Recent Federal Developments
May 15, 2015

TSCA/FIFRA/IRIS/NTP/TRI

EPA Releases TSCA Work Plan Chemical Problem Formulation, Initial Assessment For 1,4-Dioxane: On April 28, 2015, the U.S. Environmental Protection Agency (EPA) released the Toxic Substances Control Act (TSCA) Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane, a chemical used primarily as a solvent in the manufacture of other chemicals. 80 Fed. Reg. 23545. A first step in the assessment of TSCA Work Plan chemicals, the 1,4-Dioxane Problem Formulation and Initial Assessment examined likely exposure and hazard scenarios to workers and consumers to identify scenarios where further risk analysis may be necessary. The conclusions from this Problem Formulation and Initial Assessment are that: EPA will further assess potential risks to workers exposed during product formulation and use as a cleaning agent; EPA will further assess potential risks to workers and consumers exposed during the use of products that contain 1,4-dioxane as a contaminant, such as paints, varnishes, adhesives, cleaners, and detergents; risk to the general population through inhalation exposure to ambient air emissions is estimated to be low; an assessment of risk from exposure through drinking water is not needed at this time because 1,4-dioxane is currently being monitored -- EPA will determine whether or not regulatory action is needed as part of EPA's Regulatory Determination process; and based on the low hazard profile for 1,4-dioxane to aquatic organisms, risks to these organisms are expected to be low. EPA believes that it does not have the hazard data needed to determine if there are risks to sediment and soil organisms, and further analysis of environmental risk is not planned.

1,4-Dioxane is the first chemical for which EPA has released a Problem Formulation and Initial Assessment document under the TSCA Work Plan Chemical Assessment Program. EPA plans to develop Problem Formulation and Initial Assessment documents for TSCA Work Plan chemicals going forward. Additional Problem Formulation and Initial Assessment documents are targeted for release in Spring 2015. The Problem Formulation and Initial Assessment document is available at http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html. Comments are due by **June 29, 2015**.

NTP Sets Peer Review For Pentabromodiphenyl Ether: On April 23, 2015, the National Toxicology Program (NTP) announced it would peer review a report on a mixture of pentabromodiphenyl ether and related chemicals on **June 25, 2015**. 80 Fed. Reg. 22737. A draft technical report summarizing results from NTP's carcinogenicity and related studies was scheduled to be released by May 14, 2015. Public comments on the draft are due **June 11, 2015**. Information about the meeting, registration, and a copy of the draft technical report will be available at http://ntp.niehs.nih.gov/go/36051.

EPA Issues Interim Guidance Concerning Antimicrobial Data Requirements: On April 30, 2015, EPA issued interim guidance that clarifies its toxicology data requirements for antimicrobial pesticides used on food contact surfaces. If pesticide residues in food resulting from use on food contact surfaces are 200 parts per billion (ppb) or less, EPA requires certain toxicology data. If residues are greater than 200 ppb, additional data may be required, depending on other conditions such as test results. The interim guidance clarifies that the 200 ppb trigger is based on total estimated daily dietary intake for an individual, and not on the amount of residue present on a single food. According to EPA, its interpretation is consistent with the U.S. Food and Drug Administration's (FDA) policy. The interim guidance also clarifies EPA's 2013 amendments to data requirements for antimicrobial pesticides that were designed to make the registration process for these pesticides more efficient and transparent. The interim guidance is intended to fulfill a condition of a March 2, 2015, settlement agreement between EPA and the American Chemistry Council (ACC), following ACC's lawsuit challenging the data requirements regulation in the U.S. Court of Appeals in the District of Columbia. Under the settlement agreement, EPA is required to propose by **September 2, 2017**, certain corrections to 40 C.F.R. § 158.2230(d) to make the rule's language consistent with the FDA's use of the 200 ppb. EPA also issued a letter to antimicrobial registrants with information about how the Agency has been implementing Part 158W with respect to existing registered antimicrobial pesticides as well as new and pending antimicrobial pesticide applications. Both the interim guidance and the implementation letter are available online at http://www2.epa.gov/pesticide-registration/epa-data-requirements-registration-antimicrobial-pesticides-part-158w. The settlement agreement and additional documents are available at http://www.regulations.gov in docket EPA-HQ-OPP-2008-0110. For more information on antimicrobial policies and guidance, visit http://www.epa.gov/oppad001/regpolicy.htm.

SAB Schedules Review Of IRIS Assessment: On May 12, 2015, EPA's Science Advisory Board (SAB) Staff Office announced a public teleconference to review three draft SAB reports on the EPA's Integrated Risk Information System (IRIS) assessments for ammonia, trimethylbenzenes, and ethylene oxide, respectively. 80 Fed. Reg. 27166. The public teleconference for the Chartered SAB will be conducted on Monday, **June 8, 2015**, from 1:00 p.m. to 5:00 p.m. (Eastern Time).

FDA

FDA Publishes Guidance On Expedited Access For Premarket Approval: On April 13, 2015, FDA's Centers for Devices and Radiological Health (CDHR) issued guidance entitled "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions." 80 Fed. Reg. 19669. FDA intends the guidance to assist companies through a voluntary program for certain devices that are subject to premarket approval and also details how the Expedited Access Pathway (EAP) program will provide patients with access to breakthrough technologies for unmet medical needs. The EAP program became effective April 15, 2015.

FDA Publishes Guidance On Data Collection: On April 13, 2015, CDRH issued guidance entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval." 80 Fed. Reg. 19672. The guidance outlines how FDA considers postmarket controls for reduction of data collection for premarket approval while ensuring access to devices that are safe and effective.

FDA Issues Draft Guidance On Clinical Studies: On April 21, 2015, CDRH issued draft guidance entitled "Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States." 80 Fed. Reg. 22205. The purpose of the draft guidance is to provide industry insight into FDA's current policy regarding the use and acceptance of clinical data in support of premarket approval collected from studies conducted outside the U.S. and includes important details that should be considered. To ensure that FDA considers comments on this draft guidance before it begins work on the final version, comments should be submitted by **July 20, 2015**.

