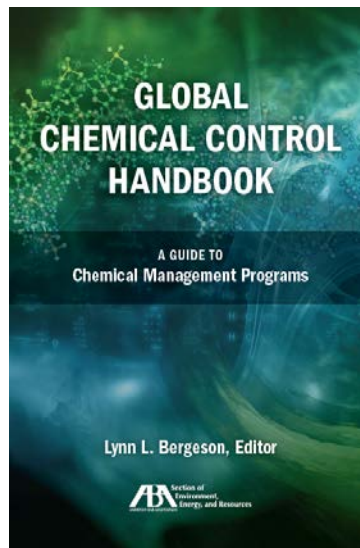


Recent Federal Developments December 15, 2014

Bergeson & Campbell, P.C. extends its best wishes to our clients and many friends and we wish you and your family a happy, healthy, and peaceful New Year. As we have for many years, the firm has made a contribution to the House of Ruth, a shelter for battered women and their children, in lieu of gifts to our clients, and on our clients' behalf.

***Global Chemical Control Handbook* Published by ABA SEER**



The attorneys, scientists, and regulatory professionals of Bergeson & Campbell, P.C. (B&C[®]) and The Acta Group (Acta[®]) are proud to have authored *Global Chemical Control Handbook: A Guide to Chemical Management Programs*, recently released by the American Bar Association Section of Environment, Energy, and Resources. Lynn L. Bergeson, Managing Partner of B&C and President of Acta, provided the guiding vision for this comprehensive desk reference book as editor and co-author.

Reflecting on the work of her colleagues, and others, on this book, Ms. Bergeson stated: “The *Global Chemical Control Handbook* reflects the expert counsel and advice of seasoned professionals that have been honed by years of ‘in the trenches’ experience with the global chemical programs outlined in the book. Readers can expect from the Handbook the hands-on information they need quickly to point them in the right direction when addressing an

increasingly complex set of legal, regulatory, and commercial challenges occasioned by these global chemical management regulations.”

The Handbook is organized by country and/or regulatory program and includes stand-alone sections discussing forecasts and trends, and includes sections on:

- United States -- Toxic Substances Control Act (TSCA)/Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and State Law.
- Canada -- Canadian Environmental Protection Act, 1999 (CEPA 1999).
- Europe -- European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Restriction of Hazardous Substances (RoHS), Waste from Electric and Electronic Equipment (WEEE), and Biocidal Products Regulation (BPR).
- Mexico, Central America, and South America chemical regulation.
- Asia -- K-REACH, Toxic Chemicals Control Act (TCCA), Order No. 7, and Decree No. 591.

Each of the focused chapters in the Handbook, and the helpful commentary and resources, help to ground environmental professionals and readers-at-large in the diverse regulatory structures that they may encounter in hands-on interactions with chemical management regulations in the United States or abroad. Knowing what to expect, and how to prepare for it, are essential steps in successfully navigating these systems.

Global Chemical Control Handbook: A Guide to Chemical Management Programs is available for purchase via the [ABA online bookstore](#) for \$149.95, or \$119.95 for ABA SEER members.

TSCA/FIFRA/IRIS/EPCRA/NTP

EPA Schedules Public Teleconference Of Science Advisory Board Chemical Assessment Advisory Committee For Review Of Draft Ammonia Assessment: On November 17, 2014, the U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announced two public teleconferences of the SAB Chemical Assessment Advisory Committee Augmented for the Review of the Draft Ammonia Assessment (CAAC Ammonia Panel) to discuss its draft report concerning EPA’s draft Integrated Risk Information System (IRIS) *Toxicological Review of Ammonia* (August 2013 Revised External Review Draft). 79 Fed. Reg. 68440. The EPA SAB Staff Office augmented the SAB CAAC with subject matter experts to

provide advice through the chartered SAB regarding this IRIS assessment. The SAB CAAC Ammonia Panel held a public meeting on July 14-16, 2014. The purpose of that meeting was to receive a briefing on the EPA’s enhancements to the IRIS Program and develop responses to the peer review charge on the Agency’s draft IRIS *Toxicological Review of Ammonia* (August 2013 Revised External Review Draft). The purpose of these public teleconferences is for the Panel to discuss its draft report peer reviewing the Agency’s draft toxicological review. The two public teleconferences will be held on **Wednesday, December 17, 2014, and Friday, December 19, 2014, from 1:00 p.m. to 5:00 p.m. (EST) on both days.**

