Recent Federal Developments
April 15, 2016

TSCA/FIFRA/IRIS/NTP/TRI

EPA Issues SNUR For TCE: On April 8, 2016, the U.S. Environmental Protection Agency (EPA) issued a final Significant New Use Rule (SNUR) under the Toxic Substances Control Act (TSCA) for trichloroethylene (TCE). 81 Fed. Reg. 20535. The significant new use is the manufacture or processing for use in a consumer product, with the exception for use of TCE in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. The rule is effective **June 7, 2016**.

EPA Schedules Chemical Safety Advisory Committee: On March 16, 2016, EPA announced a three-day meeting of the Chemical Safety Advisory Committee (CSAC) to consider and review the draft risk assessment for TSCA Work Plan chemical, 1-bromopropane (Chemical Abstracts Service Registry Number (CASRN) 106-94-5). 81 Fed. Reg. 14111. The CSAC was established to provide advice and recommendations on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches. During the meeting, the CSAC will focus on the external peer review of the draft document entitled, "TSCA Work Plan Chemical Risk Assessment 1-Bromopropane (n-Propyl Bromide): Spray adhesives, dry cleaning, and degreasing uses (CASRN: 106-94-5)." Given the range of endpoints (*i.e.*, cancer, non-cancer; the latter includes potential effects on the developing fetus and adults of both sexes), EPA notes that susceptible populations are expected to include adults (including pregnant women) in commercial uses and children (as bystanders) and adults of all ages (including pregnant women) for consumer uses. The assessment will focus on all humans and life stages. The meeting will be held on **May 24-26, 2016**.

EPA Schedules CSAC Orientation Meeting: On April 13, 2016, EPA announced the scheduling of a half-day orientation meeting of the new CSAC. 81 Fed. Reg. 21864. The CSAC will consider and review information on the TSCA Work Plan Chemical program and aspects of the TSCA risk assessment process. CSAC members are available at https://www.epa.gov/csac. The meeting is scheduled for **May 11, 2016.**

EPA Issues SNURs For Three Substances: On April 13, 2016, EPA proposed SNURs for three substances. 81 Fed. Reg. 21830. EPA issued a direct final rule on October 2, 2015, to which commenters submitted adverse comment. According to EPA, the three chemicals are analogous to diisocyanates, a group of chemicals that the National Institute for Occupational Safety and Health (NIOSH) believes can cause asthma, lung damage, and death. The generic names of these chemicals are:

- Isocyanate prepolymer, an ingredient in an industrial adhesive (P-15-221);

- Methylene diisocyanate polymer with diols and triols, an industrial adhesive (P-15-247); and

- Polymer of isophorone diisocyanate and amine-terminated propoxylatedpolyol, which is used to make polymers (P-15-278).

The SNURs would require any company making any of the three chemicals to take precautions, such as ensuring potentially exposed workers are in well-ventilated workspaces and wearing NIOSH-certified respirators that meet specific criteria. Comments must be received by **May 13, 2016**.

EPA Issues Draft Guidance On Process For Making Claims Against Emerging Vital Pathogens: On April 7, 2016, EPA released a guidance document intended to assist registrants in making claims against emerging viral pathogens not on EPA-registered disinfectant labels. EPA is proposing a two-stage voluntary process to enable use of certain EPA-registered disinfectant products against emerging viral pathogens not identified on the product label. In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant product may submit a request via label amendment to add a designated statement to the master label and additional terms to the product registration. If the product meets the eligibility criteria suggested in this guidance, EPA generally will approve the amendment. Approval of the amendment would include additional terms and conditions of registration regarding how the designated statement may be published and communicated. The second stage of this process occurs during a human or animal disease outbreak caused by an emerging virus. In this stage, registrants of products with the previously mentioned label amendment and terms of registration would be allowed to use the designated statement in off-label communications intended to inform the use community/public that the disinfectant product(s) may be used against the specific emerging viral pathogen. These off-label statements can inform the public about the utility of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label. Comments must be submitted by **May 6, 2016.** The guidance document is available at http://src.bna.com/d0i.

ICCVAM Schedules Public Meeting: On March 17, 2016, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announced it will convene a public meeting in Bethesda, Maryland. The meeting is intended to foster discussion on new types of scientific methods to eliminate or diminish the use of animals in scientific research. More information is available at http://tinyurl.com/hswxfhw. Information about the meeting will be posted by May 1, 2016. The meeting is scheduled for **May 25, 2016**.

OPP Releases Guidance Documents On Strategic Vision For Adopting 21st Century Science Methodologies: On March 17, 2016, EPA's Office of Pesticide Programs (OPP) announced that it has developed new tools to "enhance the quality of its risk assessments and risk management

decisions and better ensure protection of human health and the environment from pesticide use." These tools have been developed as part of EPA's efforts to implement OPP's Strategic Vision for Adopting 21st Century Science Methodologies (Strategic Vision) initiative. As part of this initiative, OPP released two guidance documents: Final Guidance: Process for Evaluating & Implementing Alternative Approaches to Traditional In Vivo Acute Toxicity Studies for FIFRA Regulatory Use. OPP states that this guidance will "expand the acceptance of alternative methods for acute toxicity testing" and "describes a transparent, stepwise process for evaluating and implementing alternative methods of testing for acute oral, dermal, and inhalation toxicity, along with skin and eye irritation and skin sensitization." The second document is a Draft Guidance: Retrospective Analysis & Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations. OPP states that this draft guidance "to waive all acute lethality dermal studies for formulated pesticide products" was developed through an analysis "across numerous classes representing conventional pesticides, antimicrobials, and biopesticides [that] examined the utility of the acute dermal toxicity study for formulations in pesticide labelling for end-use products." Comments on the draft guidance for waiving acute dermal toxicity tests are due **May 16, 2016**.

