Recent Federal Developments
October 15, 2015

On October 15, 2015, Bergeson & Campbell, P.C. (B&C®) and the Woodrow Wilson International Center for Scholars (Wilson Center) issued a report, "The DNA of the U.S. Regulatory System: Are We Getting It Right For Synthetic Biology?," authored by the legal experts, scientists, and policy specialists of B&C and released through the Wilson Center's Synthetic Biology Project.

A panel discussion and live webcast, "Leveraging Synthetic Biology's Promise and Managing Potential Risk," was held to launch the report, featuring Lynn L. Bergeson, Sheryl Lindros Dolan, and Richard E. Engler, Ph.D., of B&C., and Todd Kuiken, Ph.D., Senior Program Associate, Synthetic Biology Project, Wilson Center. The webcast was recorded and will be made available on the Wilson Center's website. Panelists discussed how synthetic biology applications would be regulated by the U.S. *Coordinated Framework for Regulation of Biotechnology*, how this would affect the market pathway of these applications, and whether the existing framework will protect human health and the environment.

"The DNA of the U.S. Regulatory System: Are We Getting It Right For Synthetic Biology?," includes a survey of the current commercial applications of synthetic biology, analysis of issues facing U.S. regulatory systems and agencies called into play by products of synthetic biology, case studies illustrative of how novel technologies challenge the regulatory infrastructure and can induce competing and sometimes conflicting jurisdictional oversight, and a review of recommendations for improvement, including those contained in the July 2, 2015, memorandum issued by the White House Office of Science and Technology Policy directing the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to update the 1986 *Coordinated Framework for Regulation of Biotechnology*.

B&C and affiliated consulting firm, The Acta Group (Acta®), have been at the forefront of addressing legal, regulatory, and policy implications of synthetic biology and other emerging transformative technologies worldwide. Additional resources include *Lynn L. Bergeson, Charles M. Auer, Oscar Hernandez*, "Creative Adaptation: Enhancing Oversight of Synthetic Biology Under the Toxic Substances Control Act," *Industrial Biotechnology*, October 2014; Biotechnology and Synthetic Biology Memoranda from the B&C website; and Biotechnology and Synthetic Biology Articles from the B&C website.

TSCA/FIFRA/IRIS/NTP/TRI

EPA Releases Final SNUR For HBCD: On September 23, 2015, EPA issued a final significant new use rule (SNUR) for hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane. 80 Fed. Reg. 57293. Under the final rule, persons who intend to manufacture (including import) or process HBCD for use in consumer textiles (other than for use in motor vehicles) must notify

EPA at least 90 days before commencing that activity. EPA notes that in this SNUR, the exemption for persons importing or processing a chemical substance as part of an article does not apply to importers and processors of HBCD as part of a textile article (*e.g.*, as part of a bolt of cloth or part of an upholstered chair). The rule designates use of HBCD in consumer textiles (other than for use in motor vehicles) as a significant new use. EPA states that it concluded that the only current use of HBCD for consumer textiles is in motor vehicles. The SNUR does not cover that use or other current uses of HBCD (*e.g.*, in nonconsumer textiles and in building insulation), "not because EPA has determined that these uses are not 'significant,' but because they are ongoing and thus not 'new uses.'" For more information, *see* B&C's memorandum entitled "TSCA: EPA Releases Final SNUR for HBCD, and EPA's SNUR Reach Over Imported Article Continues." The final rule will be effective **November 23, 2015**.

OSTP Seeks Comment On The Coordinated Framework For The Regulation Of Biotechnology: On October 6, 2015, the White House Office of Science and Technology Policy (OSTP) issued a Request for Information (RFI) to solicit relevant data and information, including case studies, that can assist in the development of the proposed update to the Coordinated Framework for the Regulation of Biotechnology (CF) to clarify the current roles and responsibilities of EPA, FDA, and USDA and the development of a long-term strategy consistent with the objectives described in a July 2, 2015, Executive Office of the President (EOP) memorandum. 80 Fed. Reg. 60414. In addition to this RFI, the update to the CF will undergo public comment before it is issued in final. Comments on the RFI are due **November 13, 2015, at 5:00 p.m. (EST)**. More information is available in B&C's memorandum entitled "Biotechnology: OSTP Seeks Comment on Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology."

EPA Issues Direct Final SNURs For 30 Chemical Substances: On October 2, 2015, EPA issued a direct final rule authorizing SNURs for 30 chemical substances. 80 Fed. Reg. 59593. Nine of the 30 substances are subject to TSCA Section 5(e) consent orders. The rule is effective on **December 1, 2015,** unless adverse comment is submitted by **November 2, 2015**. If so, EPA will withdraw that portion of the direct final rule and propose it as a proposed rule.

EPA Denies TSCA Section 21 Petitions: On October 7, 2015, EPA denied two Toxic Substances Control Act (TSCA) Section 21 petitions. The first was from the Center for Biological Diversity and Donn J. Viviani, Ph.D. The petitioners requested EPA to initiate rulemaking under TSCA to address risks related to carbon dioxide emissions, particularly those associated with ocean acidification, or, in the alternative, that EPA initiate rulemaking under TSCA to require testing to determine toxicity, persistence, and other characteristics of carbon dioxide emissions that affect human health and the environment. 80 Fed. Reg. 60577. After consideration, EPA denied the TSCA Section 21 petition. The second was from the Natural Resources Defense Council (NRDC) and the Northeast Waste Management Officials' Association (NEWMOA) on June 24, 2015. 80 Fed. Reg. 60584. The petitioners requested EPA to "promulgate a TSCA section 8(a) rule that requires persons who manufacture, process, or

import into the United States mercury, mercury compounds, or mercury-added products to keep records of and submit information to EPA concerning such manufacture, processing, or importation of mercury." After consideration, EPA denied the TSCA Section 21 petition.