FDA Issues Letter To Bottled Water Manufacturers: On April 27, 2015 FDA's Center for Food Safety and Applied Nutrition (CFSAN) issued a letter to industry regarding recommendations for fluoride added to bottled water. FDA and the U.S. Public Health Service (PHS) conducted a review of the scientific literature with a panel of scientists and determined the recommended levels to ensure fluoride levels in drinking bottled water are not excessively high, leading to increase risk of discoloration of tooth enamel in children. For more details, *see* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/BottledWaterCarbonatedSoftDrinks/ucm444373.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

FDA Issues Draft Guidance For Assessment Of Drugs With Potential Estrogenic, Androgenic, Or Thyroid Pathway Activity: FDA announced on April 29, 2015, the release of draft guidance for industry entitled ''Environmental Assessment: Questions and Answers Regarding Drugs with Estrogenic, Androgenic, or Thyroid Activity" in accordance with 21 C.F.R. § 10.115. 80 Fed. Reg. 23802. This guidance addresses specific considerations for drugs that have potential estrogenic, androgenic, or thyroid pathway activity (E, A, or T activity) in environmental organisms. The draft guidance document is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444658.pdf. Sponsors of drugs with potential E, A, or T activity should consult with FDA early in product development to determine whether an environmental assessment will be required for new drug applications (NDA) and certain NDA supplements, or whether a claim of categorical exclusion would be acceptable, and what information should be included in either case. Categorical exclusions for actions related to human drugs and biologics are listed in 21 C.F.R. § 25.31. This guidance focuses on the categorical exclusion for actions on NDAs and NDA supplements that would increase the use of an active moiety, but at an estimated concentration of the substance at the point of entry into the aquatic environment below 1 ppb (21 C.F.R. § 25.31(b)). Once issued in final, this guidance will represent FDA's current thinking on this topic, but will not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative approaches could be used to satisfy the requirements of applicable statutes and

regulations. Electronic or written comments on this draft guidance may be submitted at any time, but comments to be considered during FDA's review of the draft guidance should be submitted by **June 29, 2015**.

FDA Seeks Comments On Risk Assessment For Drug Residues In Milk: On April 30, 2015, CFSAN announced the availability for comment of a risk assessment entitled "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products." 80 Fed. Reg. 24260. This project was in response to a request from the National Conference of Interstate Milk Shipments (NCIMS) and provides a ranking model for four specific criteria to assist in scientific decision support. The model also addresses potential data gaps and research needs. Comments are due by **July 29, 2015**.

FDA Announces GUDID Public Website: On May 4, 2015, FDA's CDRH announced that the data submitted to the Global Unique Device Identification Database (GUDID) are now publicly available. The website, in partnership with the National Library of Medicine, is part of the phase-in for the Unique Device Identification compliance timeline and offers anyone access to search or download information submitted for medical devices. For more details, *see* http://accessgudid.nlm.nih.gov/.

FDA Issues Draft Question And Answer Guidance On Mandatory Food Recall: On May 7, 2015, CFSAN announced the availability for comment on draft guidance to industry on the implementation of the mandatory food recall provisions of the Food Safety Modernization Act (FSMA). 80 Fed. Reg. 26269. The draft guidance provides industry with a question and answer format to address how FDA is going to implement non-voluntary recalls of food (food articles as defined in 21 U.S.C. § 321(f), including dietary supplements) that are considered to be misbranded and adulterated and could cause serious adverse health consequences as part of the ongoing implementation efforts of enacting the FSMA. Comments are due by **July 6, 2015**.

RCRA/CERCLA

EPA Publishes RCRA Coal Combustion Residuals Rule: On April 17, 2015, EPA published its controversial final rule establishing management standards under the Resource Conservation and Recovery Act (RCRA) for coal combustion residuals (CCR). 80 Fed. Reg. 21301. Signed by EPA Administrator Gina McCarthy on December 19, 2014, EPA stated that the publication delay was caused by the need to remove potentially confusing or contradictory language in the regulation. EPA released a redline version of the rule showing changes from the December 2014 version. The rule becomes effective on **October 14, 2015**. EPA chose to regulate CCRs as non-hazardous waste under Subtitle D of RCRA, rather than hazardous waste under Subtitle C, and that decision has sparked significant controversy, particularly in light of the massive Kingston, Tennessee, coal ash spill. The rule includes minimum standards for existing and new CCR landfills and surface impoundments. These standards include location restrictions, design and operating standards, groundwater monitoring, corrective action, closure requirements, post-closure care standards, recordkeeping, and notification requirements. Publication of the rule

triggers the 90-day clock for stakeholders to file suit against EPA over the rule, and it is almost certain that the rule will be challenged by coal-fired utilities, environmental groups, and state agencies. Any suit filed against the rule could become moot, however, if federal legislation is enacted that creates standards for CCRs. Such legislation passed the House Energy and Commerce Committee on April 15, 2015. The bill, H.R. 1734, would codify much of EPA's rule but would vest states with the primary authority to craft and implement CCR disposal programs, rather than EPA's approach setting nationwide standards.

EPA Revises RCRA Guidance For Hazardous Waste Analysis At Generator Sites And TSDFs: In April, EPA released revised final guidance on hazardous waste analysis at hazardous waste generator sites and hazardous waste treatment, storage, and disposal facilities (TSDF). Entitled Waste Analysis at Facilities that Generate, Treat, Store, and Dispose of Hazardous Wastes, the document updates EPA's 1994 guidance. One of the most notable changes in the document is an emphasis on EPA's "single exceedance philosophy." EPA states in the revised guidance that it "will generally measure compliance with the hazardous waste regulations based on a detailed chemical and physical analysis of a representative sample of the waste(s) in question." The guidance goes on to state, however, that an inspector may gauge compliance with "do not exceed" standards based on a single sample based on professional judgment. The revised guidance also provides more detail on how frequently waste streams should be reanalyzed. It provides an algorithm for doing so, although use of the algorithm is not mandatory.

DOT/Hazardous Materials

DOT Issues Final Rule Strengthening Tank Car Standards And Operational Controls For High-Hazard Flammable Trains: On May 1, 2015, U.S. Transportation Secretary Anthony Foxx signed the U.S. Department of Transportation's (DOT) long awaited final rule strengthening standards for trains carrying flammable petroleum-based products. Foxx announced the rule with Canadian Minister of Transport Lisa Raitt in a show of solidarity between the U.S. and Canada on the rail transportation of petroleum-based products. The rule was published in the *Federal Register* on May 8, 2015. 80 Fed. Reg. 26643. It becomes effective on **July 7, 2015**. The rule applies to "high-hazard flammable trains" (HHFT), which DOT defines as "a continuous block of 20 or more tank cars loaded with a flammable liquid or 35 or more tank cars loaded with a flammable liquid dispersed through a train." The rule has four main components: enhanced tank car standards and an aggressive retrofitting schedule for older tank cars carrying crude oil and ethanol; a new braking standard for certain trains; new operational protocols for trains transporting large volumes of flammable liquids, such as routing requirements, speed restrictions, and information for local government agencies; and new sampling and testing requirements to improve classification of energy products placed into transport. A summary of retrofit deadlines is below.

