Recent Federal Developments
June 15, 2016

TSCA/FIFRA/IRIS/NTP/TRI

TSCA Reform Bill Is Sent To President Obama For Signature: It has been reported that on June 14, 2016, House Speaker Paul Ryan (R-WI) and Senate President Pro Tempore Orrin Hatch (R-UT) signed the bill to reform the Toxic Substances Control Act (TSCA), sending it to President Barack Obama for his signature. On June 7, 2016, the Senate passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act by voice vote. It is anticipated that President Obama will sign the bill next week. Information on the revisions to TSCA is available in our memorandum "An Analysis of Key Provisions and Fundamental Shifts in the Amended TSCA." Bergeson & Campbell, P.C.'s (B&C®) webinar on June 13 hosted by Chemical Watch attracted almost 2,000 attendees. We will be circulating shortly the dates for three additional webinars on TSCA reform.

EPA And PMRA To Release New Harmonized Product Chemistry Templates: Under the umbrella of the United States – Canada Regulatory Cooperation Council (RCC) workplan, Health Canada's Pest Management Regulatory Agency (PMRA) and the U.S. Environmental Protection Agency (EPA) have developed harmonized product chemistry templates for use by registrants when submitting pesticide registration packages. According to EPA, the templates are based on the Organization for Economic Cooperation and Development (OECD) format but have been streamlined to address a single product/application and will facilitate the review of product chemistry data for global and joint registrations, as well as other actions. EPA and PMRA encourage applicants to begin using these templates to organize and summarize the product chemistry data for each product and/or registration package submitted to the corresponding regulatory agency. The templates will be available for review at www.epa.gov/pesticide-registration/study-profile-templates#chemistry.

OMB Issues Spring Regulatory Agenda: On May 18, 2016, the Office of Management and Budget (OMB) released the Spring Regulatory Agenda. According to EPA's portion of the agenda, EPA is anticipating the release of four new chemical proposed rulemakings, one new pesticide rulemaking, and expanding one chemical rulemaking. The four new proposed chemical rulemakings are:

- Trichloroethylene (TCE); SNUR for Non-Aerosol Spray Degreasers: A proposed significant new use rule (SNUR) for TCE in non-aerosol spray degreasers (anticipated proposal in **July 2016**; RIN:2070-AK18);

- Trichloroethylene; Rulemaking Under TSCA Section 6(a); Vapor Degreasing: A proposed rule restricting or banning the use of TCE in

vapor degreasing (anticipated proposal in **October 2016**; RIN:2070-AK11);

- Polychlorinated Biphenyls (PCB); Reassessment of Use Authorizations for PCBs in Small Capacitors: A proposed rule to reauthorize the use of PCBs in small capacitors, in particular, fluorescent light ballasts (anticipated proposal in **October 2016**; RIN:2070-AK12); and

- Test Rule; Various Esters of Brominated Phthalate Acids: A proposed rule to require the generation of new toxicity or other information for the brominated phthalate acid group of flame retardants (anticipated proposal in **December 2016**; RIN:2070-AK19).

A SNUR for n-ethylpyrrolidone (NEP) in paint removers, Alkylpyrrolidone Products, published in the Fall 2015 Regulatory Agenda, is being expanded to include additional chemicals (anticipated proposal in **August 2016**; RIN:2070-AK09). It would cover not only NEP, but also n-propylpyrrolidone (NPP), n-isopropylpyrrolidone (NiPP), n-isobutylpyrrolidone (NiBP), n-sec-butyl pyrrolidone (N-sec-BP), and n-t-butyl pyrrolidone (NtBP). EPA's new pesticide rulemaking, Restructuring of Pesticide Adverse Effects Reporting Regulations, will restructure the existing pesticide incident reporting regulations at 40 C.F.R. Part 159, subpart D, and remove obsolete references (RIN:2070-AK14). The regulatory agenda states that EPA is considering issuing this as a final rule by **October 2016**, as it does not intend on making any substantive changes to the existing requirements.

EPA Proposes To Add HBCD To Toxics Release Inventory: On June 2, 2016, EPA proposed to add a hexabromocyclododecane (HBCD) category to the Toxics Release Inventory (TRI) list of reportable chemicals. 81 Fed. Reg. 35275. HBCD is a brominated flame retardant used mainly in expanded polystyrene foam (EPS) and extruded polystyrene foam (XPS). EPS and XPS are used primarily for thermal insulation boards in the building and construction industry. HBCD may also be used as a flame retardant in textiles. EPA has determined that HBCD meets the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 chronic human health effects criterion for listing because it presents potential concerns for developmental and reproductive effects. EPA also believes that HBCD meets the environmental effects criterion for listing because it is toxic to aquatic and terrestrial organisms and, according to EPA, HBCD bioaccumulates and is persistent in the environment. As a result, HBCD meets the TRI criteria for a persistent, bioaccumulative, and toxic (PBT) chemical and is proposed to be designated as a chemical of special concern, with a 100-pound reporting threshold. Comments on the proposal are due by **August 1, 2016**.

EPA Makes Final Revisions To EPCRA Hazard Categories: On June 13, 2016, EPA issued final revisions to EPCRA Sections 311 and 312 occasioned by changes to the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS). 81 Fed.

Reg. 38104. Under the revised HCS, chemical manufacturers and importers are required to evaluate their chemicals according to the new criteria adopted from the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) to ensure that they are classified and labeled appropriately. Manufacturers and importers are also required to develop standardized Safety Data Sheets (SDS) (formerly known as Material Safety Data Sheets) and distribute them to downstream users of their chemicals. These changes in HCS affect the reporting requirements under EPCRA Sections 311 and 312. Based on the new classification criteria that OSHA adopted, EPA is revising the existing hazard categories for hazardous chemical inventory form reporting under EPCRA Section 312 and for list reporting under Section 311. In this action, EPA is also making a few minor corrections in the hazardous chemical reporting regulations. The final rule was effective June 13, 2016. The compliance date is **January 1, 2018**.