EPA Revises FIFRA Farm Worker Protection Standards: Accompanied by much social media fanfare, EPA on September 28, 2015, announced revisions to the farm Worker Protection Standards (WPS) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Codified at 40 C.F.R. Part 170, EPA has not revised the WPS since 1992. The revisions are intended to reduce occupational pesticide exposure and incidents of related illness among agricultural workers and pesticide handlers, and to protect bystanders and others from exposure to agricultural pesticide use. The rule specifically seeks to protect and reduce the risks of injury or illness resulting from those who perform hand-labor tasks in pesticide-treated crops, such as harvesting, thinning, pruning, and those who mix, load, and apply pesticides on farms, forests, nurseries, and greenhouses. The rule requires employers to ensure that workers and handlers receive pesticide safety training every year on the required protections. Currently, training is only once every five years. Employers are required to retain records of the training for two years. The final rule also eliminates the grace period that allowed employers to delay providing full pesticide safety training to workers (for up to five days under the existing rule and for up to two days under the proposal) from the time worker activities began, if the workers received an abbreviated training prior to entering any treated area. The rule also includes a first-time ever minimum age requirement: children under 18 years of age are prohibited from handling pesticides. Employers must also post warning signs around treated areas in outdoor production when the product used has a restricted-entry interval (REI) greater than 48 hours and provide to workers performing early-entry tasks, *i.e.*, entering a treated area when an REI is in effect, information about the pesticide used in the area where they will work, the specific task(s) to be performed, the personal protective equipment (PPE) required by the labeling, and the amount of time the worker may remain in the treated area. The final rule requires employers to post pesticide application information and a safety data sheet (SDS) for each pesticide used on the establishment at a central location, a departure from the proposal to eliminate the existing requirement for a central display of pesticide application-specific information. The final rule also requires the employer to maintain and make available to workers and handlers, their designated representatives, and treating medical personnel, upon request, the pesticide application-specific information and the SDSs for pesticides used on the establishment for two years. The final rule designates the area immediately surrounding the application equipment as the area from which workers and other persons must be excluded. This "application exclusion zone" differs from the proposed "entry-restricted areas," which would have extended a specified distance around the entire treated area during application based on the application equipment used. The final rule requires handlers to suspend application, rather than cease application, if they are aware of any person in the application exclusion zone other than a properly trained and equipped handler involved in the application. To enhance worker protection, the final rule cross-references Occupational Safety and Health Administration (OSHA) requirements for respirator use that employers will be required to comply with, including fit test, medical evaluation, and

training for handlers using pesticides that require respirator use. The final rule maintains the existing exception from the handler PPE requirements when using a closed system to transfer or load pesticides, and adopts a general performance standard for closed systems. The rule should be published in the *Federal Register* within the next two months. A pre-publication version of the rule and associated information are available online.

EPA Denies EPCRA EGBE Petition: On October 8, 2015, EPA denied a petition to remove ethylene glycol monobutyl ether (EGBE) from the category Certain Glycol Ethers under the list of chemicals subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). 80 Fed. Reg. 60818. EPA reviewed the available data on this chemical and determined that EGBE does not meet the deletion criterion of EPCRA Section 313(d)(3). EPA denied the petition because EPA's review of the petition and available information resulted in the conclusion that EGBE meets the listing criterion of EPCRA Section 313(d)(2)(B) due to its potential to cause serious or irreversible chronic health effects in humans, specifically, liver toxicity and concerns for hematological effects. The Petition was submitted by the American Chemistry Council's Ethylene Glycol Ethers Panel.

NTP Seeks Responses To Office Of The Report On Carcinogens And Office Of Health Assessment And Translation Request For Information: On October 7, 2015, the National Toxicology Program (NTP) Office of the Report on Carcinogens (ORoC) and Office of Health Assessment and Translation (OHAT) requested information on nine substances, mixtures, and exposure circumstances. 80 Fed. Reg. 60692. Six substances are nominated for possible review for future editions of the Report on Carcinogens (RoC). Three substances are being considered by OHAT for evaluation of non-cancer health outcomes. The six substances nominated for possible review for the RoC are: flame retardants (pentabromodiphenyl ether mixture (DE-71); tetrabromobisphenol A, CASRN 79-94-7), water disinfection byproducts (dibromoacetonitrile, CASRN 3252-43-5; di- and tri-haloacetic acids (as a class), specifically, those haloacetic acids with similar functional or structural properties that may cause similar health hazards); and others (fluoride, CASRN 7681-49-4; vinylidene chloride, CASRN 5-35-4). The three substances being considered for OHAT evaluation of non-cancer health outcomes are: mountaintop removal mining (health impacts on surrounding communities); neonicotinoid pesticides; and fluoride (developmental neurotoxicity and endocrine disruption).