EPA Extends Comment Period On Proposed Significant New Use Rule (SNUR): On November 28, 2014, EPA extended the comment period on its proposed SNUR issued on October 1, 2014, concerning 15 related chemical substances commonly known as nonylphenols (NP) and nonylphenol ethoxylates (NPE). 79 Fed. Reg. 70823. For 13 NPs and NPEs, EPA proposed to designate any use as a “significant new use,” and for two additional NPs, EPA proposed that any use other than use as an intermediate or use as an epoxy cure catalyst would constitute a “significant new use.” Comments are now due on **January 15, 2015.**

EPA Announces PRIA Workshop On Inert Ingredient Applications: On December 16, 2014, EPA will host a half-day workshop on the application process for the use of inert ingredients in pesticide products. The workshop will take place in Arlington, Virginia. The goal of the workshop is to clarify the necessary elements of an application for approval to use an inert ingredient in a pesticide product. Complete application packages save applicants time and money, and reduce the number of application rejections. The workshop will cover: selection of a Pesticide Registration Improvement Act (PRIA) category, elements of an application, EPA’s evaluation process, and a retrospective review of inerts under PRIA. EPA will answer stakeholder questions throughout the workshop.

EPA Issues SNURS For Ethylene Glycol Ethers: On December 10, 2014, EPA issued a prepublication of a final rule on seven ethylene glycol ethers (glymes) chemicals believed to cause health effects. Some of these chemicals are currently used in consumer products, including paints, inks, and glues. The ethylene glycol ethers and the significant new use for each chemical substance subject to this SNUR are identified in Table 1.

Table 1. Chemicals with Significant New Use(s)

Chemical Name	Chemical Abstracts (CA) Index Name	Chemical Abstracts Service Registry No. (CASRN)	Significant New Use(s)¹
Monoethylene glycol dimethyl ether or monoglyme	Ethane, 1,2,-dimethoxy-	110-71-4	Any use in a consumer product

Chemical Name	Chemical Abstracts (CA) Index Name	Chemical Abstracts Service Registry No. (CASRN)	Significant New Use(s) ¹
Diethylene glycol dimethyl ether or diglyme	Ethane, 1,1'-oxybis[2-methoxy-	111-96-6	Any use in a consumer product
Diethylene glycol diethyl ether or ethyldiglyme	Ethane, 1,1'-oxybis[2-ethoxy-	112-36-7	Any use in a consumer product except as a component of inks, coatings and adhesives, and as a component of paint/graffiti removers
Triethylene glycol dimethyl ether or triglyme	2,5,8,11-Tetraoxadodecane	112-49-2	Any use in a consumer product, except as a solvent in consumer adhesives, in brake fluid, as a component of consumer paint/graffiti removers, and in consumer paints
Diethylene glycol dibutyl ether or butyldiglyme	Butane, 1,1'-[oxybis(2,1-ethanedioxy)]bis-	112-73-2	Any use in a consumer product except as a solvent in consumer inks, coatings and adhesives, and as a component in soldering compounds
Ethylene glycol diethyl ether or ethylglyme	Ethane, 1,2-diethoxy	629-14-1	Any use in a consumer product
Triethylene glycol dibutyl ether or butyltriglyme	5,8,11,14-Tetraoxaoctadecane	63512-36-7	Any use

¹ In defining the significant new use for each chemical, the exceptions listed in this table reflect the identified ongoing uses, where they exist, that are excluded from the definition of significant new use.

The rule will require persons who intend to manufacture (including import) or process any of the seven ethylene glycol ethers for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing such manufacture or processing. The required notifications would provide EPA with the opportunity to evaluate the intended use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs. EPA is also making a technical amendment to the codified list of control numbers for approved information collection activities so that it includes the control number assigned by the Office of Management and Budget (OMB) to the information collection activities contained in this rule.

NTP To Review Coal-Washing Chemicals: The National Toxicology Program (NTP) announced on December 10, 2014, that it will study nine coal-washing chemicals that spilled into West Virginia's Elk River in January 2014. The Centers for Disease Control and Prevention (CDC) requested the research last July, and studies reportedly are under way as announced at a meeting of the NTP Advisory Board on December 10, 2014. More information is available at the NTP website tracking its work on the chemicals spilled into the Elk River, which is available at <http://ntp.niehs.nih.gov/results/areas/wvspill/>.