EPA Issues Final Rule Granting Partial CDR Exemptions For Biodiesel Products: On March 29, 2016, EPA issued a final rule exempting manufacturers of six biodiesel chemicals from reporting processing and use information under the Chemical Data Reporting (CDR) rule under TSCA Section 8(a). 81 Fed. Reg. 17392. In 2014, the Biobased and Renewable Products Advocacy Group (BRAG®), managed by Bergeson & Campbell, P.C.'s (B&C®) affiliate, B&C® Consortia Management, L.L.C. (BCCM) filed a regulatory petition to exempt the chemicals, requesting the same exemption that EPA currently provides to manufacturers of petroleum-based versions of the chemicals. The rule was originally issued as a direct final rule in February 2015 before being withdrawn due to the submission of a single comment EPA considered adverse. The final rule is consistent with the direct final rule issued in July of 2015 and applies to manufacturers of:

- Fatty acids, C14-18 and C16-18 unsaturated, methyl esters (CASRN 67762-26-9);
- Fatty acids, C16-18 and C-18 unsaturated, methyl esters (CASRN 67762-38-3);
- Fatty acids, canola oil, methyl esters (CASRN 129828-16-6);
- Fatty acids, corn oil, methyl esters (CASRN 515152-40-6);
- Fatty acids, tallow, methyl esters (CASRN 61788-61-2); and

- Soybean oil, methyl esters (CASRN 67784-80-9).

As with all the chemicals currently afforded partial exemption status, the biodiesel chemicals would no longer be eligible for the partial reporting exemption if they were to become the subject of a TSCA Section 4, 5(a)(2), 5(b)(4), or 6 rule (proposed or final), an enforceable consent agreement, a Section 5(e) order, or relief granted under a civil action under Section 5 or 7. Because EPA completed the rulemaking process in time for the CDR reporting cycle starting in **June 2016,** manufacturers of these chemical substances can avail themselves of the exemption and save about two weeks of time that would otherwise have been spent preparing processing and use data for Form U. The rule was immediately effective.

IRIS Program Announces Availability Of General Comments Docket: On March 31, 2016, EPA announced the availability of an Integrated Risk Information System (IRIS) Program General Comments Docket (Docket ID #EPA-HQ-ORD-2014-0211) open for public comments that have broad applicability to the IRIS Program. 81 Fed. Reg. 18625. This docket was opened in 2014 and will remain open continuously. Stakeholders interested in submitting general comments to the IRIS Program are encouraged to use this docket. EPA also announced the dates for the 2016 IRIS public science meetings. Meetings will be held on **May 10, 2016**; **June 29-30, 2016**; **September 7-8, 2016**; and **October 26-27, 2016**. Finally, EPA announced that all future notices about the availability of draft IRIS assessments for public comment (Step 4a) or IRIS public science meetings will be posted on the IRIS website at http://www.epa.gov/iris and no longer announced in the *Federal Register*. EPA states that to provide information to stakeholders in a timely and efficient manner, the IRIS Program will now announce public comment periods, docket numbers, and information on the availability of draft IRIS assessments solely on the IRIS website. This change only applies to assessments released by the IRIS Program for comment and discussion at future IRIS public science meetings and does not apply to external peer review draft IRIS assessments managed by EPA's Science Advisory Board (SAB) Staff Office.

Petitioners' Requests To Proceed With Review Of Enlist Duo During Remand And Retain Jurisdiction Are Denied: On March 28, 2016, a three-judge panel of the U.S. Court of Appeals for the Ninth Circuit, Case Nos. 15-71207, *et al.* (consolidated), denied the Petitioners' March 10, 2016, motion asking the court to adjudicate their challenges to EPA's registration of the pesticide Enlist Duo during remand of the registration decision to EPA, and their alternative request that the court stay issuance of its mandate and retain jurisdiction pursuant to the original petition for review. The brief three-sentence order did not offer any explanation as to why the court denied the Petitioners' motion. The Petitioners' March 10, 2016, motion stated that it is "appropriate to adjudicate those arguments now, because Enlist Duo remains on the market during the limited remand, causing petitioners continued harm." In support of their motion, Petitioners argued that the purpose of the remand was to address the "narrow question" of "synergistic effects of Enlist Duo's two main ingredients on non-target plants," and that an ultimate decision by EPA on this narrow issue "may have no bearing on the arguments petitioners have already briefed in this Court." Petitioners also argued that the registrant and

intervenor Dow AgroSciences LLC (DowAgro) has "reneged on its promise to the Court not to sell Enlist Duo" during the remand. EPA and DowAgro both filed responses on March 21, 2016, opposing the Petitioners' motion. EPA's response to the motion stated that the court's order remanding the matter to EPA was general in scope, and "EPA may properly choose to revisit the issues raised in Petitioners' briefs while it also considers the new information provided by Dow regarding the synergistic effects of Enlist Duo's two active ingredients." Thus, if the court were to consider the Petitioners' claims during remand, "the Court would be advising EPA as to the outcome of its remand work, which is contrary to the Court's function." EPA also opposed the request to stay the mandate and retain jurisdiction "because Petitioners will have ample opportunity to challenge any new agency action that EPA issues after concluding its remand work."