NTP requests information on each substance regarding: (1) data on current production, use patterns, and human exposure; (2) published, ongoing, or planned studies related to evaluating adverse health outcomes (*e.g.*, cancer, development, reproductive, or immunological disorders); (3) scientific issues important for prioritizing and assessing adverse health outcomes; and (4) names of scientists with expertise or knowledge about the substance -- please include any bibliographic citations when available. NTP will use this information in determining which substances to propose for formal health hazard evaluations. Information is due by **November 6, 2015**.

EPA Issues Revised PRIA Fee Schedule: On September 22, 2015, EPA released its revised fees schedule for products registered under FIFRA. 80 Fed. Reg. 57166. The Pesticide Registration Improvement Act of 2003 (PRIA) established FIFRA Section 33, creating a registration fee-for-service system for certain types of pesticide applications, establishment of tolerances, and certain other regulatory decisions under FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 33 also created a schedule of decision review times for applications covered by the service fee system. EPA began administering the registration service fee system for covered applications received on or after March 23, 2004. PRIA has been reauthorized twice, most recently by the Pesticide Registration Improvement Extension Act (PRIA 3) signed on September 28, 2012. PRIA 3 revised FIFRA Section 33, reauthorized the service fee system through fiscal year (FY) **2017**, and established fees and review times for applications received during FYs 2013 through **2017**. The registration fees for covered pesticide registration applications received on or after October 1, 2015**,** increase by five percent from the fees published for FY 2015 in the *Federal Register* notice issued September 26, 2013, Pesticides; Revised Fee Schedule for Registration Applications. The notice retains the format of prior PRIA tables; it identifies the registration service fees and decision times and is organized according to the three Office of Pesticide Programs (OPP) registration divisions within EPA, with the additional sections for inert ingredients and other actions added as part of PRIA 3. Thereafter, the categories within main sections of the table are further organized according to the type of application being submitted, including new active ingredients, new uses, new products, and registration amendments. There are 189 categories of activities spread across the three OPP divisions: Registration Division (63 categories), Antimicrobials Division (39 categories), and Biopesticides and Pollution Prevention Division (69 categories), plus ten inert ingredient and eight miscellaneous categories. Each has its own decision review time and service fee for FYs **2016-2017**. The scale of the fees differs between the three registration divisions. We note that not all submissions are subject to PRIA 3; generally speaking, any submission requiring data review will be subject to PRIA 3. The notice also provides information on how to pay fees, how to submit applications, and the addresses for applications. More information on the registration fees is available on EPA's webpage FY **2016/17** Fee Schedule for Registration Applications. The new fees became effective on October 1, 2015.

EPA Launches New Pesticides Website: On October 7, 2015, EPA announced that it launched a new pesticides website: http://www2.epa.gov/pesticides, and a new biopesticides website: http://www2.epa.gov/pesticides/biopesticides, among others. EPA states that this gradual move to new versions of its content is part of a larger EPA effort to build a more user-friendly website. The updated biopesticides website focuses on providing general information on biopesticides, as well as tools to assist applicants for registration, and is organized into the following areas: what are biopesticides?; biopesticide registration information; plant incorporated protectants (PIP); and where can I find more information on biopesticides? With this transition, web page addresses will be different, which may cause links and bookmarks to break. EPA states that it is working to fix any broken links. The majority of the old pesticide pages will redirect to the new web areas, but bookmarks will still need to be updated. EPA's new "Page Not Found"

notification will help website users find what they are looking for by providing suggested search terms, links to the A-Z index, and other helpful links. The search feature available on every EPA web page and in the archive (archive.epa.gov) can also be useful in finding content. Other updated pesticide related links are:

- Pesticide Registration: http://www2.epa.gov/pesticide-registration;
- Bed Bugs: http://www2.epa.gov/bedbugs;
- Occupational Pesticide Safety and Health: http://www2.epa.gov/pesticide-worker-safety;
- Protecting Bees and Other Pollinators from Pesticides: http://www2.epa.gov/pollinator-protection;
- Protecting Endangered Species from Pesticides: http://www2.epa.gov/endangered-species;
- Reporting Unintended Exposure and Harm from Pesticides: http://www2.epa.gov/pesticide-incidents;
- Pesticide Labels: http://www2.epa.gov/pesticide-labels;
- Managing Pests in Schools: http://www2.epa.gov/managing-pests-schools; and
- Pest Control and Pesticide Safety for Consumers: http://www2.epa.gov/safepestcontrol.

FDA

FDA Announces Public Comment Period On Menu Labeling: On September 16, 2015, FDA's Center for Food Safety and Applied Nutrition (CFSAN) announced the public comment period for draft guidance for industry on the Menu Labeling rule entitled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods -- Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11); Draft Guidance for Industry." 80 Fed. Reg. 55564. The draft guidance is intended to provide industry with the nutritional labeling requirements of the recently published final rule (79 Fed. Reg. 71156). The comment period is open until **November 2, 2015**.

FDA Announces Seven New Medical Device Educational Modules: On September 16, 2015, FDA's Center for Devices and Radiological Health (CDRH) announced that it posted seven new modules to the CDRH Learn Program website. The modules are intended to provide additional insight into the program basics, resources, and feedback processes of the CDRH. With the addition of these seven new modules, there are currently over 80 modules on the program site. For more details, *see* CDRH Learn.