FDA

FDA Updates Guidance On Food Facility Registration: On November 19, 2014, the U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) announced the availability of a question and answer guidance document for industry entitled "Questions and Answers Regarding Food Facility Registration (Sixth Edition)." 79 Fed. Reg. 68810. The guidance is part of the ongoing actions, including registration activities, taking place under the Food Safety Modernization Act (FSMA) and is intended to provide more details on certain changes, including to the term "farm." For more details, see http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

FDA Announces Improvements To Color Additives Screening: On November 21, 2014, FDA announced it was now able to provide more specified concentration results for lead and arsenic content for certificates of analysis of certain color additives. FDA indicates with improvements in techniques, values can now be reported down to the actual part per million (ppm) levels and offers a more quantitative result replacing the pass test (PT) notation that was previously utilized. For more details, see http://www.fda.gov/ForIndustry/ColorAdditives/ColorCertification/ucm423846.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

FDA Issues Final Requirements On Menu And Vending Machine Labeling On Food Facility Registration: On December 1, 2014, the FDA CFSAN issued two rules related to the labeling of menu items in restaurants if they are part of a chain of 20 or more locations and articles of food in vending machines by those who own or operate 20 or more vending machines. 79 Fed. Reg. 71155; 79 Fed. Reg. 71259. Both rules are meant to ensure caloric and nutritional information be visible to consumers at the point of purchase and are part of ongoing efforts by the FDA to implement provisions of the Patient Protection and Affordable Care Act of 2010. Both rules are open for comments until **December 31, 2014**.

FDA CDRH Issues Final Guidance To Industry: On December 2, 2014, FDA Center for Devices and Radiological Health (CDRH) issued a final guidance to industry entitled “Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is Not Made with Natural Rubber Latex.” The guidance was created to clarify the appropriate labeling statements for medical products that are regulated by FDA and were manufactured not using natural rubber latex or synthetic derivatives of natural rubber latex. For more details, *see* Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex - Guidance for Industry and Food and Drug Administration Staff.

RCRA/CERCLA

EPA Releases Final RCRA Definition Of Solid Waste Rule: On December 10, 2014, EPA Administrator Gina McCarthy signed a final rule revising the Definition of Solid Waste (DSW) under the Resource Conservation and Recovery Act (RCRA). The 500 plus page-long rule will be published in the *Federal Register* shortly. The rule overturns or significantly revises several hazardous waste recycling exclusions previously contained in a 2008 EPA final rule. 73 Fed. Reg. 64688 (Oct. 30, 2008). Perhaps the biggest revision in the rule is EPA’s withdrawal of the transfer-based exclusion codified in the 2008 rule. In its place, EPA created the “verified recycler exclusion.” This new provision requires that all recyclers operating under this provision have RCRA permits or obtain variances prior to reclaiming hazardous secondary materials. The rule retains the exclusion for hazardous secondary materials that are legitimately reclaimed under the control of the generator (generator-controlled exclusion), but adds several conditions to the exclusion, including notification and recordkeeping requirements and emergency preparedness and response conditions. EPA also modified the transfer-based exclusion by adding several conditions, including one that recyclers have financial assurance in place to manage the materials left behind when the facility closes. An addition to the rule is the remanufacturing exclusion, which exempts certain higher-value solvents transferred from one manufacturer to another for the purpose of extending the useful life of the solvent by remanufacturing the spent solvent back into commercial grade solvent. Another major change in the rule is the codification of legitimacy criteria that all recyclers of hazardous secondary materials must meet. These criteria are: (1) the hazardous secondary material must provide a useful contribution to the product or recycling process; (2) the recycling process must produce a valuable product or intermediate; (3)

the hazardous secondary material must be managed as a valuable commodity; and (4) the recycled product must be comparable to a legitimate product or intermediate. The rule will become effective 180 days after it is published in the *Federal Register*. Because states are authorized by EPA to administer the RCRA hazardous waste program, however, the changes in the rule will not become effective in RCRA-authorized states until those states revise their programs to adopt the changes, and after EPA approves the states' revised programs.