Timeline for the Retrofit of Affected Tank Cars for Use in North American HHFTs			
Tank Car Type / Service	**US Retrofit Deadline**	**Tank Car Type / Service**	**TC Retrofit Deadline**
Non Jacketed DOT-111 tank cars in PG I service	(January 1, 2017) January 1, 2018	Non Jacketed DOT-111 tank cars in Crude Oil service	May 1, 2017
Jacketed DOT-111 tank cars in PG I	March 1, 2018	Jacketed DOT-111 tank cars in Crude Oil service	March 1, 2018
Non Jacketed CPC-1232 tank cars in PG I service	April 1, 2020	Non Jacketed CPC-1232 tank cars in Crude Oil service	April 1, 2020
Non Jacketed DOT-111 tank cars in PG II service	May 1, 2023	Non Jacketed DOT-111 tank cars in Ethanol service	May 1, 2023
Jacketed DOT-111 tank cars in PG II service	May 1, 2023	Jacketed DOT-111 tank cars in Ethanol service	May 1, 2023
Non Jacketed CPC-1232 tank cars in PG II service	July 1, 2023	Non Jacketed CPC-1232 tank cars in Ethanol service	July 1, 2023
Jacketed CPC-1232 tank cars in PG I and PG II service and all remaining tank cars carrying PG III materials in an HHFT (pressure relief valve and valve handles).	May 1, 2025	Jacketed CPC-1232 tank cars in in Crude and Ethanol service and all remaining tank cars carrying PG III materials in an HHFT (pressure relief valve and valve handles).	May 1, 2025

DOT Inspector General To Audit PHMSA Progress In Meeting Congressional Mandates: On May 5, 2015, DOT announced that its Inspector General (IG) has launched an audit of DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA) at the request of Representative Peter DeFazio (D-OR), Ranking Member of the House Transportation and Infrastructure Committee. In its announcement of the audit, the IG's office stated that DeFazio is concerned about how long PHMSA has taken to establish new regulations for railroad tank cars carrying crude oil and to implement mandates from the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011. The IG stated that its objective in the audit will be to assess PHMSA's progress in addressing Congressional mandates and recommendations from the National Transportation Safety Board (NTSB), the Government Accountability Office (GAO), and the IG's office since 2005. The IG will also evaluate PHMSA's process for implementing mandates and recommendations and efforts to coordinate and address operating administrations' safety concerns.

DOT Agencies Take Coordinated Actions To Increase The Safe Transportation Of Energy Products: On April 17, 2015, DOT announced with its agencies, the Federal Railroad Administration (FRA) and PHMSA, a package of targeted actions that are intended to address some of the issues identified in recent train accidents involving crude oil and ethanol shipped by rail. The actions include one Emergency Order, two Safety Advisories, and notices to industry intended to further enhance the safe shipment of Class 3 flammable liquids. DOT states that preliminary investigation of one recent derailment indicates that a mechanical defect involving a broken tank car wheel may have caused or contributed to the incident. FRA is therefore recommending that only the highest skilled inspectors conduct brake and mechanical inspections of trains transporting large quantities of flammable liquids, and that industry decrease the threshold for wayside detectors that measure wheel impacts, to ensure the wheel integrity of tank cars in those trains. Recent accidents revealed that certain critical information about the train and its cargo needs to be available immediately for use by emergency responders or federal investigators who arrive on scene shortly after an incident. To address the information gap, DOT is taking several actions to remind both the oil industry and the rail industry of their obligation to provide these critical details: PHMSA is issuing a safety advisory reminding carriers and shippers of the specific types of information that they must make immediately available to emergency responders; FRA and PHMSA are issuing a joint safety advisory requesting that specific information also be made readily available to investigators; FRA is sending a request to the Association of American Railroads (AAR) asking the industry to develop a formal process by which this specific information becomes available to both emergency responders and investigators within 90 minutes of initial contact with an investigator; and FRA submitted to the *Federal Register* a notice proposing to expand the information collected on certain required accident reports, so that information specific to accidents involving trains transporting crude oil is reported. DOT has determined that public safety compels issuance of an Emergency Order (EO) to require that trains transporting large amounts of Class 3 flammable liquid through certain highly populated areas adhere to a maximum authorized operating speed limit of 40 miles per hour in High Threat Urban Areas. Under the EO, an affected train is one that contains: (1) 20 or more loaded tank cars in a continuous block, or 35 or more loaded tank cars, of Class 3 flammable liquid; and (2) at least one DOT Specification 111 (DOT-111) tank car (including those built in accordance with AAR Casualty Prevention Circular 1232 (CPC-1232)) loaded with a Class 3 flammable liquid.

CAA/CWA/SDWA

EPA Publishes 20th Annual U.S. Greenhouse Gas Inventory: EPA on April 16, 2015, released the 20th Inventory of U.S. Greenhouse Gas Emissions and Sinks, showing a two percent increase in greenhouse gas emissions in 2013 from 2012 levels, but a nine percent drop in emissions since 2005. Total U.S. greenhouse emissions were 6,673 million metric tons of carbon dioxide equivalent in 2013. By sector, power plants were the largest source of emissions, accounting for 31 percent of total U.S. greenhouse gas pollution. The transportation sector was the second largest source, at 27 percent. Industry and manufacturing were the third largest source, at 21

percent. EPA states that the increase in total national greenhouse gas emissions between 2012 and 2013 was due to increased energy consumption across all sectors in the U.S. economy and greater use of coal for electricity generation. The annual inventory presents historical emissions since 1990 and covers seven key greenhouse gases: carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, sulfur hexafluoride, and nitrogen trifluoride. In addition to tracking U.S. greenhouse gas emissions, the inventory also calculates carbon dioxide that is removed from the atmosphere through the uptake of carbon in forests and other vegetation. EPA has been publishing the inventory since 1994, but tracks back to 1990.

NANOTECHNOLOGY

ECETOC Nano Task Force Proposes Decision-Making Framework For The Grouping And Testing Of Nanomaterials: The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Nano Task Force published an article in *Regulatory Toxicology and Pharmacology* entitled "A decision-making framework for the grouping and testing of nanomaterials (DF4nanoGrouping)." The DF4nanoGrouping consists of three tiers to assign nanomaterials to four main groups, to perform sub-grouping within the main groups, and to determine and refine specific information needs. According to the abstract, the DF4nanoGrouping covers all relevant aspects of a nanomaterial's life cycle and biological pathways. Use (including manufacture), release, and route of exposure are applied as qualifiers within the DF4nanoGrouping to determine if, *e.g.*, nanomaterials cannot be released from a product matrix, which may justify the waiving of testing. The four main groups encompass: (1) soluble nanomaterials; (2) biopersistent high aspect ratio nanomaterials; (3) passive nanomaterials; and (4) active nanomaterials. The abstract states that the DF4nanoGrouping aims to group nanomaterials by their specific mode-of-action, resulting in an apical toxic effect that is eventually directed by a nanomaterial's intrinsic properties. Since the exact correlation of intrinsic material properties and apical toxic effect is not yet established, however, the abstract states that the DF4nanoGrouping uses the functionality of nanomaterials for grouping rather than relying on intrinsic material properties alone. The abstract describes the DF4nanoGrouping as a hazard and risk assessment tool that applies modern toxicology and contributes to the sustainable development of nanotechnological products. It ensures that no studies are performed that do not provide crucial data and, therefore, saves animals and resources.