FDA Public Meeting On FSMA Final Rules: On September 22, 2015, FDA's CFSAN announced a public meeting to discuss the recently issued final rules for the Preventive Controls for Human Food and Preventive Controls for Animal Food. 80 Fed. Reg. 57136. The preventive rules are part of the Food Safety Modernization Act (FSMA). The public meeting will take place in Chicago on **October 20, 2015**. The final preventive rules are to begin in **September 2016**. For more details, *see* online.

FDA FY 2016 User Fees: FDA's CDRH recently posted the Fiscal Year 2016 User Fees for Medical Devices. The fees are applicable from October 1, 2015 - September 30, 2016. For more details, *see* online.

RCRA/CERCLA

EPA Proposes Changes To RCRA Hazardous Waste Export And Import Regulations: Prompted by a 2013 Commission for Environmental Cooperation (CEC) report on hazardous waste exports from the U.S. and changes to the 2001 Organization for Economic Cooperation and Development's (OECD) Council Decision for waste exports and imports, on September 24, 2015, EPA announced proposed changes to 40 C.F.R. Parts 260-267, 271, and 273 regarding the export and import of hazardous wastes from and into the United States. EPA also issued the changes to address and respond to several of the concerns outlined in the EPA Office of the Inspector General's (OIG) July 6, 2015, report entitled "EPA Does Not Effectively Control or Monitor Imports of Hazardous Waste." One of the more significant changes EPA proposes is to require shipments of spent lead-acid batteries (SLAB) exported for reclamation be accompanied by international shipping documents, akin to hazardous wastes manifests. Currently there is no requirement that SLAB exports be covered by such documents. EPA's determination that some revisions to the SLAB import/export regulations are needed is bolstered by a 2013 CEC report and its recommendations. The CEC report found that U.S. net exports of SLABs to Mexico for recycling had increased by an estimated 449-525 percent, and that there were significant discrepancies between summary data on export shipments reported to EPA annually and individual export shipment data collected under U.S. Census Bureau (Census) authority. Based on its findings, the CEC report recommended that the U.S. require the use of manifests for each international shipment of SLABs, require exporters to obtain a certificate of recovery from foreign recycling facilities, explore establishing an electronic export annual report, and better share import and export data between environmental and border agencies. EPA proposes to incorporate most of these recommendations into the revised regulations. The rule would also

consolidate the hazardous waste import and export standards into one set of requirements: 40 C.F.R. Part 262 Subpart H. The rule also proposes mandatory electronic reporting to EPA. The rule also would link the consent to export with the exporter declaration submitted to U.S. Customs and Border Protection (CBP), which should provide for more efficient compliance monitoring. In addition, EPA seeks to ensure clearer matching of waste stream level consent numbers with waste streams listed on Resource Conservation and Recovery Act (RCRA) hazardous waste manifests for import and export shipments. EPA is also proposing to require the filing of export consent information as part of the exporter's electronic declaration to CBP.

A pre-publication version of the proposed rule is available at http://www2.epa.gov/hwgenerators/pre-publication-version-hazardous-waste-export-import-revisions-proposed-rule. Comments will be due 60 days after the proposed rule is published in the *Federal Register*.

CAA/CWA/SDWA

EPA Lowers Ozone NAAQS: EPA on October 1, 2015, lowered the National Ambient Air Quality Standard (NAAQS) for ground-level ozone to 70 parts per billion (ppb). EPA states that the rule is based on extensive scientific evidence about ozone's effects on public health and welfare. EPA claims that the updated standards will improve public health protection, particularly for at-risk groups, including children, older adults, people of all ages who have lung diseases such as asthma, and people who are active outdoors, especially outdoor workers. They also will improve the health of trees, plants, and ecosystems. Critics of the rule argue that it will result in severe economic harm. EPA countered that the public health benefits of the updated standards are significant -- estimated at $2.9 to $5.9 billion annually in **2025** and outweighing estimated costs of $1.4 billion. EPA projections show the vast majority of U.S. counties will meet the standards by **2025** with federal and state rules and programs now in place or underway. A pre-publication version of the final rule and a fact sheet are available at http://www3.epa.gov/airquality/ozonepollution/actions.html#current. The rule will become effective 60 days after publication in the *Federal Register*.

EPA Issues Final NPDES Reporting Rule: On September 24, 2015, EPA Administrator Gina McCarthy signed the final National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule. EPA states that the rule is the latest step in an extensive multi-year outreach effort with EPA's state, tribal, and territorial partners. This rule will replace most paper-based Clean Water Act (CWA) NPDES permitting and compliance monitoring reporting requirements with electronic reporting. The rule requires that NPDES-regulated entities electronically submit the following permit and compliance monitoring information instead of using paper reports:

- Discharge Monitoring Reports (DMR);
- Notices of Intent to discharge in compliance with a general permit; and
- Program reports.

Authorized NPDES programs will also electronically submit NPDES program data to EPA to ensure that there is consistent and complete reporting nationwide, and to expedite the collection and processing of the data, thereby making it more accurate and timely. The final rule will clearly make facility-specific information, such as inspection and enforcement history, pollutant monitoring results, and other data required by NPDES permits accessible to the public through EPA's website. Importantly, while the rule changes the method by which information is provided, it does not increase the amount of information required from NPDES-regulated entities under existing regulations. EPA estimates that, once the rule is fully implemented, the 46 states and the Virgin Islands Territory that are authorized to administer the NPDES program will collectively save approximately $22.6 million each year as a result of switching from paper to electronic reporting. A pre-publication version of the final rule and a fact sheet are available at http://www2.epa.gov/compliance/final-national-pollutant-discharge-elimination-system-npdes-electronic-reporting-rule. The rule will become effective 60 days after publication in the *Federal Register*.