EPA Issues Report On Future Of RCRA Program: On October 29, 2014, at the winter meeting of the Association of State and Territorial Solid Waste Management Officials (ASTSWMO), EPA issued a report on the RCRA program that appears intended to serve as both a defense of the RCRA program and an argument for its continued relevancy. Entitled "RCRA's Critical Mission & The Path Forward," the report details the accomplishments of the RCRA program, identifies existing challenges, and lays out a path forward for the program. The report serves as a "messaging document" to highlight the successes of the RCRA program and the necessity for its continued evolution. According to the report, this new evolution is taking the form of Sustainable Materials Management (SSM). In the report, EPA states that it and state hazardous waste agencies are expanding the "resource conservation aspect of the RCRA program" towards SSM. The report describes SSM as "an approach that considers the entire lifecycle of materials and casts a far broader net than traditional waste and chemicals management approaches." EPA claims that "SSM can transform production processes, minimizing the amount of materials involved and the associated environmental impacts." EPA acknowledges in the report that its current RCRA regulatory structure is ill-suited to address SSM, but it pledges to integrate its separate environmental programs to address systematically material movement through the environment. The report is available [online](#).

EPA Holds Webinar On Electronic RCRA Hazardous Waste Manifest: On November 20, 2014, EPA held a webinar on the implementation of its electronic hazardous waste manifest under the RCRA program. During the webinar, EPA staff stated that the so-called "e-manifest" will be operational no later than the spring of 2018. EPA cautioned, however, that delays in contracting work or Congressional funding could delay its completion. The e-manifest is required under the Hazardous Waste Electronic Manifest Establishment Act. Under that law, the e-manifest system was to have been fully operational by October 5, 2015, but it claims that insufficient Congressional funding will delay that deadline. A PDF version of the slides is available at <http://www.epa.gov/osw/hazard/transportation/manifest/e-man.htm>.

CAA/CWA/SDWA

EPA Proposes Stricter Ozone NAAQS: On November 25, 2014, EPA proposed to strengthen the National Ambient Air Quality Standard (NAAQS) for ground-level ozone. "Based on extensive recent scientific evidence about the harmful effects of ground-level ozone, or smog," EPA is proposing to lower the ozone NAAQS to within a range of 65 to 70 parts per billion (ppb), while taking comment on a level as low as 60 ppb. The Clean Air Act (CAA) requires that

EPA review the standards every five years; EPA last updated these standards in 2008, setting them at 75 ppb. The law also requires EPA to set two types of NAAQS for ozone: a primary standard to protect public health with an “adequate margin of safety,” and a secondary standard to protect the public welfare. EPA is proposing to update both the primary ozone standard, to protect public health, and the secondary standard, to protect the public welfare. Both standards would be 8-hour standards set within a range of 65 to 70 ppb. In addition to lowering the NAAQS, EPA seeks to expand the ozone monitoring season for many states and update the Air Quality Index to ensure people are notified when air quality is unhealthy. According to EPA’s analysis, lowering the NAAQS for ozone will improve significantly protection for children, preventing from 320,000 to 960,000 asthma attacks and from 330,000 to 1 million missed school days. EPA estimates that the benefits of meeting the proposed standards will significantly outweigh the costs. If the standards are promulgated in final, EPA claims that “every dollar we invest to meet them will return up to three dollars in health benefits.” EPA values these health benefits at \$6.4 to \$13 billion annually in 2025 for a standard of 70 ppb, and \$19 to \$38 billion annually in 2025 for a standard of 65 ppb. Annual costs are estimated at \$3.9 billion in 2025 for a standard of 70 ppb, and \$15 billion for a standard at 65 ppb. Comments will be due 90 days after the date of publication of the notice in the *Federal Register*. EPA intends to convene three public meetings on the proposal.

EPA Seeks Additional Comment On NPDES Electronic Reporting Rule: On December 1, 2014, EPA requested additional comment on the proposed National Pollutant Discharge Elimination System (NPDES) Electronic Reporting Rule that would require electronic reporting instead of current paper-based NPDES reports. 79 Fed. Reg. 71066. This rule would, according to EPA, modernize NPDES reporting, save time and resources for regulated entities and regulatory agencies, better protect the Nation’s waters by improving compliance, and provide the public with access to information that affects their communities. Comments are due by **January 30, 2015**.