NIOSH Announces Publication Of Paper From Industrywide Study On Carbon Nanotube And Nanofiber Exposure: On April 27, 2015, the National Institute for Occupational Safety and Health (NIOSH) announced publication of "Carbon Nanotube and Nanofiber Exposure Assessments: An Analysis of 14 Site Visits" in *Annals of Occupational Hygiene*. The paper is the second report from NIOSH's Industrywide Study. According to NIOSH, the findings illustrate which tasks have the highest exposures, trends in exposure, nature and character of materials involved, effectiveness of controls when used, and continued refinement of the methods used to evaluate exposure of this high-priority class of nanomaterials. NIOSH visited 14 sites to assess exposures to carbon nanotubes (CNT) (13 sites) and carbon nanofibers (CNF)

(one site). According to the abstract, overall, elemental carbon personal breathing zone and area time-weighted average samples were below the NIOSH recommended exposure limit (REL) of one microgram per cubic meter (µg/m^3) elemental carbon as a respirable mass (96 percent were less than one µg/m^3 at the respirable size fraction), while 30 percent of the inhalable personal breathing zone elemental carbon samples were found to be greater than one µg/m^3. The abstract states: "Until more information is known about health effects associated with larger agglomerates, it seems prudent to assess worker exposure to airborne CNT and CNF materials by monitoring [elemental carbon] at both the respirable and inhalable size fractions. Concurrent [transmission electron microscopy] samples should be collected to confirm the presence of CNT and CNF."

USDA Announces $3.8 Million Awarded In Grants For Nano Research: The U.S. Department of Agriculture (USDA) National Institute of Food and Agriculture (NIFA) announced on April 27, 2015, that it awarded more than $3.8 million in grants "focused on using nanotechnology to find solutions to societal challenges such as food security, nutrition, food safety, and environmental protection." The grants were made through NIFA's Agriculture and Food Research Initiative (AFRI), which is authorized by the 2014 Farm Bill. According to USDA's press release, past projects include a Cornell University and Rensselaer Polytechnic Institute venture that led to the development of a new nanotechnology that could prevent bacteria from sticking to medical equipment and food processing machinery, and a Harvard School of Public Health project investigating the effectiveness of a chemical-free, nanotechnology-based method for the inactivation of pathogenic and spoilage microorganisms on the surface of fruits and vegetables. The press release lists the following fiscal year 2014 projects:

- The University of Georgia, Athens, Georgia, $496,192;
- University of Iowa, Iowa City, Iowa, $496,180;
- University of Kentucky Research Foundation, Lexington, Kentucky, $450,000;
- University of Massachusetts, Amherst, Massachusetts, $444,200;
- North Dakota State University, Fargo, North Dakota, $149,714;
- Rutgers University, New Brunswick, New Jersey, $450,000;
- Pennsylvania State University, University Park, Pennsylvania, $447,788;
- West Virginia University, Morgantown, West Virginia, $496,168; and

- University of Wisconsin-Madison, Madison, Wisconsin, $450,100.

EPA Will Hold Public Meeting On Proposed Rule On Nanoscale Materials: EPA published a notice in the May 8, 2015, *Federal Register* announcing a public meeting on **June 11, 2015**, to discuss EPA's April 6, 2015, proposed rule concerning reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale. 80 Fed. Reg. 26518. This is a very important opportunity for stakeholders to offer comments on a rulemaking that has important implications for the nano community. EPA intends the public meeting to provide an opportunity for further discussion of the proposed requirements and the meeting is intended to facilitate comments on all aspects of that proposed rule. The meeting will be held on **June 11, 2015**, from 9:00 a.m. to 4:00 p.m., at the East William Jefferson Clinton Building, Room 1153, 1201 Constitution Avenue, NW, Washington, D.C. Requests to participate in the meeting must be received by **June 1, 2015**.

NNCO Will Hold SME Webinar On May 20: The National Nanotechnology Coordination Office (NNCO) will hold its next webinar focusing on the experiences, successes, and challenges for small- and medium-sized enterprises (SME) working in nanotechnology and on issues of interest to the business community on **May 20, 2015, from 2:00-3:00 p.m. (EDT)**. The webinar will include the following speakers: Dr. Ajay P. Malshe, Founder, Executive Vice President, and Chief Technical Officer of NanoMech. NanoMech has developed patented platform nanotechnology innovations in machining and manufacturing, lubrication and energy, adaptive chemistries for advanced textile coatings, metal surface coatings, biomedical implant coatings, and strategic military applications; and Dr. Matthew Putnam, Chief Executive Officer of Nanotronics Imaging. Nanotronics Imaging uses a convergence in computational processing, automation, and artificial intelligence algorithms to image and analyze materials at the nanoscale for development of new semiconductors, medical devices, regenerative organs, and photovoltaics. The speakers will provide an overview of their experiences, successes, and challenges in the nanotechnology SME space. This will be followed by a question and answer segment with members of the public. Questions for the panel can be submitted to webinar@nnco.nano.gov through the end of the webinar. A webcast will be posted afterwards.

Nano Community Members Can Benefit From Membership In The Sustainable Nanotechnology Organization: Membership in the Sustainable Nanotechnology Organization (SNO) offers a number of benefits to members of the nano community. SNO's purpose is to provide a professional society forum to advance knowledge in all aspects of sustainable nanotechnology, including both applications and implications. SNO is comprised of individuals and institutions that are engaged in:

- Research and development of sustainable nanotechnology;
- Implications of nanotechnology for environment, health, and safety (EHS);

- Advances in nanoscience, methods, protocols, and metrology;
- Education and understanding of sustainable nanotechnology; and
- Applications of nanotechnology for sustainability.

As SNO is a non-profit, membership fees are tax-deductible. New membership fees will be good for the **November 8-10, 2015**, conference, to be held in Portland, Oregon. Technical sessions will be held concerning sustainable nanotechnology in industrial systems; food systems; governance systems; water systems; material use and waste management systems; "natural" ecosystems; social systems; energy systems; health systems; transportation systems; urban systems; and information technology systems.

BIOBASED/RENEWABLE PRODUCTS

BRAG Biobased Products News And Policy Report: Bergeson & Campbell, P.C.'s (B&C®) 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.