EPA ALJ Issues Initial Decision In Bayer Flubendiamide Cancellation Proceeding: On June 1, 2016, Administrative Law Judge (ALJ) Susan L. Biro issued an Initial Decision in the matter of Bayer CropScience LP and Nichino America, Inc. (BCS/NAI), EPA Docket No. FIFRA-HQ-2016-0001. The decision was issued following BCS/NAI's request for a hearing to contest EPA's Notice of Intent to Cancel Pesticide Registrations (NOIC). BCS/NAI challenged EPA's position that a conditional registration term in the relevant registrations required BCS/NAI to cancel voluntarily their flubendiamide registrations within one week of notification by EPA that the currently registered flubendiamide products will result in unreasonable adverse effects on the environment, and EPA's issuance of a NOIC for all BCS/NAI flubendiamide products as a result of BCS/NAI's decision declining EPA's request to cancel voluntarily all flubendiamide registrations. In an earlier order, Judge Biro denied BCS/NAI's Motion for Accelerated Decision and ruled that as a matter of law EPA was authorized to cancel the conditional registrations under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 6(e) and did not need to provide BCS/NAI the full Section 6(b) cancellation process. More information regarding that decision is available in our blog item EPA ALJ Denies Bayer's Motion for Accelerated Decision. Without the ability to review the bases underlying EPA's determination that the continued registration of flubendiamide does not meet the Registration Standard under Section 6(b), the only two issues for consideration under Section 6(e) were: (1) whether BCS/NAI "initiated and pursued appropriate action to comply" with the voluntary cancellation provision of their conditional flubendiamide registration; and (2) whether EPA's existing stocks determination was consistent with FIFRA. With regard to the first issue, the ALJ found that new arguments offered by BSC/NAI were not timely raised, and even if they had been, the ALJ was "not persuaded by the merits of these objections." The ALJ concluded that BCS/NAI was not excused from the voluntary cancellation provision that was a condition of BSC/NAI's registrations and did not submit a voluntary cancellation request, thus triggering the Section 6(e) cancellation proceedings. With regard to the second issue concerning existing stocks, BCS/NAI had challenged EPA's determination that the use of the flubendiamide technical registration product or the further distribution and sales of the end-use products would be prohibited, but use of the end-use products by end-users would be allowed. BCS/NAI argued

that FIFRA is a risk-based statute and the facts supported an existing stocks policy that allows for sale, distribution, and use of the limited existing stocks available at the time of cancellation. The ALJ found, however, that EPA's decision was consistent with FIFRA since FIFRA grants EPA the discretion to allow the continued sale and use of a cancelled pesticide but does not require that EPA make any "determination" that continued use and sale is consistent with FIFRA's purposes. BCS/NAI have indicated they will appeal the matter to the Environmental Appeals Board. A key issue in this forthcoming appeal will be whether EPA had discretion to adopt a condition of registration so restrictive in nature that it deprived BCS/NAI of any meaningful right to contest EPA's subsequent scientific determinations. Most conditional registrations do not include a comparable condition, but it is common for EPA to issue conditional registrations under FIFRA Section 3(c)(7) that remain in effect only for a limited period during the pendency of data development. This case illustrates the difficulty that a registrant may encounter subsequently contesting any condition that it has nominally accepted. Applicants should be wary and should carefully scrutinize any conditions that EPA may propose. It may be worthwhile in some instances to consider contesting a particularly onerous condition.

EPA Issues Draft Guidance On Managing Pesticide Resistance: On June 7, 2016, EPA made available for a 60-day comment period two draft Pesticide Registration (PR) Notices that are aimed at combating pesticide resistance. The first PR Notice (PR Notice 2016-X) is titled "Draft Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling" and the second PR Notice (PR Notice 2016-XX) is titled "Draft Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship." Pesticides can be used to control a variety of pests, such as insects, weeds, rodents, bacteria, and fungi. Over time, many pesticides have gradually lost their effectiveness because pests have developed resistance -- a significant decrease in sensitivity to a pesticide, which reduces the field performance of these pesticides. EPA is concerned about resistance issues and believes that managing the development of pesticide resistance, in conjunction with alternative pest-management strategies and Integrated Pest Management programs, is an important part of sustainable pest management. To address the growing issue of resistance and preserve the useful life of pesticides, EPA is beginning to embark on a more widespread effort that is aimed at combating and slowing the development of pesticide resistance. The release of these two PR Notices will allow EPA to communicate (and seek comment) on potential strategies to combat pesticide resistance. Draft PR Notice 2016-X, which revises and updates PR Notice 2001-5, applies to all conventional agricultural pesticides (*i.e.*, herbicides, fungicides, bactericides, insecticides, and acaricides). The updates in PR Notice 2016-X focus on pesticides labels and are aimed at improving information about how pesticide users can minimize and manage pest resistance. Updates fall into the following three categories: (1) additional guidance to registrants and a recommended format for resistance-management statements or information to place on labels; (2) references to external technical resources for guidance on resistance management; and (3) instructions on how to submit changes to existing labels to enhance resistance-management language. Draft PR Notice 2016-XX, which only applies to herbicides, communicates EPA's current thinking and approach to address herbicide-resistant weeds by providing guidance on labeling, education,