EPA Delays Implementation Deadlines For Cross-State Air Pollution Rule: On November 21, 2014, EPA Administrator Gina McCarthy signed an interim final rule that delays the implementation deadlines for its Cross-State Air Pollution Rule (CSAPR). On December 3, 2014, EPA issued a rule that also revises the CSAPR’s emissions allowances that utilities can use to comply with the air trading program. 79 Fed. Reg. 71674. The revised implementation deadlines are necessary to comply with a ruling by the U.S. Court of Appeals for the District of Columbia Circuit, which initially imposed a stay on implementing CSAPR in 2011 while it heard litigation over the rule, then issued a 2-1 ruling in August 2012 vacating the rule. But the Supreme Court in an April 2014 decision overturned that ruling and reinstated the CASPR. The high court’s 6-2 decision rejected claims that the emissions cap-and-trade program violated the CAA, and sent litigation over the rule, *EME Homer City Generation, L.P. v. EPA*, back to the D.C. Circuit to address remaining issues that the appellate court never addressed in its ruling. EPA subsequently asked the court to lift the stay so that it could reinstate CSAPR; the court lifted the stay on October 23, 2014. In the interim final rule, EPA delayed the implementation

dates for the CASPR's Phase 1 emissions budgets to 2015 and 2016, and compliance with the rule's Phase 2 emissions budgets to 2017. In a Notice of Data Availability (NODA) issued on December 3, 2014, EPA reset the pollution allowances for individual power plants to compensate for the three-year delay in implementation of the CSAPR.

EPA Announces Delay In Issuing 2014 Standards For The Renewable Fuel Standard Program: On December 9, 2014, EPA announced that it will not be issuing in final 2014 applicable percentage standards under the Renewable Fuel Standard (RFS) program before the end of 2014. 79 Fed. Reg. 73007. In light of this delay in issuing the 2014 RFS standards, EPA announced that the compliance demonstration deadline for the 2013 RFS standards will take place in **2015**. EPA will be making modifications to the EPA-Moderated Transaction System (EMTS) to ensure that Renewable Identification Numbers (RIN) generated in 2012 are valid for demonstrating compliance with the 2013 applicable standards.

NANOTECHNOLOGY

EP Committee Study On Legislative Areas Of The TTIP Addresses Nanomaterials: The European Parliament (EP) Committee on Environment, Public Health, and Food Safety (ENVI) has posted a study entitled [ENVI Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations \(TTIP\)](#). The study analyzes the main differences between EU and U.S. legislation in eight areas: human medicines and medical devices; cosmetics; food and nutrition; sanitary and phyto-sanitary; nanomaterials; cloning; raw materials and energy; and motor vehicles. According to the study, while nanomaterials are regulated under REACH regulation in the EU and TSCA in the U.S., "REACH is much more stringent than TSCA." Under REACH, all chemicals on the EU market must be registered, which includes the submission of safety data. Under TSCA, the submission of safety data is required only in particular cases, and chemicals on the market before 1976 can remain on the market without any testing or registration requirements. In addition, the study states, fewer restrictions on chemicals are imposed in the U.S., "where a large amount of information on chemicals may be kept confidential." While there are currently no nanomaterial labeling policies in the U.S., several EU regulations require the labeling of nanomaterials contained in specific products, in particular cosmetics and food. According to the study, specific legislation dedicated to nanomaterials is still under development in the EU and U.S. The study states that, in addition to explicit rules for nanomaterials, "a definition of [nanomaterials] should be agreed at international level to enhance the dialogue between stakeholders from different countries or sectors and thus the harmonisation of legislation related to [nanomaterials]."

European Companies Appeal ECHA Titanium Dioxide Decision: The European Chemicals Agency (ECHA) published on November 3, 2014, an [announcement of appeal](#) of a June 17, 2014, contested decision following a compliance check of the REACH registration submitted by Tiioxide Europe Limited for titanium dioxide. In the contested decision, ECHA requested Tiioxide Europe Limited submit the following information: name or other identifier of the

substance; composition of the substance; and description of the analytical methods used. The appellants request that the Board of Appeal annul the contested decision in so far as it requests the submission of information related to phases, nanoforms, and surface treated nanoforms as described in the contested decision. According to the appellants, the information related to the identification of titanium dioxide currently included in the registration dossier complies fully with the REACH requirements, taking into account the available guidance documents, and in particular the ECHA guidance for identification and naming of substances under REACH and the regulation on classification, labeling, and packaging of substances and mixtures.

France Posts Report On Nanomaterials Reported As Of June 2014: The Ministry of Ecology, Sustainable Development, and Energy published [a report](#), available only in French, concerning the second round of mandatory reporting of nanomaterials. Under Decree No. 2012-232, companies that manufacture, import, and/or distribute a “substance with nanoparticle status” in an amount of at least 100 grams per year must submit an annual report with substance identity, quantity, and use information. According to the report, 10,417 declarations were submitted by June 1, 2014, compared to 3,409 declarations submitted as of July 1, 2013.