DowAgro's response stated that "[t]his Court's order did not limit the scope of the remand, so the agency is free to alter, amend, or supersede the existing registration." DowAgro also argued that adjudicating petitioners' claims during remand would lead to improper "piecemeal review" because "petitioners' challenges to the original registration may be substantially altered or mooted entirely." With respect to the Petitioners' allegation that DowAgro "reneged" on a promise not to sell Enlist Duo during the remand, DowAgro stated that this offer was only for "the interim period while this Court was considering the remand motion, not the indefinite period the matter was on remand to the agency." More information regarding the court's original remand order is available in our blog item Ninth Circuit Denies EPA Motion for Vacatur, Grants EPA Motion for Remand. Many believe it would have been surprising for the court to agree to adjudicate Petitioners' claims concerning the registration decision for Enlist Duo during the period that decision is remanded to EPA for further action. Similarly, it is not surprising to many that the court declined to retain jurisdiction, since the remand to EPA will not operate to constrain the ability of the Petitioners to raise the same claims in the event that EPA decides to issue a new registration for Enlist Duo following remand. It is unclear whether EPA will be inclined to reconsider its views concerning any of the Petitioners' claims during the remand process. Petitioners likely will have another opportunity to seek review concerning their claims, assuming they participate in the administrative process during remand, and EPA does not alter its original decision in a manner that moots those claims.

EPA OIG To Evaluate EPA's Management Of Resistance Issues Related To Herbicide Tolerant GE Crops: On March 25, 2016, EPA's Office of Inspector General (OIG) sent a memorandum to Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP), announcing that it plans to begin preliminary research to assess EPA's management and oversight of resistance issues related to herbicide tolerant genetically engineered (GE) crops. OIG states that its review will include OPP, as well as other applicable headquarters and regional offices. OIG's objectives are to determine: what processes and practices, including alternatives, EPA has provided to delay herbicide resistance; what steps EPA has taken to determine and validate the accurate risk to human health and the environment for approved pesticides to be used to combat herbicide resistant weeds; and whether EPA

independently collects and assesses data on, and mitigates actual occurrences of, herbicide resistance in the field. OIG states that the anticipated benefit of the project "is a greater understanding of herbicide resistance[,] which will lead to an enhancement of EPA's herbicide resistance management and oversight." Pesticide resistance is not a new issue and is one that EPA has affirmatively addressed when granting registrations for new products, GE or not, for some time. That newer chemistries often have a more niche mode of action to reduce potential toxicity concerns has led some observers to speculate that greater resistance is one potential trade-off for the development of less toxic materials. This investigation may appear to some to be a response to concerns raised by critics of GE crops generally and to a recent EPA decision to approve Enlist Duo herbicide, a new formulation of 2,4,-D and glyphosate designed to address the problem of weed resistance to glyphosate-tolerant crops. EPA recently proposed to approve another GE strain, dicamba-tolerant crops, to control glyphosate tolerant weeds. To critics of GE crops, using more herbicides to control problems caused by what they claim is overuse of another herbicide is evidence of a troubling "pesticide treadmill," that they believe should not have been allowed to occur in the first place. Rebutting this criticism, others assert that resistance is a problem for all pesticides, not only genetically modified ones, and that with sufficient controls, resistance can be delayed, if not avoided. Registrants point out that it is in their self-interest to take steps to avoid resistance to their products -- once that occurs; the market viability of the product is significantly reduced.

RCC Schedules Stakeholder Meeting In May: The Canada-U.S. Regulatory Cooperation Council (RCC) will convene an RCC Stakeholder Event on **May 4-5, 2016**, in Washington, D.C. The meeting is intended to update stakeholders on RCC activities and will also include sessions specific to various areas of collaboration, including chemical management. These sessions will facilitate Canadian and U.S. government representatives to meet and to engage with stakeholders to address areas of shared interest and future collaboration under the RCC as set forth in the Regulatory Partnership Statement issued in May 2015 (http://www.ec.gc.ca/international/default.asp?lang=En&n=FD4CFB5C-1). Additional information is available by contacting the U.S. RCC Secretariat at RCC-Chemicals@epa.gov.

EPA Schedules PPDC Meeting: On April 15, 2016, EPA announced the scheduling of the next Pesticide Program Dialogue Committee (PPDC) meeting. 81 Fed. Reg. 22260. The meeting will address a range of topics pertinent to the pesticide community. The meeting is scheduled for **May 18-19, 2016,** in Crystal City, Virginia.

RCRA/CERCLA

***EPA Tentatively Denies Petition To Amend RCRA Corrosivity Characteristic*:** On April 11, 2016, EPA tentatively denied a petition by Public Employees for Environmental Responsibility (PEER) seeking to expand the corrosivity characteristic (40 C.F.R. § 261.22) under the Resource Conservation and Recovery Act (RCRA). 81 Fed. Reg. 21295. PEER's petition sought a revision of the pH regulatory value and the addition of nonaqueous waste to the corrosivity

characteristic. Current regulations define, in part, a corrosive hazardous waste as an aqueous waste that has a pH greater than 12.5 and nonaqueous solutions that corrode steel at a certain rate. PEER's petition asked EPA to lower the pH limit to 11.5. It also sought an expansion of the characteristic to include nonaqueous corrosive wastes. PEER argued 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 responded that 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 not consistent with the way pH is used in the RCRA corrosivity regulation. EPA also concluded that the dust to which September 11 first responders and others were exposed was a complex mixture from which no single property of the dust could be reliably identified as the cause of the adverse health effects. EPA further stated 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. Comments on the denial are due by **June 10, 2016**.