training, and stewardship for herbicides undergoing registration review or registration (*i.e.*, new herbicide actives, new uses proposed for use on herbicide-resistant crops, or other case-specific registration actions). It is part of a more holistic, proactive approach to slow the development and spread of herbicide-resistant weeds and prolong the useful lifespan of herbicides and related technology. EPA is focusing on the holistic guidance for herbicides first because (1) herbicides are the most widely used agricultural chemicals; (2) no new herbicide mechanism of action has been developed in the last 30 years; and (3) herbicide-resistant weeds are rapidly increasing. In the future, EPA plans to evaluate other types of pesticides (*e.g.*, fungicides, bactericides, insecticides, and acaricides) to determine whether and what guidance may be appropriate for these types of pesticides. To view and provide comments on these draft PR Notices and any supporting material, please visit EPA-HQ-OPP-2016-0242 for PRN 2016-X and EPA-HQ-OPP-2016-0226 for PRN 2016-XX. The comment period for each closes on **August 2, 2016**. *See* Slowing and Combating Pest Resistance to Pesticides for more information on pesticide resistance management. *See also* our blog entitled EPA Solicits Comments on Draft Guidance for Pesticide Registrants on Managing Pesticide Resistance.

EPA Issues Draft Guidance On Minor Use Determination: On June 14, 2016, EPA announced the availability of and requested public comment on a draft PR Notice entitled "Determination of Minor Use under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 2(ll)." 81 Fed. Reg. 38704. The draft PR Notice would update Section 5 of PR Notice 97-2 and provide guidance to the registrant as to how EPA determines a "minor use." EPA seeks to identify and encourage the registration of pesticides for minor uses to protect communities from harmful pests. This draft PR Notice revises the method used by EPA for evaluating "sufficient economic incentive" under FIFRA. The draft PR Notice explains how qualitative information may be used to inform the quantitative analysis and interpret the results, and clarifies that the most recent United States Department of Agriculture (USDA) Census of Agriculture is the appropriate source for data on acreage in the United States to establish a minor use under the acreage definition in FIFRA Section 2(ll)(1). Comments are due by **August 15, 2016.**

RCRA/CERCLA

EPA Extends Comment Period On RCRA Corrosive Dust Petition For Six Months: EPA on June 10, 2016, extended until **December 7, 2016**, the comment period on its April 11, 2016 (81 Fed. Reg. 21295) tentative denial of a petition by Public Employees for Environmental Responsibility (PEER) to amend regulations under 40 C.F.R. § 261.22 regarding the definition of corrosive hazardous wastes under the Resource Conservation and Recovery Act (RCRA). 81 Fed. Reg. 37565. The petition sought a revision of the pH regulatory value for defining waste as corrosive from pH 12.5 to pH 11.5 and the addition of nonaqueous waste to the RCRA corrosivity definition. PEER asserted that the pH 11.5 value is widely used as a threshold for identifying corrosive materials and that corrosive properties of inhaled dust caused injury to first responders and others at the World Trade Center (WTC) disaster of September 11, 2001. EPA concluded that use of the pH 11.5 value in other regulatory frameworks is either optional or a

presumption that may be rebutted by other data and that such a use is inconsistent with the way pH is used in the RCRA corrosivity regulation. EPA also stated in the tentative denial that the dust to which 9/11 first responders and others were exposed was a complex mixture from which no single property of the dust can be reliably identified as the cause of the adverse health effects and that the injuries that were suffered by those exposed to the WTC dust did not appear to include corrosive injuries. In addition, EPA concluded that the petition failed to demonstrate that waste management activities resulted in the exposures of concern.

EPA To Hold Webinar On Hazardous Waste Electronic Manifest: On June 30, 2016, EPA will conduct a webinar on its latest progress regarding the implementation of the Hazardous Waste Electronic Manifest (e-Manifest) system under RCRA. The e-Manifest is a national system that will facilitate the electronic transmission of the uniform manifest form. EPA claims that this system will improve access to higher quality and more timely shipment data and will significantly reduce burden associated with the current paper system. This webinar will specifically provide an overview of EPA's proposed rule notice requesting public comment on a methodology that EPA will use in setting and revising user fees to recover the full costs of the system. EPA will also provide a brief update on the e-Manifest system development. Interested parties can register for the webinar online.

CAA/CWA

EPA Releases Lifetime Drinking Water Health Advisories For Two Perfluorinated Chemicals: On May 25, 2016, EPA released lifetime drinking water health advisories for two fluorinated chemicals. 81 Fed. Reg. 33250. EPA issued an advisory of 0.07 microgram per liter (µg/L) for perfluorooctane sulfonate (PFOS), a chemical that is used for soil and stain resistance in various products, and an advisory of 0.07 µg/L for perfluorooctanoic acid (PFOA), a chemical found in products such as non-stick cookware. These types of advisories are non-enforceable, offering a guideline and benchmark for determining whether the concentrations of chemicals in tap water from utilities are safe for public consumption. These advisories replace EPA's provisional health advisories for PFOA and PFOS issued by EPA in January 2009. Based on data and analysis conducted at that time, EPA determined the health guideline levels for PFOA and PFOS are 0.4 µg/L and 0.2 µg/L, respectively. Elevated levels of perfluorinated chemicals (PFC) have been identified in New York, New Hampshire, and Vermont. Earlier this year, EPA set an action level for PFOA of 100 parts per trillion (ppt) for drinking water in the Town of Hoosick and the Village of Hoosick Falls, New York. The State of Maine set an action level of 100 ppt for PFOA, and the State of Vermont went further and set a health advisory level for PFOA at 20 ppt for drinking water. The variation among the health advisory and action levels for PFCs is the source of considerable confusion, a point that undoubtedly is pressuring EPA to revisit the 2009 provisional health advisory levels. The Vermont Congressional delegation (Senators Patrick Leahy (D) and Bernard Sanders (D) and Representative Peter Welch (D)) sent a letter dated April 19, 2016, to Senators James Inhofe (R-OK) and Barbara Boxer (D-CA) and Representatives Fred Upton (R-MI) and Frank Pallone (D-NJ) urging quick Congressional action

