg. 55352. EPA selects enforcement initiatives every three years to focus its resources on what it considers to be the most important environmental problems where noncompliance is a significant contributing factor and where federal enforcement attention can make a difference. EPA's Office of Enforcement and Compliance Assurance (OECA) is specifically requesting comment on which of the current

six NEIs should continue, be expanded, or returned to the standard enforcement program, and whether it should address new NEIs.

EPA's current six NEIs are:

- **Reducing air pollution from the largest sources**. This NEI has focused on ensuring that large industrial facilities comply with the Clean Air Act (CAA) when building new facilities or making modifications to existing facilities. EPA has targeted this effort on coal-fired power plants, as well as acid, glass, and cement manufacturing facilities. Large percentages of facilities in these sectors are now under enforceable commitments to reduce pollution, although EPA states there are still violating facilities.
- **Cutting toxic air pollution.** This NEI has focused on "the substantial illegal emissions of hazardous air pollutants (HAPs) from leaks, flares, and excess emissions at industrial facilities." EPA is considering expanding this initiative into new focus areas and sources where it believes noncompliance is a growing threat.
- **Assuring energy extraction and production activities comply with environmental laws.** EPA has been working with states to assure that domestic land-based natural gas extraction and production is done in an environmentally protective manner and in compliance with environmental laws. EPA has brought a number of high impact enforcement actions to address serious violations in this industry. This sector continues to develop and change rapidly, and EPA is evaluating the best way to address pollution problems in this sector, including opportunities for greater use of advanced monitoring.
- **Reducing pollution from mineral processing operations:** EPA states that "mining and mineral processing facilities generate more toxic and hazardous waste than any other industrial sector." Through this NEI, EPA has thus focused on the largest and highest risk mineral processing operations, to ensure that they properly manage their wastes and have sufficient financial assurance to close facilities. This NEI has resulted in a number of large, high impact cases to ensure proper handling of these hazardous wastes. By the end of FY16, many of the highest risk mineral processing facilities are expected to be under enforceable agreements or orders that will require them to address properly hazardous waste.
- **Keeping raw sewage and contaminated storm water out of our nation's waters:** Under this NEI, EPA has tackled significant water pollution problems within communities that result from Clean Water Act (CWA) noncompliance. Many communities with raw sewage discharges are now under enforceable commitments to reduce pollution, including numerous communities that have embraced green infrastructure as a

solution. EPA states that it will need to continue to monitor implementation of these long-term agreements, and adapt them to changing circumstances and new information, such as the increasing commitment of cities to implement green infrastructure, changes in financial capability, or technological advances.

- **Preventing animal waste from contaminating surface and ground water:** The focus of this NEI has been reduction of animal waste pollution that impairs our nation's waters, threatens drinking water sources, and adversely impacts communities. EPA's enforcement strategy for this NEI has focused on animal agriculture operations that have a significant impact or where action is necessary to ensure that all operations in the sector play by the same rules. EPA is considering an updated strategy to explore the use of nutrient recovery technologies that show promise to reduce water pollution, implementation of in-stream monitoring to demonstrate impacts to water quality and identify violations, as well as new tools to identify the most significant violators.

New NEIs being considered by EPA are:

- **Protecting communities from exposure to toxic air emissions:** EPA is considering expanding its current air toxics NEI to include emissions from additional sources and industries, with a primary focus on organic liquid storage tanks and hazardous waste air emissions. With respect to the latter, EPA is particularly concerned about the toxic air emissions from hazardous waste TSDFs and LQGs that are not properly controlling hazardous waste releases to the air.
- **Keeping industrial pollutants out of the nation's waters:** EPA states that many waters (including sediments) around the country are polluted by nutrients and metals. This potential NEI would focus on the top sectors that have many violations and that EPA claims are responsible for contributing to surface water pollution and putting drinking water at risk. This includes the mining, chemical manufacturing, food processing, and primary metals manufacturing sectors. In addition to being a focused attempt to reduce serious water pollution across the nation, selecting this as an NEI would allow for a national approach for those companies that operate in more than one state and would support a consistent national strategy to achieve compliance across industry sectors.
- **Reducing the risks and impacts of industrial accidents and releases:** This potential NEI would be a targeted focus on the facilities and the chemicals that pose the greatest risks of industrial accidents and releases. EPA would take a proactive approach under this NEI, instead of

addressing problems after accidents happen, thereby reducing the risk of harm to communities and workers.

Comments are due on or before **October 14, 2015**.

Court Finds Articles Incorporated As Components Of A Complex Product Must Be Notified To ECHA: The Court of Justice of the EU announced in a September 10, 2015, press release, "Articles incorporated as components of a complex product must be notified to the European Chemicals Agency when they contain a substance of very high concern in a concentration above 0.1%," that each of the articles incorporated as a component of a complex product is covered by the relevant duties to notify and provide information when the articles contain an SVHC in a concentration above 0.1 percent of their mass. As reported in The Acta Group's March 2015 Global Regulatory Update, in 2014, two French trade bodies initiated legal proceedings to resolve the issue. The Federations of Commerce and Distribution Undertakings and of Do-It-Yourself (DIY) and Home Improvement Stores lodged a request for a preliminary ruling with the French Council of State, challenging the position of the French Ministry of Ecology, Sustainable Development, and Energy. The parties sought a ruling on whether REACH applies only with regard to the assembled article or to each of the elements that meet the definition of' "article." The EC, supported by a majority of the Member States, has maintained that the proportion of the SVHC should be calculated by reference to the assembled article. Some Member States, including the majority of the parties to the case, contended that it is sufficient if the proportion is reached in the individual components. In its September 10, 2015, decision, the court rules that each of the articles incorporated as a component of a complex product is covered by the relevant duties to notify and provide information when they contain an SVHC in a concentration above 0.1 percent of their mass. The court found that the producer's duty to notify covers only those articles that the producer itself has made or assembled and is not applicable to an article that, although used by the producer as input, was made by a third party. The court stated that the third party is also subject to the duty to notify in respect of the article that it makes or assembles. Similarly, according to the court, the importer of a product, the composition of which comprises one or more of the objects falling within the definition of the term "article," must also be considered to be the importer of that article or those articles. The court noted that the fact that it can be difficult for importers to obtain the required information from suppliers based in non-EU countries does not alter their duty to notify. The court found that the duty to provide information with regard to the recipients and consumers of the product is not restricted to the producers and importers, but applies to all operators along the supply chain when that person supplies an article to a third party. The press release states: "It is therefore for the person supplying a product one or more constituent articles of which contain(s) a substance of very high concern in a concentration above 0.1% to fulfil his duty to provide information and provide the recipient and the consumer of the product, as a minimum, with the name of the substance in question." The duty to communicate information on articles containing SVHCs is not limited to direct EU importers or producers. It is the responsibility of the supplier of the article containing an SVHC

above 0.1 percent to provide at least the substance name of the SVHC to all members of the supply chain, not limited to the importer and/or consumer.