EPA Direct Final Rule Includes SNURs For Several Biobased Chemicals: On May 8, 2015, EPA promulgated through a direct final rule significant new use rules (SNUR) for 25 chemical substances that were the subject of premanufacture notices (PMN). 80 Fed. Reg. 26448. The SNURs require persons who intend to manufacture (including import) or process any of these 25 chemical substances for an activity that is designated in the SNUR as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification provides EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. The draft final rule includes SNURs for several biobased chemicals. The SNURs for fatty acids, satd. and unsatd alkyl-, esters with polyol (generic) (PMN Number P-13-139) and fatty acids reaction products with polyethylenepolyamine and naphthenic acids (generic) (PMN Numbers P-14-616 and P-14-617) limit uses of those substances to those in the PMNs, but that aquatic toxicity testing could demonstrate lower hazard and obviate the need for the SNUR. A SNUR for 1,2,3-propanetriol, homopolymer, dodecanoate (PMN Number P-14-395), which could be a biobased chemical, limits "use of the substance that results in releases to surface waters exceeding 18 ppb." Again, aquatic toxicity testing could demonstrate lower hazard and lead to a higher concentration limit or obviate the need for the SNUR. These SNURs demonstrate what we have stated many times, namely that biobased chemicals are "renewable," but not necessarily non-toxic. Esters are a category that triggers concerns according to EPA's New Chemicals Program Chemical Categories report, so regulations to limit releases of these substances to water should not be a surprise. When submitting PMNs to EPA for new biobased chemicals, companies should keep in mind that robust pollution prevention statements can offset

possible concerns by putting the new biobased substance in a risk context with incumbent technologies that it may replace. EPA can make a reduced risk determination and forgo regulation if they have sufficient information to substantiate the relative risk of the new substance and the incumbent it will displace. The rule will be effective **July 7, 2015**.

LEGISLATIVE DEVELOPMENTS

Compromise TSCA Bill Clears Senate Committee; Bill Gains Support: The Senate Environment and Public Works (EPW) Committee on April 28, 2015, overwhelmingly approved a bill seeking to reform TSCA. By a vote of 15-5, the Committee approved S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, over the objections from the Committee's Ranking Member, Barbara Boxer (D-CA), and other Democrats. The Committee actually passed a bipartisan, compromise version of the bill, which was introduced as a substitute amendment to the original bill. The revised bill is intended to assuage concerns voiced by Democrats, environmental and public health advocates, and EPA about the originally introduced version of S. 697. Reportedly, the amendments were the result of negotiations between Senators David Vitter (R-LA) and Tom Udall (D-NM), the original co-sponsors of the legislation, and EPW Committee members Senators Sheldon Whitehouse (D-RI), Jeff Merkley (D-OR), and Cory Booker (D-NJ). The "amendment in the nature of a substitute" revised arguably the most controversial provisions of the original bill, those addressing preemption of state chemical regulatory programs. The bill would limit preemption of state regulation to a period beginning when EPA defines the scope of uses of a chemical and ending when EPA makes a safety determination on a chemical. Also included is an automatic waiver from preemption if EPA misses a deadline set forth in the law. The amended bill would also allow states to be "co-enforcers" with EPA of chemical regulations and would modify the process EPA must take to designate a chemical as a high priority. The substitute would also alter the safety standard to be consistent with existing law while clarifying the term "unreasonable risk." Lawmakers also agreed to changes to the threshold for when EPA may regulate substances in articles, qualitative deadlines for EPA to take action on a chemical that fails to meet the safety standard, changes to confidential business information (CBI) provisions, and a mechanism for the public to challenge low priority designations. The Committee's passage of the bill is significant: it marks the first time in many years that a TSCA reform bill has progressed through a House or Senate Committee and the first time such legislation secured bipartisan support. This support is swelling. The recent addition of the 14 new co-sponsors brings the total support for the bill, including Vitter and Udall, to 36 Senators. The seven new Democratic supporters announced on May 7, 2015, are Sheldon Whitehouse (RI), Cory Booker (NJ), Claire McCaskill (MO), Tim Kaine (VA), Jeff Merkley (OR), Chris Murphy (CT), and Jeanne Shaheen (NH). Seven Republicans are also new supporters of the legislation: John Barrasso (WY), John Cornyn (TX), Tom Cotton (AR), Lisa Murkowski (AK), Marco Rubio (FL), and Tim Scott (SC).

House Subcommittee Unanimously Passes TSCA Bill: The House Energy and Commerce Environment and Economy Subcommittee on May 14, 2015, gave unanimous support for a draft

bill to reform TSCA entitled the TSCA Modernization Act of 2015. On a 21-0 vote, the Subcommittee agreed to forward the bill to the full panel. According to a summary of the bill provided by the Subcommittee, the legislation would "provide EPA the tools to ensure chemicals in commerce are safe for consumers." It seeks to create a new system for EPA to evaluate and manage risks associated with chemicals already on the market. Under the bill, either EPA or a manufacturer (who is willing to pay the cost) may designate a chemical for risk evaluation and the risk evaluation must stand up to rigorous scientific standards set out in the legislation. If unreasonable risk is determined, EPA must immediately draft a rule to manage the risk. The bill sets deadlines for EPA to take action on risk evaluations (three years) and to develop risk management rules following completion of risk evaluations (90 days). The work would be funded by user fees paid to EPA. State law is provided with a limited preemption under the bill. Specifically, once EPA makes a final decision on a chemical, either a new rule or a determination that it poses no unreasonable risk, EPA action would apply in all states. Prior state laws that do not conflict with TSCA, and private rights of action under tort or contract law, are preserved. Revisions to the draft bill are likely to come before the bill heads to the full Committee, stated the bill's author and Subcommittee Chair John Shimkus (R-IL).

House Passes Bill That Would Force The Withdrawal Of WOTUS Proposal; Senate To Hold Hearing On Its Version: By a vote of 261-155, the House of Representatives on May 12, 2015, passed the Regulatory Integrity Protection Act of 2015 (H.R. 1732), which would require EPA and the U.S. Army Corps of Engineers (the Corps) to withdraw their joint Waters of the United States (WOTUS) proposed rule, or any final rule stemming from that proposal. EPA and the Corps proposed the rule on April 21, 2014. 79 Fed. Reg. 22187. The rule seeks to change the definition of "waters of the U.S." to clarify which bodies of water are subject to Clean Water Act (CWA) jurisdiction. The rule comes in the wake of several U.S. Supreme Court decisions that confused the issue, frequently requiring EPA and the Corps to render case-by-case determinations, EPA and the Corps claim. EPA received over one million comments on the proposal. H.R. 1732 would require EPA and the Corps to withdraw the rule and reissue it after considering feedback on the initial proposal, the results of a cost-benefit analysis, and certain scientific studies. They would also need to consult with a broad range of state and local officials and other stakeholders and seek to reach a consensus before moving forward. On April 29, 2015, the White House issued a Statement of Administration Policy threatening to veto the bill. The White House stated that the rule was grounded in science and would "protect clean water, safeguard public health, and strengthen the economy." Contrary to the arguments of the bill's proponents, the Administration claimed, the bill would weaken regulatory certainty for business and communities. The Senate EPW Committee has scheduled a **May 19, 2015**, hearing on its version of the bill (S. 1140), which was introduced by Senator John Barrasso (R-WY). Witnesses scheduled to appear are Patrick Parenteau, professor at the Vermont Law School; Andrew Lemley, government affairs representative for the New Belgium Brewing Company; Mark Pifher, a manager at Colorado Springs Utilities; Assistant Kansas Agriculture Secretary Susan Metzger; and Robert Pierce of Wetland Training Institute, Inc.