on reform of TSCA. The Vermont delegation cited PFOA's presence in drinking and surface water in the Vermont communities of North Bennington, Bennington, and Pownal as evidence of TSCA's failure to regulate effectively existing chemicals as PFOA is among the chemicals grandfathered under TSCA when it was enacted in 1976. The letter made a strong pitch for minimal or no preemption of state action, and specifically urged reliance upon the principles outlined in a letter sent in January from twelve state Attorneys General.

FDA

FDA Amends Labeling Regulations For Conventional Foods And Dietary Supplements: On May 27, 2016, the U.S. Food and Drug Administration (FDA) issued a final rule to amend its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. 81 Fed. Reg. 33742. The changes to the labeling regulations include:

- An updated list of nutrients that are required or permitted to be declared;
- Updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports;
- Amended requirements for foods represented or purported to be specifically for children under the age of four years and pregnant and lactating women and the establishment of nutrient reference values specifically for these population subgroups; and
- Revisions to the format and appearance of the Nutrition Facts label.

The final rule becomes effective on **July 26, 2016**. For manufacturers with $10 million or more in annual food sales, the compliance date of the final rule is **July 26, 2018**, and for manufacturers with less than $10 million in annual food sales, the compliance date is **July 26, 2019**.

FDA To Require Domestic And Foreign Food Facilities To Address Public Health Hazards: On May 27, 2016, as part of the implementation of the Food Safety Modernization Act (FSMA), FDA issued a final rule that will require domestic and foreign food facilities to address hazards that may be introduced with the intention to cause wide scale public health harm. 81 Fed. Reg. 34166. This directive only applies to domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under this final rule, these food facilities will be required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to minimize significantly or prevent significant vulnerabilities identified at actionable process steps in a food operation. This rule becomes effective on **July 26, 2016**.

FDA Issues Draft Guidance To Explain "Qualified Facility" Determination Process: On May 16, 2016, FDA issued a notice announcing the availability of a draft guidance for industry, "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)." 81 Fed. Reg. 30219. FDA states that this draft guidance explains its thinking on how to determine whether a business is a "qualified facility" that is subject to modified requirements, as well as its thinking on how a business would submit Forms FDA 3942a and 3942b, attesting to its status as a qualified facility, under two of its rules: (1) "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (the Preventive Controls for Human Food Rule); and (2) "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (the Preventive Controls for Animal Food Rule). The notice also announces FDA's solicitation of comments on the proposed collection of information embodied in Forms FDA 3942a and 3942b. Comments on the proposed collection of information are due by **July 15, 2016**; comments on the draft guidance are due by **November 14, 2016**.

FDA Issues Draft Guidance On FAQs About Medical Foods: On May 13, 2016, FDA issued a notice announcing the availability of a draft guidance for industry, "Frequently Asked Questions About Medical Foods; Second Edition," which provides responses to additional questions regarding the definition and labeling of medical foods, and updates some prior responses. 81 Fed. Reg. 29866. FDA published earlier versions of the guidance in May 1997 and May 2007. The notice states that comments on this guidance will be accepted at any time.

NANOTECHNOLOGY

Mexico Begins Public Consultation On Draft Nanotechnology Standards: On May 3, 3016, Mexico's Ministry of Economy published a notice beginning a public consultation on two draft nanotechnology standards. Proposed standard PROY-NMX-R-80004-5-SCFI-2015 is identical to ISO/TS 80004-5:2011, "Nanotechnologies -- Vocabulary -- Part 5: Nano/bio interface." ISO/TS 80004-5:2011 lists terms and definitions related to the interface between nanomaterials and biology. It is intended to facilitate communications between scientists, engineers, technologists, designers, manufacturers, regulators, non-governmental organizations (NGO), consumer organizations, members of the public, and others. Proposed standard PROY-NMX-R-12901-1-SCFI-2015 is identical to ISO/TS 12901-1:2012, "Nanotechnologies -- Occupational risk management applied to engineered nanomaterials -- Part 1: Principles and approaches."* ISO/TS 12901-1:2012 provides guidance on occupational health and safety measures relating to engineered nanomaterials, including the use of engineering controls and appropriate personal protective equipment, guidance on dealing with spills and accidental releases, and guidance on appropriate handling of these materials during disposal. It is intended for use by competent personnel, such as health and safety managers, production managers, environmental managers, industrial/occupational hygienists, and others with responsibility for the safe operation of facilities engaged in production, handling, processing, and disposal of engineered nanomaterials. Publication of the notice began a 60-day public comment period.

* The notice cites standard ISO/TS 12901-1:2012 but provides an incorrect title, "Guidance on the labelling of manufactured nano-objects and products containing manufactured nano-objects. Part 1 -- Principles and approaches." We have provided the correct title of the standard, which matches the title of the draft Mexican standard.