CAA/CWA

EPA Proposes Changes To SNAP Program: In a pre-publication version of a proposed rule signed by Administrator McCarthy on March 29, 2016, EPA proposed to list a number of substances as acceptable, subject to use conditions, to list several substances as unacceptable, and to modify the listing status for certain substances from acceptable to unacceptable or acceptable, subject to narrowed use limits. Consistent with Clean Air Act (CAA) Section 612, EPA proposed both initial listings and certain modifications to the current lists based on its evaluation of the substitutes addressed in the action using the Significant New Alternatives Policy (SNAP) Program criteria for evaluation and considering the current suite of other alternatives for the specific end-use at issue. EPA found significant potential differences in risk with respect to one or more specific criteria, such as flammability, toxicity, or local air quality concerns, while otherwise posing comparable levels of risk to those of other alternatives in specific end-uses. EPA also proposed that the existing listing decisions for foam blowing agents apply to closed cell foam products and products containing closed cell foam. In addition to proposing to list propane as acceptable, subject to use conditions, as a refrigerant in new self-contained commercial ice machines, in new water coolers, and in new very low temperature refrigeration equipment, EPA also proposed to exempt propane in these end-uses from the venting prohibition under CAA Section 608. EPA proposed to list as acceptable, subject to use conditions, HFO-1234yf in newly manufactured medium-duty passenger vehicles (MDPV), heavy-duty (HD) pickup trucks, and complete HD vans, and 2-bromo-3,3,3-trifluoropropene (2-BTP) in the fire suppression and explosion protection sector. Finally, EPA proposed clarifications for the listing for Powdered Aerosol D (Stat-X®), which is currently listed as both "acceptable subject to use conditions" and "acceptable," by removing the earlier listing of "acceptable subject to use conditions." A copy of the pre-publication of the proposed rule signed by Administrator McCarthy on March 29, 2016, is available at

https://www.epa.gov/snap/proposed-rule-advanced-version-administrator-signed-march-29-2016. Comments will be due 45 days after publication in the *Federal Register*.

Hazardous Materials Transportation (HMT)

PHMSA Issues Safety Advisory On Transportation Of Lithium Batteries: The U.S. Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) on April 7, 2016, issued a Safety Advisory Notice regarding the transport of lithium batteries. 81 Fed. Reg. 20443. PHMSA is using the notice to inform persons engaged in the transport of lithium batteries about the recent action taken by the International Civil Aviation Organization (ICAO) to ban the transport of lithium ion cells and batteries as cargo aboard passenger carrying aircraft. The ban applies to lithium cells and batteries that are not contained in or packed with equipment and it also does not apply to batteries contained in personal electronic devices carried by passengers.

FDA

FDA Extends Comment Period On Draft EA And Preliminary FONSI For Genetically Engineered Mosquitoes: On April 7, 2016, in response to requests from the public, the U.S. Food and Drug Administration (FDA) extended the comment period for the draft Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) concerning investigational use of Oxitec OX513A mosquitoes. The extension of the comment period is intended to allow the public greater time to read and consider the EA and FONSI so that they may submit informed comments to the FDA. The comment period will now end on **May 13, 2016.**

FDA Issues Final Rule To Ensure Food Safety During Transport Under FSMA And SFTA: On April 6, 2016, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued a final rule establishing requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. 81 Fed. Reg. 20092. FDA states that this action is part of its larger effort to focus on prevention of food safety problems throughout the food chain under the Food Safety Modernization Act of 2011 (FSMA) and the Sanitary Food Transportation Act of 2005 (2005 SFTA). The final rule is effective on **June 6, 2016**. On **April 25, 2016**, FDA will be presenting a webinar on key pieces of the final rule.

FDA Proposes To Ban Absorbable Powder And Powdered Gloves: On March 22, 2016, FDA CFSAN issued a proposed rule to ban powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove, due to its determination that these medical devices present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling or a change in labeling. 81 Fed. Reg. 15173. FDA states

that the risks posed by powdered gloves, including health care worker and patient sensitization to natural rubber latex (NRL) allergens, surgical complications related to peritoneal adhesions, and other adverse health events not necessarily related to surgery, such as inflammatory responses to glove powder, outweigh the benefits that these devices pose to patients. FDA states that its conclusions were generated through its review and consideration of evidence from multiple sources, including its 1997 Report on Medical Glove Powder and the scientific and clinical literature references from the report; its analysis of reported adverse events due to the use of gloves; its analysis of glove market availability as well as new market availability data; its more contemporary analysis of relevant scientific literature and of adverse events related to medical glove use from 1992 through 2014; the information contained in citizen petitions and comments associated with the petitions; and statements and actions of other U.S. government agencies, U.S. health care organizations, and of foreign governments concerning powdered NRL gloves. The comment period ends **June 20, 2016**.

FDA Announces Availability Of Draft Guidance On Labeling For Biosimilar Products Under PHS Act: On April 4, 2016, FDA's Center for Drug Evaluation and Research (CDER) announced the availability of a draft guidance for industry entitled "Labeling for Biosimilar Products." 81 Fed. Reg. 19194. FDA states the draft guidance is intended to assist applicants in developing draft prescription drug labeling for proposed biosimilar products, and that it provides an overview of FDA's recommendations for labeling for biosimilar products licensed under the Public Health Service Act (PHS Act). FDA describes a demonstration of biosimilarity as meaning that "FDA has determined that there are no clinically meaningful differences between the proposed product and the reference product in terms of safety, purity and potency." As such, biosimilar applicants should incorporate relevant data and information from the reference product labeling with appropriate product-specific modifications, as described in the draft guidance. The comment period ends **June 3, 2016**.