EPA Revises Effluent Limitation Guidelines For Discharges For Steam Electric Power Plants: EPA on September 30, 2015, issued a final CWA rule that revises the effluent limitation guidelines (ELG) for discharges from steam electric power plants. EPA claims the rule will reduce discharges of toxic metals by 1.4 billion pounds annually, as well as reduce water withdrawal by 57 billion gallons per year, resulting in an estimated benefit of $463 million per year. The final rule establishes new requirements for wastewater streams from the following processes and byproducts associated with steam electric power generation: flue gas desulfurization, fly ash, bottom ash, flue gas mercury control, and gasification of fuels such as coal and petroleum coke. The final rule phases in the new, more stringent requirements in the form of effluent limits for arsenic, mercury, selenium, and nitrogen for wastewater discharged from wet scrubber systems and zero discharge of pollutants in ash transport water. These stringent new limits must be incorporated into the plants' NPDES permits. The rule encourages plants to commit to meeting even more stringent limits for pollutants in the flue gas desulfurization wastewater, plus a limit on total dissolved solids, based on evaporation technology, by giving them until the end of **2023** to meet the more stringent limits. The rule also establishes zero discharge pollutant limits for flue gas mercury control wastewater, and stringent limits on arsenic, mercury, selenium, and total dissolved solids in coal gasification wastewater, based on evaporation technology. The rule also includes even more stringent controls for any new coal or petroleum coke plants that may be built in the future. Each plant must comply between **2018 and 2023** depending on when it needs a new CWA permit. A pre-publication version of the final rule and a fact sheet are available at http://www2.epa.gov/eg/steam-electric-power-generating-effluent-guidelines-2015-final-rule. The rule will become effective 60 days after publication in the *Federal Register*.

NANOTECHNOLOGY

OECD Posts Preliminary Guidance Notes On Nanomaterials Concerning Interspecies Variability Factors In Human Health Risk Assessment: OECD posted a new publication in its Series on the Safety of Manufactured Nanomaterials, *Preliminary Guidance Notes on Nanomaterials: Interspecies Variability Factors in Human Health Risk Assessment*. The report includes the following recommendations for further work:

- The Expert Opinion prepared in support of the project noted a general lack of availability of data from repeated-dose toxicity studies in different species. In particular, studies of extended duration such as 90-day subchronic or chronic toxicity studies were only available for a minor part of the analyzed nanomaterials and routes of exposures. The majority of the compiled studies did not determine a no-observed-adverse-effect level (NOAEL) or a lowest-observed-adverse-effect level (LOAEL), and only few studies determined both. Further testing should be considered on a set of representative materials, with identical materials tested under comparable exposure conditions for various exposure times in different species; and

- Physiologically-based models are receiving increased attention in human health risk assessment. With the available data on lung burden following inhalation exposure to nanomaterials, a useful comparison of measured vs. predicted data has been possible in this project for rats, suggesting that further refinement of the multiple path particle dosimetry (MPPD) model is required before it can be applied to (sub)chronic scenarios. Unfortunately, corresponding information has not been available for humans, preventing comparisons between rats and humans.

NNI Announces Nanotechnology Signature Initiative Webinar Series, Opens Registration For Introduction To Nanoinformatics: The National Nanotechnology Coordination Office will host a series of webinars from **October to December 2015** sponsored by federal agencies participating in the Nanotechnology Knowledge Infrastructure and Nanotechnology for Sensors and Sensors for Nanotechnology Signature Initiatives. The webinar series will include an introduction to nanoinformatics, an overview of nanosensor technology and applications, a regulatory case study for the development of nanosensors, and an overview of nanoinformatics applications. The National Nanotechnology Initiative (NNI) encourages members of the nanotechnology business community, industry, non-governmental organizations, academia, and federal, state, and local governments to participate. Webinar viewers will be able to submit questions during each webinar for the panelists to answer during the question and answer period. The webinar "Introduction to Nanoinformatics" was held October 2, 2015. The webinars are

free and open to the public. Registration is on a first-come, first-served basis and will be limited to 200 people.

NSF Will Provide $81 Million To Support New NNCI: NNI announced on September 17, 2015, that the National Science Foundation (NSF) will provide a total of $81 million over five years to support 16 sites and a coordinating office as part of a new National Nanotechnology Coordinated Infrastructure (NNCI). The awards are for up to five years and range from $500,000 to $1.6 million each per year. Nine of the sites have at least one regional partner institution. The 16 sites are located in 15 states and involve 27 universities. The NNCI sites are intended to provide researchers from academia, government, and companies with access to university user facilities with leading-edge fabrication and characterization tools, instrumentation, and expertise within all disciplines of nanoscale science, engineering and technology. One of the newly awarded sites will be chosen to coordinate the facilities, including establishing a web portal to link the individual facilities' websites to provide a unified entry point to the user community of overall capabilities, tools, and instrumentation. The new NNCI awards include:

- Mid-Atlantic Nanotechnology Hub for Research, Education and Innovation, University of Pennsylvania with partner Community College of Philadelphia, principal investigator (PI): Mark Allen;
- Texas Nanofabrication Facility, University of Texas at Austin, PI: Sanjay Banerjee;
- Northwest Nanotechnology Infrastructure, University of Washington with partner Oregon State University, PI: Karl Bohringer;
- Southeastern Nanotechnology Infrastructure Corridor, Georgia Institute of Technology with partners North Carolina A&T State University and University of North Carolina-Greensboro, PI: Oliver Brand;
- Midwest Nano Infrastructure Corridor, University of Minnesota Twin Cities with partner North Dakota State University, PI: Stephen Campbell;
- Montana Nanotechnology Facility, Montana State University with partner Carlton College, PI: David Dickensheets;
- Soft and Hybrid Nanotechnology Experimental Resource, Northwestern University with partner University of Chicago, PI: Vinayak Dravid;

- The Virginia Tech National Center for Earth and Environmental Nanotechnology Infrastructure, Virginia Polytechnic Institute and State University, PI: Michael Hochella;

- North Carolina Research Triangle Nanotechnology Network, North Carolina State University with partners Duke University and University of North Carolina-Chapel Hill, PI: Jacob Jones;

- San Diego Nanotechnology Infrastructure, University of California, San Diego, PI: Yu-Hwa Lo;

- Stanford Site, Stanford University, PI: Kathryn Moler;

- Cornell Nanoscale Science and Technology Facility, Cornell University, PI: Daniel Ralph;

- Nebraska Nanoscale Facility, University of Nebraska-Lincoln, PI: David Sellmyer;

- Nanotechnology Collaborative Infrastructure Southwest, Arizona State University with partners Maricopa County Community College District and Science Foundation Arizona, PI: Trevor Thornton;

- The Kentucky Multi-scale Manufacturing and Nano Integration Node, University of Louisville with partner University of Kentucky, PI: Kevin Walsh; and

- The Center for Nanoscale Systems at Harvard University, Harvard University, PI: Robert Westervelt.

Registration Open For Nanosensor Technologies And Applications Webinar: NNI announced that registration is now open for an **October 16, 2015**, webinar entitled "Nanosensor Technologies and Applications." Dr. Meyya Meyyappan, Chief Scientist for Exploration Technology at the National Aeronautics and Space Administration (NASA) Ames Research Center, will lead the webinar. He will introduce basic mechanisms of nanosensing and terminologies, and will review the current status of nanosensor development and challenges for commercial applications. The webinar is supported by the Nanotechnology for Sensors and Sensors for Nanotechnology Signature Initiative. Webinar viewers will be able to submit questions during the question and answer period, as well as to webinar@nnco.nano.gov beginning a week before the date of the webinar through the end of the event.

NanoSafety Cluster Releases Closer To The Market Roadmap For Final Comments: On October 5, 2015, the European Union (EU) NanoSafety Cluster announced that the "Closer to the Market" Roadmap (CTTM) is available for final comments. The CTTM is intended to speed up the progress towards market implementation of nanotechnologies. The draft CTTM identifies key challenges to be tackled immediately and in a step-by-step approach: (1) build an inclusive collaboration network; (2) bring together scientific experts; (3) strengthen the dialog and exchange to raise synergies and safe resources; (4) implement a safety assessment framework supported by the regulatory initiatives; and (5) build service provider platforms that serve as consulting agencies assisting companies on their products' way towards market implementation. Comments are due **October 19, 2015**.

BIOBASED/RENEWABLE PRODUCTS

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

LEGISLATIVE DEVELOPMENTS

Senate Resolution Would Block WOTUS Rule: Almost half the Senate supports a September 17, 2015, joint resolution that would block implementation of EPA's Waters of the United States (WOTUS) rule. Issued jointly by EPA and the Army Corps of Engineers on June 29, 2015 (80 Fed. Reg. 37054), the rule seeks to clarify which water bodies are subject to CWA jurisdiction. Introduced by Senator Joni Ernst (R-IA), the resolution (S.J. Res. 22) has the backing of 46 Republican Senators. The resolution "disapproves" the WOTUS rule under Chapter 8, Title 5 United States Code, otherwise known as the Congressional Review Act (CRA). The CRA allows Congress to review major rules issued by federal agencies before the rules take effect. Congress may also disapprove new rules, resulting in the rules having no force or effect. *See* 5 U.S.C. § 802(a). Despite this powerful review authority, Congress has had scant success blocking rules. Since 1996, 43 resolutions have been introduced in the Senate or House of Representatives and two of those resolutions have passed one house of Congress. Only one rule, the Department of Labor rule on ergonomics, has been disapproved by Congress under the CRA. *See* Public Law 107-5. Even if the resolution passed both houses, President Obama would certainly veto it and the Senate is unlikely to garner support from Democrats to muster the 67 votes needed to overturn the veto.