Swiss Researchers Develop Model To Assess How Nanoparticles "Flow Through The Environment": The Swiss National Science Foundation issued a May 12, 2016, press release announcing that researchers from the National Research Program "Opportunities and Risks of Nanomaterials" have developed a new model to track the flow of the "most important nanomaterials in the environment." To assess how man-made nanoparticles make their way into the air, earth, or water, researchers developed a computer model to determine the environmental accumulation of nanosilver, nanozinc, nano-titanium dioxide, and carbon nanotubes. The press release notes that knowing the degree of accumulation in the environment is only the first step in the risk assessment of nanomaterials. This data must be compared with ecotoxicological test results and the statutory thresholds. According to the press release, in the case of nanozinc, "its concentration in the environment is approaching the critical level." The press release states that it "has to be given priority in future ecotoxicological studies -- even though nanozinc is produced in smaller quantities than nano-titanium dioxide." Furthermore, according to the press release, ecotoxicological tests have until now been carried out primarily with freshwater organisms. The researchers conclude that complementary investigations using soil-dwelling organisms are a priority.

EPA Promulgates SNUR For Functionalized CNTs (Generic): On May 16, 2016, EPA promulgated, through a direct final rule, SNURs for 55 chemical substances that were the subject of premanufacture notices (PMN), including functionalized carbon nanotubes (CNT) (generic). 81 Fed. Reg. 30451. EPA states that it determined that any use of the functionalized CNTs without the use of impervious gloves, where there is potential for dermal exposure; manufacturing the PMN substance for use other than as a thin film for electronic device applications; manufacturing, processing, or using the PMN substance in a form other than a liquid; use of the PMN substance involving an application method that generates a mist, vapor, or aerosol except in a closed system; or any release of the PMN substance into surface waters or disposal other than by landfill or incineration may cause serious health effects or significant adverse environmental effects. EPA states that the following tests would help characterize the health and environmental effects of the PMN substance: "a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); a 90-day inhalation toxicity test (OPPTS 870.3465) with additional testing parameters beyond those noted at CFR 870.3465, for using the 90-day subchronic protocol for nanomaterial assessment; a two-year inhalation bioassay (OPPTS Test Guideline 870.4200); and a surface charge by electrophoresis (for example, using ASTM E2865-12 or NCL Method PCC-2 -- Measuring the Zeta Potential of Nanoparticles)." The SNUR requires persons who intend to manufacture, import, or process any of the 55 chemical substances for an activity that is designated as a significant new use by the

direct final rule to notify EPA at least 90 days before commencing that activity. The direct final rule will be effective **July 15, 2016**. If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of the SNURs before **June 15, 2016**, EPA will withdraw the relevant sections of the direct final rule before its effective date.

EPA Intends To Promulgate Final Nanoscale Materials Rule In October 2016: According to an item in the Spring 2016 Regulatory Agenda, EPA is "developing a final rule related to" its April 6, 2015, proposal to require reporting and recordkeeping requirements under TSCA Section 8(a) for certain chemical substances when they are manufactured or processed at the nanoscale. EPA proposed to require persons that manufacture, import, or process, or intend to manufacture, import, or process these chemical substances to report to EPA certain information, including the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing data concerning environmental and health effects. The proposal involves one-time reporting for existing nanoscale materials and one-time reporting for new discrete nanoscale materials before they are manufactured or processed. According to EPA, this information would facilitate its evaluation of the materials and a determination of whether further action, including additional information collection, is needed. EPA notes that, consistent with the President's memorandum for Executive Departments and Agencies regarding Principles for Regulation and Oversight of Emerging Technologies, "this rule would facilitate assessment of risks and risk management, examination of the benefits and costs of further measures, and making future decisions based on available scientific evidence." While the regulatory agenda item states that EPA intends to promulgate a final rule in **October 2016**, EPA has not indicated how it intends to address comments on the proposed rule. OMB took several years to review the proposed rule. OMB's Office of Information and Regulatory Affairs (OIRA) issued a December 17, 2015, memorandum concerning "Regulatory Review at the End of the Administration," which states that "agencies should strive to complete their highest priority rulemakings by the **summer of 2016** to avoid an end-of-year scramble that has the potential to lower the quality of regulations that OIRA receives for review and to tax the resources available for interagency review." EPA has not yet submitted a final rule to OMB for review.

UK Nanosafety Group Publishes Updated Guidance To Support Safe Working With Nanomaterials: In May 2016, the UK Nanosafety Group (UKNSG) published a second edition of its guidance document, *Working Safely with Nanomaterials in Research & Development*. The second edition of the guidance provides updates to account for changes in legislation, recent studies in the literature, and best practice since 2012. In particular, according to the guidance, specific sections have been revised to account for the full implementation of the GHS, which came into force on June 1, 2015, through the Classification, Labeling, and Packaging (CLP) Regulation. The document explains the approaches that are presently being used to select effective control measures for the management of nanomaterials, more specifically control banding tools presently in use. Significant changes were made in the sections "Hazard

Banding," "Exposure Control," "Toxicology," and "Monitoring." The document draws attention to the possible health hazards that could result from exposure to particulate nanomaterials and provides advice on the precautions that may be needed to prevent or control adequately exposure as required by the Control of Substances Hazardous to Health Regulations 2002 (as amended). The aim of the document is to offer guidance on factors relating to establishing a safe workplace and good safety practice when working with particulate nanomaterials, which are defined as "nanomaterials that consist of nano-objects such as nanoparticles, nanofibres, nanotubes, nanowires, as well as aggregates and agglomerates of these materials either in their original form or incorporated in materials or preparations, from which they could be released." The guidance is aimed at employers, managers, health and safety advisors, and users of particulate nanomaterials in research and development. The document advocates a precautionary strategy to minimize potential exposure.