EPA Fall 2014 Regulatory Agenda Includes Item Concerning TSCA Section 8(a) Rule For Nanoscale Materials: EPA’s Fall 2014 Regulatory Agenda, which was posted on OMB’s website on November 21, 2014, includes [an item](#) concerning TSCA Section 8(a) reporting and recordkeeping requirements for chemical substances when manufactured or processed as nanoscale materials. According to the item, the proposed rule would require that persons who manufacture these nanoscale materials notify EPA of certain information, including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data. EPA states that the proposed reporting of these activities will provide it “with an opportunity to evaluate the information and consider appropriate action under TSCA to reduce any risk to human health or the environment.” The item states that EPA intends to publish a notice of proposed rulemaking in **January 2015**. As reported previously, on October 6, 2014, EPA submitted a proposed rule to OMB, where it currently remains under review.

USDA Announces Release Of Report Charting Path To Commercialization Of Cellulosic Nanomaterials: On November 24, 2014, the U.S. Department of Agriculture (USDA) announced that the U.S. Forest Service (USFS) has released a report that details the pathway to commercializing affordable, renewable, and biodegradable cellulose nanomaterials from trees. The report, entitled [Cellulose Nanomaterials -- A Path Towards Commercialization](#), is the result of a May 2014 workshop that brought together a wide range of experts from industry, academia, and government to ensure that commercialization efforts are driven by market and user materials needs. The USFS, in collaboration with the National Nanotechnology Initiative, organized the workshop. Participants included over 130 stakeholders from large volume industrial users, specialty users, federal government agencies, academia, non-government organizations, cellulose nanomaterials manufacturers, and industry consultants. According to USDA, the workshop

generated market-driven input in three areas: opportunities for commercialization; barriers to commercialization; and research and development roles and priorities. Issues identified by participants included the need for more data on materials' properties, performance, and environmental, health, and safety implications, and the need for a more aggressive U.S. response to opportunities for advancing and developing cellulose nanomaterial.

EP ENVI Committee Proposes Moratorium On The Use Of Nanomaterials In Food: On November 24, 2014, the EP ENVI Committee considered draft legislation concerning novel foods. The Committee amended the draft legislation, proposing a moratorium on the use of nanomaterials in food based on the precautionary principle. The Committee approved the amended draft legislation by a vote of 57-4, with two abstentions. EP Member James Nicholson (ECR, UK), who is steering the legislation through the EP, stated that he was not completely satisfied with the vote. According to Nicholson, it is "essential that cloning and nanomaterials be dealt with separately." The Committee's [press release](#) states that foods for which production processes require risk assessments, including nanomaterials, should not be authorized until they are approved by the European Food Safety Authority (EFSA). The press release notes that "[s]pecial attention should also be paid to food packaging containing nanomaterials, to prevent them migrating into food." In addition, in line with the precautionary principle, all novel food should also be subject to post-market monitoring. The Committee amended the existing definition of nanomaterials to bring it in line with EFSA recommendations, and dropped the threshold for a food ingredient to qualify as "nano" from the European Commission's (EC) proposed 50 percent to ten percent. The Committee unanimously approved a mandate for Nicholson to begin negotiations with the Council of Ministers, with one abstention. The Council has yet to adopt its negotiating position.

EU Requirement To List Engineered Nanomaterials In Food Labeling Took Effect December 13: The EC issued a December 11, 2014, [press release](#) concerning EU food labeling requirements that took effect December 13, 2014. The EP and the Council adopted the requirements in 2011. The requirements are intended to ensure that consumers receive clearer, more comprehensive, and accurate information on food content, and help them make informed choices about what they eat. Under the requirements, all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word "nano" in brackets. According to the EC, food business operators have had three years "to ensure a smooth transition towards the new labelling regime for prepacked and non-prepacked foods." In addition, the regulation "provides for exhaustion of stocks for foods placed on the market or labelled before 13 December 2014." The EC states that work is underway to develop an EU database to facilitate the identification of all EU and national mandatory labeling rules in a simple way. The work for the creation of the database should be carried out during **2015**.