NANOTECHNOLOGY

European Economic And Social Committee Publishes Opinion On Nanotechnology For A Competitive Chemical Industry: The February 24, 2016, *Official Journal of the European Union* includes the opinion of the European Economic and Social Committee (EESC) on "Nanotechnology for a competitive chemical industry." The opinion addresses nanotechnology in an innovative Europe; nanotechnology in the chemical industry and medicine; nanotechnology as an economic component; nanotechnology as an environmental component; nanotechnology as an employment/social component; opportunities and risks associated with nanotechnology; and competitiveness factors/stimulus for nanotechnology in Europe. It includes the following conclusions and recommendations:

- The EESC supports the activities for developing a European industrial policy and in particular those supporting key enabling technologies that strengthen European competitiveness;

- An initiative to promote nanotechnology can also help further develop common European industrial policy. Research and development are so complex that they cannot be undertaken by individual companies or institutions working alone. They require overarching cooperation between universities, scientific institutions, companies, and business incubators. Research hubs, such as those set up in the chemical and pharmaceutical sector, are a positive approach. It must be ensured that small- and medium-sized enterprises (SME) are included;

- European clusters of excellence (nanoclusters) should be further developed to support nanotechnology. Specialists from the world of business, science, politics, and society must form networks to promote technology transfer, digital and person-to-person cooperation, better risk assessment, a special life-cycle analysis, and the safety of nano products. The financial instruments provided for in the Horizon **2020** research framework program relating to the area of nanotechnology must be made simpler and more flexible, particularly for SMEs. Public financing must be reinforced and the supply of private capital stimulated;

- To anchor multidisciplinary nanotechnology better within education and training systems, qualified scientists and technicians from disciplines such as chemistry, biology, engineering, medicine, or the social sciences should be involved. Businesses must meet their staff's growing need for qualifications through targeted initial and further training measures. Employees, with their experience and competences, should be included;

- The European Union (EU) standardization process should be further boosted. Standards play a key role in ensuring compliance with laws, particularly where employee safety requires a risk assessment. Tools should therefore be devised for certified reference materials to test the procedures for measuring the characteristics of nanomaterials;

- Consumers should be fully informed about nanomaterials. It is essential to promote acceptance of these key enabling technologies. Regular dialogues must take place between consumer and environmental organizations, businesses, and politicians. Pan-European information platforms and tools for increasing acceptance must be developed to this end; and
- The EESC expects the European Commission (EC) to set up an observatory to record and evaluate the development processes, applications, use (recycling), and disposal of nanomaterials. It should also

monitor and assess the impact on employment and the labor market and describe the political, economic, and social conclusions to be drawn. An up-to-date 'Report on nanomaterials and nanotechnologies in Europe' should be presented before **2020**, identifying development trends to **2030**.

NNCO Announces Workshops And Webinar In Support Of The NNI: The National Nanotechnology Coordination Office (NNCO) published a *Federal Register* notice on March 14, 2016, announcing the following events in support of the National Nanotechnology Initiative (NNI):

- The "2016 NNI Strategic Planning Stakeholder Workshop," which will be held **May 19-20, 2016**. NNCO expects to obtain input from individual stakeholders that it may use to inform the development of the NNI Strategic Plan. Representatives of the U.S. research community, industry, non-governmental organizations (NGO), and interested members of the general public are invited to comment on key aspects related to the 2016 NNI Strategic Plan, currently under development by the NNI agencies. Topics covered may include future technical directions; implementation mechanisms; education and outreach activities; and approaches for promoting commercialization. Registration opened April 4, 2016.

- The "2016 U.S.-EU: Bridging NanoEHS Research Efforts Joint Workshop," which will be held **June 6-7, 2016**. NNCO will hold the workshop in collaboration with the EC. The workshop will bring together the U.S.-EU Communities of Research (COR), which serve as a platform for scientists to develop a shared repertoire of protocols and methods to overcome research gaps and barriers, and to address environmental, health, and safety questions about nanomaterials. The goal of the workshop is to publicize progress towards COR goals and objectives, clarify and communicate future plans, share best practices, and identify areas for cross-COR collaboration. Registration opened April 6, 2016.

- The NNCO will hold one or more webinars between the publication of the March 14, 2016, *Federal Register* notice and **December 31, 2016**. The first webinar will be held on or after **April 20, 2016**. Topics covered may include stakeholder input for strategic planning; technical subjects; environmental, health, and safety issues; business case studies; or other areas of potential interest to the nanotechnology community.

ECHA Announces New Approach On Hazard Assessment For Nanoforms: The European Chemicals Agency (ECHA) announced on March 23, 2016, a new publication co-authored with the Dutch National Institute for Public Health and the Environment (RIVM) and Joint Research

Center (JRC) that illustrates how to use data for different nanoforms within the same substance registration. According to ECHA, this approach "will form a cornerstone in the future guidance development on hazard assessment for nanoforms" at the EU and Organization for Economic Cooperation and Development (OECD) level. ECHA describes the paper, "Usage of (eco)toxicological data for bridging data gaps between and grouping of nanoforms of the same substance: Elements to consider," as a scientific reference paper. ECHA states that at the EU level, it offers regulators, researchers, industry, and NGOS an approach of how to justify scientifically that studies on one nanoform of a substance can be used to predict the hazard properties of other forms of the same substance. The paper outlines a stepwise approach to identify opportunities for using data between nanoforms within the same substance registration. The identification is based on grouping through an assessment of physicochemical properties and *in vitro* screening methods. According to ECHA, this may allow for a hazard assessment of several nanoforms of the same substance, minimizing the testing needed, including testing on animals, and therefore also minimizing costs.