ECHA Consults PEGs On Nanomaterial Guidance Documents: The European Chemicals Agency (ECHA) recently submitted several draft guidance documents concerning nanomaterials to Partner Expert Groups (PEG) for consultation. Following consultation with PEGs, ECHA will consult its committees and/or Forum, where relevant. The final consultation will be with the European Commission (EC) and the relevant Competent Authorities. To ensure that the guidance updating process is transparent and open to participation by relevant partners, ECHA will publish drafts of the texts and feedback from the different consultation steps on its website. According to the website, feedback on ECHA guidance can be provided by any party by using the guidance feedback form.

ECHA submitted the following draft information requirements and chemical safety assessment (IR&CSA) appendices on recommendations for nanomaterials for environmental endpoints to a PEG for consultation:

- *Appendix R7-1 Recommendations for nanomaterials applicable to Chapter R7a Endpoint specific guidance*. This document was prepared by the ECHA Secretariat for the purpose of this consultation and includes only the parts open for the current consultation, *i.e.*:
  - Update of section 2.1.1 on sample preparation to provide specific indications on the parameters for characterization, pre-requisites, and preparation as monitoring awaited for any nanomaterial;
  - Update of section 2.2.1 on water solubility to include alternative guidelines that could be used for this endpoint and to flag the non-applicability for insolubility as a waiver for other endpoints;

- Update of section 2.2.2 on partition coefficient n-octanol/water to strengthen the message that guidelines recommended for this endpoint for non-nanomaterials are not applicable for nanomaterials and recommend other parameters that could be considered instead; and

- Update of section 2.2.4 on adsorption/desorption to clarify that the methods recommended in the parent guidance for this endpoint are not applicable for nanomaterials and recommend other parameters that could be considered instead.

■ *Appendix R7-1 Recommendations for nanomaterials applicable to Chapter R7b Endpoint specific guidance*. The draft notes that the numbering of the sections has changed. It includes the following changes, and the following section numbers refer to the updated numbering of the guidance:

- New advisory note (section 1.1) on testing for ecotoxicity and fate to provide overall advice for conducting ecotoxicity and environmental fate testing for nanomaterials;

- Update of section 1.2.1 on aquatic pelagic toxicity to clarify that high insolubility cannot be used as a waiver and to include further recommendations on the text to be performed for this endpoint;

- Update of section 1.2.2. on toxicity for sediment organisms to provide advice on spiking methods and include applicability of available OECD guidelines; and

- Update of section 1.2.3 on degradation/biodegradation to clarify that waivers for hydrolysis and degradation simulation testing are not applicable as sole evidence, and provide advice on photocatalytic degradation and general advice on performing the tests.

■ *Appendix R7-2 Recommendations for nanomaterials applicable to Chapter R7c Endpoint specific guidance*. This document was prepared by the ECHA Secretariat for the purpose of this consultation and includes only the parts open for the current consultation, *i.e.*:

- Update of section 2.1.1. on aquatic bioaccumulation to explain the general limitations of the octanol-water partitioning coefficient (K_{ow}) as the basis for a waiver for nanomaterials and provide advice on the applicability of the available OECD guidelines; and

- Update of section 2.1.2 on effects on terrestrial organisms to provide advice on spiking methods and use of different metrics.

A different PEG is reviewing *Appendix 4: Recommendations for nanomaterials applicable to the Guidance on Registration*. ECHA developed the draft Appendix to provide advice to registrants preparing their registration dossiers for nanomaterials. The aim of the Appendix is to define the term "nanoform," the minimum criteria for distinguishing between different nanoforms, and the minimum set of parameters that must be reported to characterize a reported nanoform. According to the draft Appendix, a "nanoform" is a form of a substance that meets the requirements of the EC definition of a nanomaterial and always has a specific shape and a specific surface chemistry as additional parameters. The three minimum elements for defining a nanoform are: (1) whether it meets the EC recommendation on the definition of a nanomaterial; (2) its shape; and (3) its surface chemistry. ECHA notes that these are simply the minimum elements necessary to characterize registered nanoforms in a registration dossier. Depending on the substance, additional elements and/or additional refinement of these elements (*i.e.*, specific size ranges, specific shapes, etc.) may need to be reported depending on their impact on properties as determined in the data collected/generated to fulfill information requirements. The draft Appendix states: "Where nanoforms are not reported transparently in the registration dossier for the substance, it is understood as an explicit statement made by the registrants of that substance that nanoforms are not within the scope of their registered substance." The minimum parameters to be reported when nanoforms are registered are: (1) size; (2) shape; and (3) surface chemistry.

A PEG is consulting on *Appendix R.6-1: Recommendations for nanomaterials applicable to the Guidance on QSARs and Grouping*. ECHA intends the document to provide an approach on how to justify the use of hazard data between nanoforms of the same substance, and it is presented as an Appendix to Chapter R.6 of the Guidance on IR&CSA on quantitative structure-activity relationships (QSAR) and grouping "because general concepts on grouping of chemicals are applicable to [nanomaterials]."

A PEG is consulting on *Appendix R7-1 Recommendations for nanomaterials applicable to Chapter R7a Endpoint specific guidance and Appendix R7-2 Recommendations for nanomaterials applicable to Chapter R7c Endpoint specific guidance*. This document is a proposed amendment to specific extracts only of the following guidance documents: Appendix R7-1 to Chapter R.7a. (section 3 only); and Appendix R7-2 to Chapter R7c (section 2.1.3 only).