Senate Passes Bill Making Federal Agency Settlements More Transparent: On September 21, 2015, the Senate passed the Truth in Settlements Act (S. 1109). Introduced by Senators Elizabeth Warren (D-MA) and James Lankford (R-OK), the bill is intended to make more transparent legal settlements reached between federal agencies and parties that sue them over

regulations. The legislation would require federal agencies to post information about settlements and make available copies of those settlements on their respective websites. Agencies would also be required to explain why any information related to the settlements that is not posted is confidential. An amendment offered by Senator David Vitter (R-LA) and approved during debate on the bill would also require federal agencies to disclose the terms of any settlement in which the government agrees to pay more than $200,000 in attorney's fees to a private party. It would also require public disclosure of the details of any settlement requiring the government to take regulatory actions and would force agencies to issue annual reports with details, including the total number of settlements requiring regulatory changes.

Bipartisan Super Pollutants Act Introduced In Senate: Senators Chris Murphy (D-CT) and Susan Collins (R-ME) on September 23, 2015, reintroduced legislation intended to curb emissions of non-carbon greenhouse gases, including hydrofluorocarbons (HCFC). The Senators initially introduced the Super Pollutants Act of 2015 in September 2014. Murphy and Collins announced the reintroduction of the bill ahead of Pope Francis' address to a joint session of Congress on September 24, 2015, where the Pope called for more meaningful action on climate change. The bill aims to reduce emissions of short-lived climate pollutants (SLCP). The Senators claim that the legislation will reduce SLCPs in the atmosphere by enabling federal agencies to work with the business and non-profit communities to speed the adoption of SLCP-reducing technologies and policies, while supporting American-led innovations. SLCPs, referred to as "super pollutants," are non-carbon dioxide greenhouse emissions responsible for an increasing share of global warming. SLCPs range from refrigerants leaking from refrigerators and air conditioners, to soot from diesel engines and cookstoves, to methane emitted by landfills and oil and gas exploration. The legislation does not vest EPA with any new authority to regulate emissions of SLCPs. Instead, it seeks to coordinate efforts that are already underway within the Obama Administration to reduce emissions of SLCPs.

House Passes RAPID Act In Face Of White House Veto Pledge: On September 25, 2015, the House of Representatives passed the Responsibly and Professionally Invigorating Development (RAPID) Act of 2015 (H.R. 348). The bill would require EPA and other federal agencies to streamline the regulatory review, environmental decision-making, and permitting process for major federal actions that are construction activities undertaken, reviewed, or funded by federal agencies. The bill would limit major infrastructure projects to one environmental impact statement and one environmental assessment to be prepared under the National Environmental Policy Act (NEPA), except for supplemental environmental documents prepared under NEPA or environmental documents prepared pursuant to a court order. After the lead agency issues a record of decision, federal agencies may only rely on the environmental document prepared by the lead agency in reviewing the project. The bill also sets forth provisions concerning requirements for initiating and completing the environmental review for a project, including for determining the range of alternatives to be considered in environmental review documents, and a schedule and deadlines for completing the review. Federal agencies would also be barred from using the social cost of carbon in the environmental review or environmental decision-making

process. Even before the bill passed the House, however, the Obama Administration issued a veto threat. On September 16, 2015, the White House issued a Statement of Administration Policy stating that the bill would "increase litigation, regulatory delays, and potentially force agencies to approve a project if the review and analysis cannot be completed before the proposed arbitrary deadlines." The statement vowed to veto the bill if it is presented to the President.

Senate Bill Seeks To Provide Relief To States And Communities Complying With Ozone NAAQS: On September 24, 2015, Senators Orrin Hatch (R-UT) and Claire McCaskill (D-MO) introduced a bill under which state, local, and tribal governments may develop Early Action Compact (EAC) plans to achieve the NAAQS for ozone. The bill (S. 2072) directs EPA to implement a program that allows local communities to enter into voluntary cooperative agreements with EPA to utilize locally crafted solutions to improve air quality so that they can comply with federal standards. As reported above, EPA on October 1, 2015, lowered the NAAQS for ground-level ozone to 70 ppb. Lowering the NAAQS is likely to put many areas of the country in non-attainment. When a particular area is designated as such, it can have significant negative economic implications. In 2002, EPA initiated a program called the EAC Program to make available an option that allowed for potential non-attainment areas to enter into a voluntary cooperative agreement with EPA to take early action to prevent a non-attainment designation and provide for cleaner air sooner than might have occurred by otherwise following the timelines in the Clean Air Act (CAA). This Program was met with great success: 13 of the 14 areas that voluntarily opted into this Program were successful in improving air quality and avoiding a non-attainment designation. The EAC Program was struck down in a lawsuit, however. This legislation would not amend the CAA but would essentially resurrect the EAC program. It would give clear authorization and direct EPA to implement a similar program to the EAC so that other areas throughout the country can have the option of taking early action to improve air quality and avoid a non-attainment designation.

Bill Would Block Clean Power Plan: On September 28, 2015, Congressman Ted Poe (R-TX) reintroduced H.R. 3626, the Ensuring Affordable Energy Act of 2015. The legislation would block implementation of the Clean Power Plan. Poe stated: "The President's plan attempts to bypass Congress once again, forcing states to implement the first ever caps on carbon emissions. This plan will drastically raise consumers' costs for power." The bill would prohibit funding to EPA to be used to implement or enforce The Clean Power Plan (or any similar program) or any cap and trade program.