NNI Agencies Announce Nanotechnology Signature Initiative For Water Sustainability: NNI issued a March 23, 2016, press release concerning the launch of a Nanotechnology Signature Initiative (NSI), Water Sustainability through Nanotechnology: Nanoscale Solutions for a Global-Scale Challenge. The Office of Science and Technology posted a blog item on March 23, 2016, concerning the new NSI, stating that it is intended "to take advantage of the unique properties of engineered nanomaterials to generate game-changing breakthroughs that can alleviate stresses on the water supply and enable sustainable use of our Nation's water resources." The specific "thrusts" of the water NSI are to:

1. Increase water availability using nanotechnology;

2. Improve the efficiency of water delivery and use with nanotechnology; and

3. Enable next-generation water monitoring systems with nanotechnology.

A white paper on the water NSI highlights key technical challenges for each thrust, identifies key objectives to overcome those challenges, and notes promising areas of research and development where nanotechnology promises to provide the needed solutions. The water NSI will leverage federal agencies' existing and emerging efforts to create the necessary technical breakthroughs, including: the Department of Energy's (DOE) Water-Energy Tech Team; the Innovations at the Food-Energy-Water Nexus activity at the National Science Foundation (NSF); the U.S. Department of Agriculture's (USDA) National Institute of Food and Agriculture (NIFA); and EPA's 2014 Water Technology Innovation Blueprint, Promoting Technology Innovation for Clean and Safe Water. Other collaborating agencies include the U.S. Department of Commerce's (DOC) National Institute of Standards and Technology (NIST) and the National Aeronautics and Space Administration (NASA).

NNCO Announces Availability Of QEEN Workshop Report: On March 28, 2016, NNCO announced the release of a report entitled *Quantifying Exposure to Engineered Nanomaterials (QEEN) from Manufactured Products: Addressing Environmental, Health, and Safety Implications*. The report summarizes the July 7-8, 2015, QEEN workshop, which was sponsored by the Consumer Product Safety Commission (CPSC) and co-hosted by NNI. The main goals for the workshop were to assess progress in developing tools and methods for quantifying exposure to engineered nanomaterials across the product life cycle, and to identify new research needed to advance nanotechnology environmental, health, and safety exposure assessment for nanotechnology-enabled products. NNCO states that some of the main conclusions of the workshop include:

- State of the science: Significant progress has been made in the ability to quantify engineered nanomaterial exposures, including development of characterization tools and techniques, exposure assessment methodologies, and simulation and modeling tools. Current methods can detect nanoparticles well below known toxicity levels and beneath the threshold of economical and reasonable regulatory action.

- Incorporating "real world scenarios" in research: Exposure assessment needs have moved beyond methods and tools for fundamental laboratory studies on pristine, as-manufactured, engineered nanomaterials towards those needed to evaluate exposure risk under conditions that more closely mimic actual exposure scenarios. A better understanding of these "real world" scenarios, which consider the transformation products and interactions with environmental constituents, is still needed.

- Faster testing and results: Techniques for rapidly estimating exposures based on alternative testing models and high-throughput methods can enable timely decisions about the safe and sustainable design of nanotechnology-enabled products.

- Next steps: The community could focus on the complex issue of determining biomarkers of exposure linked to disease, which will require substantive private-public collaboration, partnership, and knowledge-sharing.

OECD Publishes Report On Delegation Developments On The Safety Of Manufactured Nanomaterials: OECD recently posted a March 29, 2016, report entitled *Developments in Delegations on the Safety of Manufactured Nanomaterials -- Tour de Table*. The report compiles information, provided by Working Party on Manufactured Nanomaterials (WPMN) participating delegations, before and after the November 2015 WPMN meeting, on current

developments on the safety of manufactured nanomaterials. OECD intends the report to provide delegations with background information on activities related to manufactured nanomaterials, as well as other activities on nanotechnologies at the international level. It includes developments from Australia, Austria, Belgium, Canada, Germany, Japan, Korea, the Netherlands, Switzerland, Turkey, United Kingdom, U.S., and the EC, as well as the Business and Industry Advisory Committee to the OECD (BIAC) and International Council on Animal Protection in OECD Programs (ICAPO).

NNI Publishes Supplement To The President's 2017 Budget: On March 31, 2016, NNI published its supplement to the President's **2017** budget request. The supplement also serves as the NNI annual report called for under the provisions of the 21st Century Nanotechnology Research and Development Act of 2003. NNI states that the President's budget request provides $1.4 billion for NNI, with a cumulative total of nearly $24 billion since the inception of NNI in 2001 (including the **2017** request), "affirming the important role that nanotechnology continues to play in the Administration's innovation agenda." The President's budget supports nanoscale science, engineering, and technology research and development at 11 federal agencies. Another nine agencies have nanotechnology-related mission interests or regulatory responsibilities. The supplement documents the progress of these agencies in addressing the goals and objectives of NNI. According to NNI, over the past year, NNI participating agencies, the White House Office of Science and Technology Policy (OSTP), and NNCO "have been charting the future directions of the NNI, including putting greater focus on promoting commercialization and increasing education and outreach efforts to the broader nanotechnology community." As part of this effort, NNI has established Nanotechnology-Inspired Grand Challenges, "ambitious but achievable goals that will harness nanotechnology to solve National or global problems and that have the potential to capture the public's imagination." OSTP announced the first Nanotechnology-Inspired Grand Challenge (for future computing) on October 20, 2015. Topics for additional Nanotechnology-Inspired Grand Challenges are under review.

NIOSH Publishes Nanotechnology Safety Program Guide For SMEs: On April 4, 2016, NIOSH published a report entitled *Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises*. The report states that employees may be at risk of exposure by inhalation, skin absorption, or ingestion. According to the report, several factors can affect their potential for exposure, including:

- The route, concentration, duration, and frequency of any exposure;
- The ability of the nanomaterial to be easily dispersed (such as a dust or aerosol); and
- The control measures in place to reduce or limit exposures.

The report states that the best way to control potential exposures and to protect workers includes creating and following a risk management plan that incorporates the hierarchy of controls: elimination, substitution, engineering controls, administrative controls, and personal protective equipment. The report lists the following elements that are "the keys to a successful health and safety program":

- Leadership by top management;
- Inclusion of employees;
- Establishment of a Safety Committee;
- Creation of a written risk-management plan that includes;
  - Identification of potential hazards;
  - Identification of exposure potential;
  - Establishment of controls following the hierarchy of controls;
  - Verification of controls;
  - Preparation for emergencies; and
  - Regulatory compliance;
- Continued evaluation of the safety program:
  - Plan, Do, Check, Act.