Senate Bill Would Roll Back Proposed Clean Power Plan: On May 13, 2015, Senator Shelley Capito (R-WV), Chair of the Senate EPW Committee's Clean Air and Nuclear Safety Subcommittee, introduced a highly controversial bill that will be the principal legislative vehicle in the Senate to thwart the proposed Clean Power Plan. The Affordable Reliable Energy Now Act (ARENA) (S. 1324) "will ensure reliable and affordable energy, put jobs and our economy first, and curb federal overreach," Capito stated in announcing the bill. Before EPA can set a technology-based standard for new power plants, the bill requires that the standard must first be achieved for at least one year at several separate power facilities. The bill also prevents EPA from using any demonstration projects to set the standard. The bill would also extend the rule's compliance dates pending final judicial review, including the dates for submission of state plans. Attempting to "hold EPA accountable," the bill would require EPA to issue state-specific model plans demonstrating how each state could meet the required greenhouse gas emissions reductions under the rule. The bill would also provide that no state would be required to implement a state or federal plan that the state's Governor determines would negatively impact economic growth, the reliability of the electricity system, or electricity ratepayers. The bill would also prevent EPA from withholding highway funds from any states for noncompliance with the Clean Power Plan. The bill has several high-powered co-sponsors, including Senate Majority Leader Mitch McConnell (R-KY), Senate Republican Whip John Cornyn (R-TX), Senate Republican Conference Chair John Thune (R-SD), and Senate EPW Committee Chair James Inhofe (R-OK). The bill is almost certain to draw a veto threat from the White House. It has already garnered scathing criticism from environmental groups; the Natural Resources Defense Council stated that "of all the legislative attempts to thwart President Obama's historic Clean Power Plan, none is more brazen or potentially dangerous than the [Capito] bill."

Secret Science Reform Act Passes Senate Committee: By a narrow 11-9 vote, the Senate EPW Committee on April 28, 2015, passed the Secret Science Reform Act (S. 544). The controversial bill would require certain EPA rulemakings to be based on data that are public and available for independent analysis. The bill's sponsor, John Barrasso (R-WY), states that the legislation would enhance EPA's regulatory process without adding new burdens on EPA. But Senator Barbara Boxer (D-CA), the Committee's Ranking Member, caustically characterized the bill as "insane" and "a joke." She predicted that the bill would cost EPA hundreds of millions of dollars to implement and would hinder EPA from issuing necessary regulations. On March 18, 2015, the House passed its version of the bill (H.R. 1030), which drew a veto threat from the White House. The bill would prevent EPA from issuing in final form any risk, exposure, or hazard assessment; criteria document; standard; limitation; regulation; regulatory impact analysis; or guidance document unless the data used as the basis for the action are publicly available and able to be independently analyzed.

Senators Introduce Bill To Strengthen Personal Care Product Oversight: ***S***enators Dianne Feinstein (D-CA) and Susan Collins (R-ME) on April 20, 2015, introduced the Personal Care Products Safety Act (S. 1014) to protect consumers and streamline industry compliance by strengthening FDA's authority to regulate the ingredients in personal care products. Federal

regulations on these products have not been updated in 75 years, according to Feinstein and Collins. The bill would require FDA to evaluate a minimum of five ingredients per year to determine their safety and appropriate use. The review process set forth in the bill would provide companies with clear guidance about whether ingredients should continue to be used and if so, what the concentration levels should be and whether consumer warnings are needed. For example, a chemical may be deemed inappropriate for use in children's products, or appropriate for professional application only. The first set of chemicals for review includes:

- Diazolidinyl urea, which is used as a preservative in a wide range of products, including deodorant, shampoo, conditioner, bubble bath, and lotion;
- Lead acetate, which is used as a color additive in hair dyes;
- Methylene glycol/formaldehyde, which is used in hair treatments;
- Propyl paraben, which is used as a preservative in a wide range of products, including shampoo, conditioner, and lotion; and
- Quaternium-15, which is used as a preservative in a wide range of products, including shampoo, shaving cream, skin creams, and cleansers.

The bill would provide streamlined federal standards so that the personal care products industry knows what to expect and companies can plan for the future with certainty. The Personal Care Products Safety Act would also:

- Provide FDA the authority to order recalls of certain personal care products that threaten consumer safety.
- Provide FDA the authority to require labeling of products that include ingredients not appropriate for children and those that should be professionally administered. Complete label information, including ingredients and product warnings, would also be required to be posted online since approximately 40 percent of personal care products are purchased over the Internet.
- Require companies to provide contact information on their products for consumers and report serious adverse events to FDA within 15 days, including death, hospitalization, and disfigurement. Health effects that

could have resulted in hospitalization without early intervention would also be required to be reported.

- Require manufacturers to register annually with FDA and provide FDA with information on the ingredients used in their personal care products.

- Direct FDA to issue regulations on Good Manufacturing Practices for personal care products.

To fund these new oversight activities, the bill would authorize FDA to collect user fees from personal care products manufacturers similar to what is done for medications and medical devices.

Crude-By-Rail Safety Act Introduced In House: Representatives Jim McDermott (D-WA), Doris Matsui (D-CA), and Ron Kind (D-WI) on April 15, 2015, introduced the Crude-By-Rail Safety Act (H.R. 1804). The legislation would establish new safety standards for rail cars transporting crude oil. According to McDermott, H.R. 1804 would "establish the strongest tank car standards to-date." It would require DOT to establish an interim national standard for the maximum volatility of crude oil transported by rail within the United States within 90 days of the bill's enactment. The new standard would take affect no later than 90 days after DOT issues it. Within two years, DOT would be required to complete a study on the best methods for reliably measuring the volatility of crude oil and the level of volatility that is consistent with the safest practicable shipment of crude oil by rail. Once the study is complete, DOT would have 90 days to issue a final rule establishing the maximum volatility of crude oil that is transported by rail. The final national standard is to be consistent with the findings of the study and require that transportation of crude oil by rail be as safe as practicable. The bill would give DOT 90 days to issue its final rule on Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains. But it would require that the rule adopt the strongest tank car design option under consideration and that all new tank cars designed to transport a Class 3 flammable liquid constructed after October 1, 2015, to meet the new standard. The use of DOT-111 tank cars and unjacketed CPC-1232 tank cars to transport crude oil would be prohibited under the legislation. The use of DOT-111 and unjacketed CPC-1232 cars to transport ethanol would similarly be banned.