Proposed Harmonized Classification And Labeling Would Apply To Nanosized Titanium Dioxide: On May 31, 2016, ECHA began a public consultation on a harmonized classification and labeling (CLH) proposal submitted by France for titanium dioxide. The proposed entry in CLP Annex VI is "Carc. 1B, H350i." The CLH report states: "Based on available evidence and information in the registration dossier (*e.g*. mechanism of carcinogenicity, characterization of the particles), the proposed scope for the Annex VI entry is: 'Titanium dioxide in all phases and phase combinations; particles in all sizes/morphologies.'" The entry would apply for both fine particles and nanoparticles of titanium dioxide without any distinction in terms of morphology, crystal phase, and surface treatment. Comments are due **July 15, 2016**. ECHA states that comments can be submitted on general issues, for example on substance identification, physicochemical properties, and data sources. Comments can also be submitted on any unclarities in the text of the CLH dossier. After the public consultation, ECHA encourages the parties concerned to coordinate their involvement in the Committee for Risk Assessment (RAC) opinion-making process with the regular and sector-specific accredited stakeholder organizations.

Germany Publishes Report On Nanomaterials In The Environment: On June 1, 2016, the German Environment Agency (UBA) published a report entitled *Nanomaterials in the environment: Current state of knowledge and regulations on chemical safety*. The aim of the report is to outline the necessary further development of chemicals regulations for nanomaterials with regard to the environment from UBA's perspective. The report is addressed "particularly to players and decision-makers involved in discussions related to the adaptation of the various regulations on chemical safety." The report presents the current state of knowledge about the environmental behavior and the effects of nanomaterials; considers general aspects of regulatory needs such as the definition of nanomaterials, their characterization, and the assessment of related risks; and describes the current consideration of nanomaterials in the existing active substance regulations and the specific requirements for adaptions. The report states that, in the view of UBA, the EC should expedite the implementation of the definition proposal of nanomaterials in regulations on the safety of chemicals, as well as the implementation of nanomaterial specific requirements into the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation "in a constructive manner." With regard to the implementation and further development of the regulations of concern and the required risk assessment instruments, UBA "will continue to cooperate closely" with the Federal Institute for Occupational Safety and Health, the Federal Institute for Risk Assessment, the Federal Office for Chemicals, and the Federal Ministry of the Environment, as well as the representatives of the other European Union Member States, ECHA, the European Food Safety Agency, the European Medicine Agency, the EC, and the OECD. According to the report, the nanomaterials research strategy developed in cooperation with other higher federal authorities is still being pursued. The report states: "The steady progress of advancement of nanomaterials has to be observed carefully in order to ensure that the adaptations of individual instruments for risk assessment currently being called for and discussed will still be adequate in the future."

Presentations Available From International Symposium On Asbestos-Like Fibers From Nanomaterials And Other Advanced Materials: On June 14, 2016, Germany's Federal Institute for Occupational Safety and Health (BAuA) posted the presentations from the April 20, 2016, symposium, "WHO fibres from nanomaterials and other advanced materials: Do we have to tackle a new asbestos problem in OSH?" The goal was to initiate a transdisciplinary debate among representatives from academia, regulatory agencies, industry, and other interested parties in the governance landscape on advanced materials. It was also addressed to the members of the World Health Organization (WHO) Guideline Development Group, "WHO Guidelines on Nanomaterials and Workers' Health," which held a face-to-face meeting on April 18-19, 2016. Presentations include:

- WHO fibres from nanomaterials -- a brief look into history;
- The Tortoise and the Hare -- Governance challenges under conditions of scientific uncertainty;
- Hazards and risks from WHO fibres at the workplace;
- National Asbestos Profile -- Germany 2014;
- WHO fiber release, workplace exposure measurement and assessment;
- Fibrous Nano and Advanced Materials; and
- Communication and Co-operation: Trans-disciplinary approaches for a safe material design.

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.

National Academies Of Sciences, Engineering, And Medicine Hold Second Public Meeting On Future Biotechnology Products And Regulatory System: On June 1 and 2, 2016, the National Academies of Sciences, Engineering, and Medicine's (NAS) Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System held a second public meeting examining future biotechnology products titled *Advances and Opportunities in Biotechnology Products and Their Regulation*. This two-day meeting was held to discuss trends in biotechnology and emerging and future products. It also

had a public comment period open to in-person attendees at the end of each day. The presenters and panelists included experts from industry and academia. The presentations and discussion were highly technical. The webpage for the public meeting includes video recordings of the event.

The June 1, 2016, topics included:

- Trends in biotechnology, including discussion on funding and tools, and investment and development;
- Enabling tools, as specifically related to tools enabling biotechnology products of the future;
- Risk framing, with a focus on certain considerations; and
- Open release biotechnology, which included a discussion of future emerging open release products;

The June 2, 2016, topics included:

- Risks of open release products;
- Tools and opportunities to enhance risk analysis; and
- Implications of accessible biotechnology, as specifically related to Do-It-Yourself (DIY) labs.

A third meeting has been scheduled for **June 27, 2016**, in San Francisco, California. Registration is available online. The topics to be covered will include new sector identification; horizon scanning with businesses and academics; small business perspectives; and potential risks associated with biotechnology in the environment. More information on the committee is available in B&C's memorandum "Biotechnology: NAS to Study Future Products of Biotechnology."