JRC Publishes Report On Harmonized Terminology For EHS Assessment Of Nanomaterials: JRC recently published a report entitled *NANoREG harmonised terminology for environmental health and safety assessment of nanomaterials*, developed within the NANoREG project: "A common European approach to the regulatory testing of nanomaterials." The report states that it represents the project's attempt at bringing common understanding and consistency in the use of key terms in the environmental health and safety (EHS) assessment of nanomaterials. The objective of the report is to publish the harmonized terminology that has been developed and used within NANoREG. According to the report, all project partners have agreed upon and adopted the terminology in their activities and related documents. The report specifically includes: (1) the methodology used to select key terms that form the harmonized terminology and to develop harmonized definitions; (2) the existing literature definitions that have been used

as a starting point to develop for each key term a harmonized definition; and (3) the reason(s) behind the choices that have been made in drafting a definition. The discussion on the key terms to be considered for the harmonized terminology led to the selection of 43 key terms. The list includes terms with international regulatory relevance, such as those defined at the OECD level, as well as terms that have a specific meaning and use under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. According to the report, it has "already proven very useful" in the context of OECD work, as a support document to the April 13-14, 2016, OECD Expert Meeting on "Grouping and read-across for the hazard assessment of manufactured nanomaterials," and in a regulatory context, as a support document to the work recently released by RIVM, ECHA, and JRC on using (eco)toxicological data for bridging data gaps between nanoforms of the same substance.

OSTP Blog Item Notes Recent Reports Highlighting Continued Federal Commitment To NanoEHS: OSTP posted on April 11, 2016, a blog item, authored by Lloyd Whitman, OSTP, and Dr. Treye Thomas, CPSC, entitled "Supporting Responsible Development of Nanotechnology." The item states that the following reports released in March 2016 highlight federal investments and activities in the area of nanotechnology environmental, health, and safety (nanoEHS) research, progress, and needs in understanding exposure from consumer products, and how businesses can protect their nanotechnology workforce:

- The recently released *NNI Supplement to the President's Budget for Fiscal Year 2017*, which serves as the annual report for NNI, highlights the programs and coordinated activities taking place across the departments, independent agencies, and commissions participating in NNI. As detailed in this report, nanoEHS activities continue to account for about ten percent of the annual NNI budget, with cumulative federal research and development investments in this area exceeding $1 billion over the past decade.

- Last month NNI released a report, *Quantifying Exposure to Engineered Nanomaterials (QEEN) from Manufactured Products: Addressing Environmental, Health, and Safety Implications*, summarizing a workshop sponsored by CPSC.

- The technical experts who participated in CPSC's workshop recommended that future work focus on determining biomarkers of exposure linked to disease, which will require substantive public-private collaboration, partnership, and knowledge sharing. Recognizing these needs, the President's 2017 Budget request for CPSC includes funds for a new nanotechnology center led by the National Institute of Environmental Health Sciences (NIEHS) to develop test methods and to quantify and

characterize the presence, release, and mechanisms of consumer exposure to nanomaterials in consumer products.

- NIOSH has issued a series of documents providing guidance intended to protect workers who manufacture nanotechnology products, including the recently released publication *Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium-Sized Enterprises*.

The blog item also notes that an upcoming workshop will explore the work of joint U.S.- EU nanoEHS communities of research in developing a shared repertoire of protocols and methods. The 2016 joint workshop will be held on **June 6-7, 2016**, in Arlington, VA, and is free and open to the public. Registration opened on April 6, 2016, on a first-come, first-served basis.

BIOBASED/RENEWABLE PRODUCTS

BRAG Biobased Products News And Policy Report: B&C's consulting affiliate, BCCM, manages 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.

LEGISLATIVE DEVELOPMENTS

Bill Would Delay Implementation Of Ozone NAAQS: Legislation introduced on March 17, 2016, by Representative Peter Olson (R-TX) would delay for eight years the implementation deadline for the ozone National Ambient Air Quality Standard (NAAQS). The Ozone Standards Implementation Act of 2016 (H.R. 4775) would give states until **October 26, 2024**, to provide to EPA their State Implementation Plans (SIP) to demonstrate compliance with the revised ozone NAAQS. The bill would also prohibit EPA from reviewing the ozone NAAQS again until **2025**. (Current law requires EPA to review NAAQS every five years.) In 2015, EPA revised the NAAQS for ozone to 70 parts per billion (ppb); the previous standard was 75 ppb. The rule would require states to submit to EPA by **October 1, 2016**, their recommendations on non-attainment areas.

Legislation Would Close Environmental Programs That Are Not Reauthorized: Representative Cathy McMorris Rodgers (R-WA), Chair of the House Republican Conference, on March 14, 2016, introduced legislation intended to restore the "power of the purse" to the American people. The Unauthorized Spending Accountability Act (USA Act; H.R. 4730) would terminate federal programs that are not formally reauthorized by Congress. At risk are major environmental programs and offices, including state revolving funds (SRF) under the Safe Drinking Water Act (SDWA), the entire Endangered Species Act (ESA), and the White House Council on Environmental Quality (CEQ). The legislation puts all programs that have not been

reauthorized on a pathway to sunset in three years. It also requires any new authorizations or reauthorizations to include a sunset clause. Many federal programs receive funding through appropriation legislation, irrespective of whether Congress has formally reauthorized the programs.