Senate Bill Would Expand And Strengthen OSH Act Authority: Senator Al Franken (D-MN), on April 28, 2015, introduced the Protecting America's Workers Act (S. 1112). Noting that the Occupational Safety and Health Act (OSH Act) has not been modified significantly in years, Franken stated that there are still major problems that need to be addressed. The bill would amend the OSH Act to cover more workers, update penalties, strengthen protections, enhance public accountability, and clarify an employer's duty to provide a safe work environment. Franken claims that over 8.5 million American workers are not covered currently by the Occupational Safety and Health Administration's (OSHA) protections. These include federal, state, and local public employees, and some private sector employees. The bill provides OSHA

protections to these workers, which include flight attendants, state correctional officers, and workers in government agencies. The legislation also strengthens penalties. Under current law, an employer may be charged -- at most -- with a misdemeanor when a willful violation of OSHA leads to a worker's death. The bill makes felony charges available for an employer's repeated and willful violations of OSHA that result in a worker's death or serious injury. The bill also updates civil penalties, which have been unchanged since 1990, and sets a minimum penalty of $50,000 for a worker's death caused by a willful violation. The legislation affords more protection for whistleblowers; the law's provisions on this topic have remained unaltered since their original adoption in 1970. Franken's bill also seeks to enhance the public's right to know about safety violations. It would mandate that the Department of Labor (DOL) investigate all cases of death or serious incidents of injury in the workplace. It gives workers and their families the right to meet with DOL investigators and requires employers to inform workers of their OSHA rights. The legislation also clarifies an employer's duty to provide a safe worksite and safety equipment and track recordable injuries and illnesses for all workers onsite. It amends the OSH Act General Duty Clause to include all workers on the work site. It also clarifies employer responsibility to provide the necessary safety equipment to their workers, such as personal protective equipment (PPE). The bill also directs DOL to revise regulations for site-controlling employers to keep a site log for all recordable injuries and illnesses among all employees on the work site.

White House Threatens Veto Of House Energy And Water Appropriations Bill: On May 1, 2015, the House passed its 2016 appropriations bill for energy and water development and related agencies, clearing the $35.4 billion appropriations package by a vote of 240-177. The White House, however, on April 28, 2015, issued a Statement of Administration Policy promising to veto the bill. The bill (H.R. 2028) would fund fiscal year 2016 operations for the Department of Energy, the Corps, and other agencies and would increase overall spending by $1.2 billion over fiscal year 2015 enacted levels. What has garnered the White House's wrath, however, is the fact that the bill is a whopping $633 million short of President Obama's budget request, and it would boost spending for nuclear and fossil fuel research and development while cutting funding for clean energy programs. "The bill drastically underfunds critical investments that develop American energy sources to build a clean and secure energy future; develop and commercialize the emerging technologies that create high-quality jobs and enhance the Nation's economic competitiveness," the White House wrote in the Statement of Administration Policy.

Bipartisan Truth In Settlements Act Introduced In Senate: Senators Elizabeth Warren (D-MA) and James Lankford (R-OK) on April 28, 2015, introduced bipartisan legislation to increase transparency around major settlements reached by federal enforcement agencies. When federal agencies close investigations and settle cases, they often tout the dollar amount obtained from the offender, but in many cases that amount is misleading because of tax deductions and other "credits" built into the settlement that reduce the settlement's true value, stated the Senators. The Truth in Settlements Act (S. 1109) will require more accessible and detailed disclosures about these agreements to allow the public to hold regulators accountable for the true value of these

deals. Under the bill, federal agencies will be required to post basic information about major settlements and provide copies of those agreements on their websites. Any written public statement that an agency issues about the value of a major settlement must include an explanation of how those settlement payments are categorized for tax purposes and whether payments may be offset by "credits" for particular conduct. Companies that settle with federal agencies will be required to disclose in their Securities and Exchange Commission (SEC) filings whether they have deducted any or all of the dollar amounts of their settlements from their taxes. To address concerns about confidentiality, the bill also requires agencies to explain publicly why confidentiality is justified in any particular instance. The Act also directs agencies to disclose basic information about the number of settlements they deem confidential each year and directs GAO to conduct a study of confidentiality procedures and to provide additional recommendations for increasing transparency. These and other provisions of the Truth in Settlements Act will increase the transparency of government settlements and permit greater public scrutiny.

House Bill Would Fund PHMSA At $227M For Fiscal Year 2016: Legislation introduced in the House would fund the fiscal year 2016 operations of PHMSA at $227 million. The funding falls short of President Obama's request by about $62 million. The bill would fund PHMSA's hazardous materials safety program at $60.5 million, less than the $64 million the White House requested, and fund the pipeline safety program at $145.9 million, significantly less than the President's requested $175 million.

Lawmakers Introduce Bills To Improve Safety Of Hazmat Rail Transport: On April 28, 2015, Senator Bob Menendez (D-NJ) and Representative Donald Norcross (D-NJ) introduced the Toxics by Rail Accountability and Community Knowledge (TRACK) Act in the Senate and House. The legislation is aimed at improving the transportation of hazardous materials by rail by implementing a series of recommendations made by the NTSB. The TRACK Act would:

- Enhance penalties for railroads that violate safety standards;
- Require up-to-date, accurate, and standardized hazardous materials information to better support first responders and emergency management officials;
- Establish new safety procedures and qualifications to improve moveable bridge crossing safety;
- Improve risk assessment and decision-making tools for railroads to ensure that safety is always the top priority; and

- Enhance public education along rail routes that carry hazardous materials to ensure communities are prepared to respond in the event of an emergency.

On April 29, 2015, just a day before DOT issued its final rule on crude oil rail transport, Senators Ron Wyden (D-OR), Chuck Schumer (D-NY), Dianne Feinstein (D-CA), Bob Casey (D-PA), Jeff Merkley (D-OR), Sherrod Brown (D-OH), and Mark Warner (D-VA) introduced the Hazardous Materials Rail Transportation Safety Improvement Act of 2015. The bill establishes a fee on DOT-111 tank cars used to transport crude oil, ethanol, or other flammable liquids. The per-car fee starts at $175 per shipment and increases annually. Funds from the fee would be used to reduce risks to communities by training first responders, hiring state railroad inspectors, and relocating tracks that carry large volumes of flammable liquids or gases. The legislation would also require the implementation of outstanding NTSB recommendations requiring railroads to establish education programs for communities along hazardous materials routes; improve information made available to emergency workers responding to railroad accidents involving hazardous materials, and strengthen track inspection standards. It would require the Energy Information Administration to publish data regarding railroad shipments of flammable energy products, including crude oil, ethanol, and liquefied natural gas. DOT would also be required to conduct a study examining national, regional, and local first responder preparedness for railroad accidents involving large volumes of flammable liquids and to study whether longer freight trains pose greater risks to health and safety.