LEGISLATIVE DEVELOPMENTS

House Passes Legislation Delaying Ozone NAAQS; White House Vows Veto: By a vote of 234-177, the House of Representatives on June 8, 2016, passed a bill that would delay implementation of the 2015 National Ambient Air Quality Standards (NAAQS) for ozone. The

Ozone Standards Implementation Act of 2016 (H.R. 4775) would delay implementation of the ozone NAAQS promulgated by EPA in 2015. The bill extends until **October 26, 2024**, the deadline for states to submit designations to implement the 2015 ozone NAAQS. It also would extend until **October 26, 2025**, the deadline for EPA to designate state areas as attainment, nonattainment, or unclassifiable areas with respect to the 2015 ozone NAAQS. States must submit a state implementation plan (SIP) by **October 26, 2026**, to implement, maintain, and enforce the 2015 ozone NAAQS. The bill also changes the review cycle for criteria pollutant NAAQS from a five-year review cycle to a ten-year review cycle. Under the bill, EPA may not complete its next review of ozone NAAQS before **October 26, 2025**. The bill provides that EPA may consider, as a secondary consideration, likely technological feasibility in establishing and revising NAAQS for a pollutant if a range of air quality levels for such pollutant are requisite to protect public health with an adequate margin of safety. Prior to establishing or revising NAAQS, EPA must obtain advice from its scientific advisory committee regarding potential adverse public health, welfare, social, economic, or energy effects that may result from attaining and maintaining NAAQS. EPA would also be required to publish regulations and guidance for implementing NAAQS concurrently with the issuance of new or revised NAAQS. New or revised NAAQS would be barred from being applied to preconstruction permits for constructing or modifying a major emitting facility or major stationary source of air pollutants until those regulations and guidance have been published. In a Statement of Administration Policy issued on June 7, the White House vowed to veto the bill. The Obama Administration "strongly opposes" the bill "because it would significantly undermine Clean Air Act (CAA) protections, would block efforts to reduce harmful ground-level ozone pollution in communities across the country, and could delay future scientific reviews for other harmful pollutants." The statement goes further, stating that "the bill would make other detrimental changes to the NAAQS core protections--most significantly allowing a fundamental shift away from the principle that the standards should be based solely on public health and welfare considerations."

House Legislation Would Subject Agency Guidance To Congressional Review: Representative Matt Salmon (R-AZ) on May 27, 2016, introduced a bill that would authorize Congress to use the Congressional Review Act (CRA) to block the implementation of guidance issued by federal agencies. The bill, H.R. 4377, would allow lawmakers to block guidance in the same manner as final regulations. Under the CRA, lawmakers are authorized to vacate a newly promulgated regulation within 60 legislative days of its publication in the *Federal Register* by passing resolutions in both chambers of Congress. Such resolutions, however, are subject to Presidential veto, greatly blunting the CRA's impact. Since the CRA's enactment in 1996, Congress has vacated only one rulemaking: the 2001 ergonomics final rule, issued in the waning days of the Clinton Administration.

House And Senate Pass Pipeline Safety Reauthorization Bill: The House of Representatives on June 8, 2016, passed legislation reauthorizing the Pipeline and Hazardous Materials Safety Administration (PHMSA). The House passed the Protecting Our Infrastructure of Pipelines and Enhancing Safety Act of 2016 (SAFE PIPES Act; S. 2276) by a voice vote. The Senate followed

suit on June 13, 2016. The bill reauthorizes PHMSA for five years and expands its authority to issue emergency orders in the wake of hazardous materials releases or other events. The legislation would also require PHMSA to publish regularly updates on regulations under development, upgrade standards for natural gas storage facilities, and undertake a review of pipeline integrity.

MISCELLANEOUS

OEHHA Added Several Pesticides To Proposition 65: On May 20, 2016, the California Office of Environmental Health Hazard Assessment (OEHHA) announced that three pesticides, malathion, parathion, and tetrachlorvinphos, would be added to the list of carcinogens for which Proposition 65 warning and labeling requirements apply. The listings were based on a document issued by the International Agency for Research on Cancer (IARC) concluding that malathion is probably carcinogenic to humans and the other pesticides are possible human carcinogens.

EPA Releases Draft Environmental Justice Strategy: On May 23, 2016, EPA released its final draft Environmental Justice (EJ) 2020 Action Agenda. The draft plan is EPA's blueprint for incorporating EJ into every action EPA takes. Specifically, the draft plan aims to infuse EJ work into everything EPA does. It centers on three goals:

- Institutionalize EJ into appropriate Agency processes and decision-making by **2020**, including rulemaking, permitting, and enforcement actions;
- Work with partners from states to other federal agencies to protect communities overburdened with environmental pollution; and
- Demonstrate environmental progress on EJ challenges in such areas as blood lead levels, drinking water, air quality, and hazardous waste sites.

The final draft of the EJ 2020 Action Agenda strategy is available at http://src.bna.com/fe9.

FTC Announces Settlement Barring Company From Making Misleading Pest-Control Claims: The Federal Trade Commission (FTC) announced on May 24, 2016, that Viatek Consumer Products Group, Inc. and Company owner and President Lou Lentine have agreed to settle FTC charges that they made deceptive claims for Viatek-brand Mosquito Shield Bands. FTC also charged Lentine and Viatek with violating a 2003 administrative order prohibiting Lentine from making product claims without "competent and reliable" evidence to support them. According to the FTC's February 2015 complaint in the U.S. District Court for the Eastern District of Tennessee, Lentine and Viatek marketed Mosquito Shield Bands, wristbands containing mint oil, claiming the wristbands would protect users from being bitten by

mosquitoes. The defendants represented that the wristbands would create a five-foot "vapor barrier," shielding persons from being bitten, and would provide users with 96-120 hours of protection. FTC stated that the defendants did not have competent and reliable scientific evidence to back up these claims, and that in making them, the defendants violated the FTC Act and the 2003 FTC order. The proposed settlement requires the defendants to have competent and reliable scientific evidence for future claims about the benefits, performance, or efficacy of any pest control product, and to have appropriate substantiation for similar claims made about any product they sell. It also prohibits the defendants from violating the 2003 FTC order and requires them to pay a $300,000 judgment.