MISCELLANEOUS

OEHHA Proposes Revisions To Its Proposed Proposition 65 Warning Regulations: On March 25, 2016, the California Office of Environmental Health Hazard Assessment (OEHHA) modified its November 27, 2015, proposed rule that would repeal and replace the Proposition 65 (Prop 65) Article 6 regulations covering "clear and reasonable warnings" requirements. OEHHA states that the proposed changes are based on its response to the written comments it received on the proposed rule, and on oral comments provided during a January 13, 2016, public hearing. The modifications proposed are intended to clarify OEHHA's intent with the proposed regulations, and to ensure consistency throughout the regulations. Although there are some modest improvements, the substantive, and more controversial, elements of the regulations remain, which makes it more likely than not that such elements will be retained in the final version of the regulations. Comments on the proposed rule are due by **April 18, 2016**.

OEHHA Proposes MADL For BPA (Dermal Exposure From Solid Materials): On March 25, 2016, OEHHA proposed a maximum allowable dose level (MADL) for bisphenol A (BPA) (dermal exposure from solid materials) of three micrograms per day. OEHHA states that it reviewed the transcript of the May 7, 2015, meeting of the Developmental and Reproductive Toxicant Identification Committee (DARTIC) and the hazard identification materials reviewed by the DARTIC at that meeting. According to OEHHA, these hazard identification materials included numerous studies of the effects of BPA on the female reproductive system, including *in vivo* studies in experimental animals and *in vitro* studies that provide additional evidence of female reproductive toxicity. OEHHA states that it relied on the study by Veiga-Lopez, *et al.* (2014) "that provides a subcutaneous [lowest observed effect level (LOEL)] of 0.05 milligrams BPA per kilogram body weight per day (mg/kg-day), for female reproductive toxicity." OEHHA identified and reviewed additional relevant studies. In the notice announcing the proposed MADL, OEHHA states that "by providing a[n] MADL, this regulatory proposal may encourage businesses to lower the amount of the listed chemical in their products to a level that does not require a warning. This in turn may reduce exposures to BPA and reduce resident, worker and environmental exposures to chemicals that cause reproductive toxicity." OEHHA will schedule a public hearing on request. Hearing requests must be made no later than **May 2, 2016**, which is 15 days before the close of the comment period. Written comments must be received by OEHHA on **May 16, 2016**.

OEHHA Proposes Emergency Regulation For Standard Warning For Exposures To BPA From Canned And Bottled Foods And Beverages: OEHHA issued on April 1, 2016, a notice of emergency action to amend Section 25603.3 of Title of the California Code of Regulations

regarding warnings for exposures to BPA from canned and bottled foods and beverages. This notice supersedes OEHHA's March 17, 2016, notice on the same emergency action. Effective **May 11, 2016**, warnings are required for all exposures to BPA, unless the person causing the exposure can show that the exposure is 1,000 times below the no observed effect level (NOEL) for the chemical. OEHHA proposes to promulgate an emergency regulation to allow temporary use of a standard point-of-sale warning message for BPA exposures from canned and bottled foods and beverages. The current regulation does not expressly allow for point-of-sale warnings for consumer products that cause exposures to listed chemicals. According to OEHHA, some canned food and beverage manufacturers plan to reduce or eliminate the use of BPA, or have recently done so, and the need for warnings will likely decrease over time. OEHHA notes that any changes made by manufacturers will not immediately affect existing retail inventories, however, because many canned foods and beverages have a "shelf life" of up to three years. OEHHA acknowledges that when the warning requirement goes into effect on **May 11, 2016**, private parties may bring suits alleging a failure to warn for BPA exposures from canned and bottled foods and beverages. OEHHA states that, given the variety of canned and bottled foods that may cause significant exposures to BPA, and the fact that retailers may not know which products currently on their shelves may require warnings, OEHHA is concerned that businesses will take inconsistent approaches to compliance, particularly in the time period immediately following **May 11, 2016**, when the warning requirement begins According to the notice, "the federal government is currently sponsoring a large series of studies intended to clarify the effects of BPA at low doses. Some of these studies, expected to be complete in **2017** or **2018**, could inform the development of an oral MADL that will provide clarity for consumers and businesses." Until then, OEHHA has concluded that both the public and the food and beverage businesses would benefit from the clarity that a uniform point-of-sale warning regulation would provide. OEHHA states that the proposed emergency regulation would expire after 180 days. During that period, OEHHA will commence a rulemaking process to adopt a regulation as an interim measure for a one-year period from date of adoption. According to OEHHA, this time period "should be sufficient to ensure an orderly transition to providing more product-specific warnings for BPA exposures, and for more manufacturers to reduce or eliminate exposures to BPA by switching to safer alternatives where feasible. It will also allow additional time for OEHHA to evaluate the emerging science that, if sufficient, would support a MADL for oral exposures to BPA, which would further clarify which products require a warning."

OSHA Issues Final Silica Standards: On March 25, 2016, the Occupational Safety and Health Administration (OSHA) issued long-awaited revised standards for occupational exposure to respirable crystalline silica. 81 Fed. Reg. 16286. OSHA is issuing two separate standards -- one for general industry and maritime, and the other for construction to tailor requirements to the circumstances found in these sectors. OSHA has determined that employees exposed to respirable crystalline silica at the previous permissible exposure limits face a significant risk of material impairment to their health. The evidence indicates that workers exposed to respirable crystalline silica are at increased risk of developing silicosis and other non-malignant respiratory diseases, lung cancer, and kidney disease. The final rule establishes a new permissible exposure

limit of 50 micrograms of respirable crystalline silica per cubic meter of air (50 $\mu g/m^3$) as an 8-hour time-weighted average in all industries covered by the rule. It also includes other provisions to protect employees, such as requirements for exposure assessment, methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping. The final rule is effective on **June 23, 2016**.