***House Bill Would Gut EPA Programs*:** Representative Sam Johnson (R-TX) on April 29, 2015, introduced a draconian bill that would terminate federal funding for 13 "wasteful" EPA programs. The Wasteful EPA Programs Elimination Act of 2015 (H.R. 2111) would also close EPA regional offices and require EPA to lease or sell all underutilized properties. The Heritage Foundation estimates this bill would save taxpayers more than $7.5 billion over ten years. The bill would terminate all EPA grant programs (and also prohibit EPA from establishing or implementing any new grant programs), the National Clean Diesel Campaign, and environmental justice programs. It would also eliminate federal funding for the Greenhouse Gas Reporting Program, the Climate Resilience Fund, the Climate Resilience Evaluation Awareness Tool, the Green Infrastructure Program, the Climate Ready Water Utilities Initiative, regulating greenhouse gas emissions from vehicles, regulating greenhouse gas emissions from fossil fuel-fired power plants, and climate research at EPA's Office of Research and Development. Even in a Republican controlled Congress, the bill is unlikely to advance. Even if it did, President Obama would be certain to veto it. The significance in the bill, however, is that it reflects the deep-seated animosity towards EPA held by many GOP lawmakers.

Senate EPW Subcommittee Holds Hearing On Legal Implications Of Clean Power Plan: On May 5, 2016, the Senate EPW Subcommittee on Clean Air and Nuclear Safety held a hearing to examine the legal implications of EPA's proposed Clean Power Plan. Testifying at the hearing were Oklahoma Attorney General (AG) E. Scott Pruitt; West Virginia AG Patrick Morrisey;

Kelly Speakes-Backman, Maryland Public Service Commission Commissioner; Roger R. Martella, Jr., Sidley Austin LLP; and Lisa Heinzerling, Georgetown University Law Center. An archived webcast of the hearing, along with witness testimonies and Committee member statements are posted online. Senate EPW Committee Chair James Inhofe (R-OK) set a tone for the hearing that was dubious of EPA's legal grounding for the Clean Power Plan. He stated that the proposal "is another attempt by the Obama Administration to circumvent the role of Congress and achieve through regulatory fiat what the President could not achieve through legislation." He noted that the President's own constitutional law professor, Lawrence Tribe, recently testified before the House Energy and Commerce Committee that EPA was attempting an "unconstitutional trifecta usurping the prerogatives of the States, Congress and the Federal Courts -- all at once." Inhofe claims that "EPA, an agency of unelected bureaucrats, expects the States to cede authority over its intra-state energy systems, so that the EPA can then tell its citizens what type and how much energy they can use." He concluded that "this proposal is legally unsound, and comes with a $479 billion compliance costs, will result in double digit electricity price increases in 43 states and have negligible environmental benefits -- environmental benefits the EPA did not even bother to measure and will be rendered pointless by one month of carbon emissions in China." Subcommittee Chair Shelly Capito (R-WV) echoed Inhofe's disdain for the rule, claiming that "we have EPA dictating to states and effectively micromanaging intrastate electricity policy decisions to a degree even the agency admits is unprecedented. This raises a broad array of legal issues and is, quite simply, bad policy." Oklahoma AG Pruitt joined this refrain, arguing that "Quite simply . . . EPA does not possess the authority under the Clean Air Act to do what it is seeking to accomplish in the so-called Clean Power Plan. The EPA, under this administration, treats states like a vessel of federal will. The EPA believes the states exist to implement the policies the Administration sees fit, regardless of whether laws like the Clean Air Act permit such action." West Virginia AG Morrissey solemnly declared that "[i]t is my duty as the chief legal officer for the State of West Virginia to fight against this unlawful power grab, which is harming our citizens." He predicted that "[g]iven the entirely unprecedented and unlawful nature of the Section 111(d) Rule, the States and other interested parties will have no shortage of legal defects to bring to the D.C. Circuit." Roger Martella summarized his testimony by predicting that the rule "ultimately is unlikely to survive judicial review in its full form, but, importantly, in the interim states and the regulated community will confront significant irreparable harm while judicial review proceeds over the next several years."

MISCELLANEOUS

EPA Seeks Public Comments On Draft EJ 2020 Action Agenda Framework: On April 16, 2015, EPA released its draft *Environmental Justice 2020 Action Agenda* (EJ 2020) framework. The document serves as EPA's overarching strategic plan for environmental justice. EPA describes EJ 2020 as a strategy to advance environmental justice through EPA's programs, policies, and activities, and that it will support the cross-agency strategy on making a visible difference in environmentally overburdened, underserved, and economically-distressed

communities. The goals of EJ 2020 are to deepen environmental justice practice within EPA programs to improve the health and environment of overburdened communities; collaborate with partners to expand our impact within communities; and demonstrate progress on outcomes that matter to communities. During the public comment period for EJ 2020, EPA will conduct informational and dialogue sessions with partners and stakeholder groups. A schedule of these sessions is posted online. EPA defines environmental justice as the fair treatment and meaningful involvement of all people, regardless of race or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA's goal is to provide an environment where all people enjoy equal access to the environmental decision-making process to maintain a healthy environment in which to live, learn, and work. EPA's environmental justice work is an outgrowth of Executive Order 12898, signed by President Clinton in 1994, that requires federal agencies to address the disproportionately high and adverse human health or environmental effects of their programs on minority and low-income populations. The EJ 2020 framework is available online. EPA is accepting comment on the draft framework until **June 15, 2015**.

EPA Releases 2015 Update To 1998 Supplemental Environmental Projects Policy: On March 23, 2015, EPA released an update to its Supplemental Environmental Projects (SEP) Policy. A SEP is an environmentally beneficial project related to a violation that can be undertaken in exchange for mitigation of a penalty. The 2015 Updated SEP Policy revises and supersedes the February 1991 Policy on the Use of SEPs in EPA Settlements, the May 1995 Interim Revised SEP Policy, and the May 1998 EPA SEP Policy. It also reflects and incorporates by reference all the policy and guidance documents listed on the site. The update is available at http://www2.epa.gov/enforcement/supplemental-environmental-projects-seps.

Chemical Safety Board To Hold Two Public Meetings In June; Proposes Changes To Board Procedures: The U.S. Chemical Safety Board (CSB) will host two public meetings in **June 2015** to increase dialogue with CSB stakeholders. The first meeting will bring together stakeholders on **June 10** to focus on what emerging safety issues CSB should be looking at in its strategic plan and how CSB can improve its investigations and recommendations. The second meeting will be held on **June 18** and is slated to be a CSB business meeting that will be open to the public. CSB on May 13, 2015, also issued a proposed rule that it states "will promote increased transparency and accountability" for CSB activities. 80 Fed. Reg. 27276. The proposed rule would alter the manner in which some CSB votes are held. It also would require the CSB to schedule at least four public meetings in Washington, D.C., each year. It will permit CSB members to add items for discussion to the agendas of such CSB public meetings. CSB is taking comments on the proposed rule until **June 12, 2015**.