Senate Committee Approves Package Of Bills Aimed At Reforming Regulatory Process: On October 7, 2015, the Senate Homeland Security and Governmental Affairs Committee passed four bills that are intended to alter significantly the federal rulemaking process. The panel approved the Independent Agency Regulatory Analysis Act of 2015 (S. 1607), the Principled Rulemaking Act of 2015 (S. 1818), the Early Participation in Regulations Act of 2015 (S. 1820), and the Smarter Regulations Through Advance Planning and Review Act of 2015 (S. 1817). In a written statement, Committee Chair Ron Johnson (R-WI) stated the bills "will address gaps

among agencies in the requirement to do cost-benefit and other analyses and to build automatic look-back procedures so that regulations are reviewed after several years." S. 1607, introduced by Senator Rob Portman (R-OH), authorizes the President to require an independent regulatory agency (such as EPA) to: (1) comply with regulatory analysis requirements applicable to other federal agencies; (2) publish and provide the Office of Information and Regulatory Affairs (OIRA) with an assessment of the costs and benefits of a proposed or final rule that is likely to have an annual effect on the economy of $100 million or more and is likely to affect adversely sectors of the economy in a material way; and (3) submit to OIRA any proposed or final economically significant rule. The Principled Rulemaking Act, sponsored by Senator James Lankford (R-OK), would codify portions of two existing Executive Orders to ensure regulatory agencies only promulgate regulations that are necessary and maximize benefits. Lankford's Early Participation in Regulations Act would require agencies to publish an advance notice of proposed rulemaking at least 90 days before advancing any major rule. S. 1817, sponsored by Senator Heidi Heitkamp (D-ND), would require federal agencies to plan retrospective reviews of major regulations.

MISCELLANEOUS

ChemSec Releases SINimilarity: On September 27, 2015, **t**he International Chemical Secretariat (ChemSec) released SINimilarity, a software program that compares a chemical name, Chemical Abstracts Service number, European Commission number, or molecular structure, to chemicals ChemSec has determined have characteristics of very high concern. The software program is a "screening tool" to assist in assessing chemicals and their replacements according to ChemSec. ChemSec's announcement and a link to the software are available at http://chemsec.org/news/pressreleases/1484-free-of-charge-chemistry-tool-empowers-non-chemists.

GAO Issues Chemicals Management Report: On October 9, 2015, the Government Accountability Office (GAO) issued the report entitled "Chemicals Management: Observations on Human Health Risk Assessment and Management by Selected Foreign Programs." The foreign programs GAO reviewed -- Canada's Chemicals Management Plan (CMP), Australia's Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, and the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) Monographs Programme and International Programme on Chemical Safety (IPCS) -- assess the human health risks of chemicals using similar analytic approaches, such as using specific criteria to determine which assessments to prioritize. There are some notable differences emphasized in these programs, however. Canada's and Australia's programs emphasize the use of screening assessments -- assessments that vary in complexity ranging from a rapid screen of information to using more complex approaches, depending on what officials determine is needed to understand adequately relevant risks, and WHO's IARC Monographs Programme and IPCS emphasize expert review by selecting internationally recognized experts to conduct or review assessments. Specifically:

- Canada completed a process through its CMP of prioritizing roughly 23,000 chemicals and other substances to identify those that warranted further assessment. That multiyear process identified about 4,300 substances for further review, and Canadian officials stated they aim to address them all by **2020**. Officials reported that, as of June 2015, they have completed screening assessments for about 2,700 substances (about 63 percent).

- Australia prioritized a list of about 38,000 industrial chemicals through its IMAP framework to identify those for further assessment. Program officials committed to assessing a list of 3,000 priority chemicals between 2012 and 2016, and they recently stated that they have met this deadline, having completed 3,185 assessments of individual chemicals by July 2015.

- WHO's IARC Monographs Programme appoints expert working groups composed of internationally recognized experts to evaluate existing information on selected chemicals and other agents to form a conclusion about their carcinogenic risks to humans. According to its website, the IARC Monographs Programme has assessed the carcinogenic risks of more than 900 chemicals and other agents since 1971.

- WHO's IPCS uses a panel of international peer reviewers selected for their scientific expertise to review an initial draft assessment of the human health risks of selected chemicals, then sends the draft to a second set of experts who determine, among other things, whether peer review comments were appropriately addressed. According to its website and a program official, since 1976, IPCS has completed about 287 assessments.

Canada uses various approaches to manage the human health risks of toxic chemicals under the Canadian Environmental Protection Act, 1999 (CEPA 1999). Specifically, for all chemicals and other substances determined to be toxic under CEPA 1999, and proposed for CEPA 1999's List of Toxic Substances, officials may use a variety of mechanisms to manage identified human health risks, such as regulations, pollution prevention plan notices, and Significant New Activity provisions. Reportedly, Senator Edward Markey (D-MA) requested the report. The report is available at http://www.gao.gov/products/GAO-16-111R.

Chemical Safety Board To Hold Public Meeting: The Chemical Safety Board (CSB) will convene a public meeting on **October 21, 2015**, in Washington, D.C. The purpose of the meeting is to review the final report and recommendations from the Caribbean Petroleum incident. The Board may then vote on the Caribbean Petroleum report. CSB also intends to

discuss the status of several current investigations, including ExxonMobil Torrance, West Fertilizer, Freedom Industries, DuPont LaPorte, Macondo, and Williams Olefins. CSB will also discuss its action plan for FY 2015 in addition to the newly confirmed Chairperson's overview of her first 60 days. Meeting details are available online.