EU-U.S. Joint NanoEHS Workshop Will Be Held In March 2015 In Italy: The National Nanotechnology Coordination Office (NNCO) announced on December 5, 2014, that, in

collaboration with the EC, it will hold the 2015 “[EU-U.S.: Bridging NanoEHS Research Efforts](#)” joint workshop on **March 12-13, 2015**, in Venice, Italy. 79 Fed. Reg. 72217. According to NNCO, the workshop will bring together the U.S.-EU Communities of Research (COR), which serve as a platform for U.S. and EU scientists to share information on nano environmental health and safety (EHS) research. NNCO states that this workshop, the fourth since 2011, is intended to develop further and support the CORs’ activities. The six CORs are:

- Exposure through the Life Cycle, with Material Characterization;
- Ecotoxicity Testing and Predictive Models, with Material Characterization;
- Predictive Modeling for Human Health, with Material Characterization;
- Databases and Ontologies;
- Risk Assessment; and
- Risk Management and Control.

Due to space limitations, pre-registration for the workshop is required. [Registration](#) is on a first-come, first-served basis and will be capped at approximately 100 participants. Registration is now open.

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>.

GREEN CHEMISTRY

EPA Encourages Submission Of Safer Chemicals: EPA’s Design for the Environment’s (DfE) office recently encouraged entities to nominate chemicals for review and possible inclusion in the Agency’s Safer Chemical Ingredients List (SCIL). EPA has expressed its desire to expand the number of ingredients on the SCIL. The list includes chemicals that have satisfied certain safety criteria developed by EPA’s DfE Program. More than 650 chemicals are currently included on the SCIL. Chemicals on the list can be used as ingredients in product that carry the DfE logo. Expanding the list, according to EPA, would encourage innovation and growth in safer products and increase markets for those products.

Safer Product Labeling Program Partner Of The Year Awards: On December 8, 2014, EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) announced the first Safer Product Labeling Program (SPLP) Partner of the Year Awards. The Awards will recognize the leadership contributions of stakeholders in making safer chemicals and safer products available to consumers and purchasers. The application period for the 2015 awards is now open, and applications are due to EPA by **January 30, 2015**. Those interested in applying may choose to submit under one or more of the following categories: product manufacturers; purchasers and distributors; retailers; supporters; and innovators. The awardees will be honored at a ceremony in Washington, D.C., in late spring of 2015. For more information about the SPLP Partner of the Year Awards and how to submit applications, please visit the Awards web page at <http://www.epa.gov/dfe/awards/>.

OSHA DEVELOPMENTS

Chemical Safety Board Urges Updating Of OSHA Process Safety Management Regulations: On December 1, 2014, the U.S. Chemical Safety Board (CSB) announced that to "modernize U.S. Process Safety Management Regulations" is the newest to its "Most Wanted Safety Improvement." CSB stated that implementation of key federal and state CSB safety recommendations will result in significant improvement of Process Safety Management (PSM) regulations. Over the last two decades, the CSB has made a number of recommendations related to the Occupational Safety and Health Administration's (OSHA) PSM program and EPA's Risk Management Program (RMP). OSHA and EPA have largely ignored CSB's recommendations. The PSM regulations have undergone little reform since their promulgation in the 1990s. The CSB points to its recent investigations of major refinery incidents that found that PSM and RMP, although written as performance-based regulations, appear to function primarily as reactive and activity-based regulatory frameworks that require extensive rulemaking to modify. This potentially results in stagnating risk levels, even as industry-recommended best practices and technology continue to advance in the U.S. and overseas, CSB stated. As a result of these investigations, the CSB made recommendations at the federal, state, and local levels to prevent major incidents by adopting a more rigorous regulatory system that requires covered facilities to continuously reduce major hazard risks. For PSM, the CSB recommended that OSHA:

- Expand the rule's coverage to include the oil and gas exploration and production sector;
- Cover reactive chemical hazards;
- Add additional management system elements to include the use of leading and lagging indicators to drive process safety performance and provide stop work authority to employees;

- Update existing Process Hazard Analysis requirements to include the documented use of inherently safer systems, hierarchy of controls, damage mechanism hazard reviews, and sufficient and adequate safeguards; and
- Develop more explicit requirements for facility/process siting and human factors, including fatigue.

For RMP, in addition to PSM program related enhancements mentioned above, the CSB recommended that EPA:

- Expand the rule's coverage to include reactive chemicals, high and/or low explosives, and ammonium nitrate as regulated substances and to change enforcement policies for retail facilities;
- Enhance development and reporting of worst case and alternate release scenarios; and
- Add new prevention program requirements, including automated detection and monitoring, contractor selection and oversight, public disclosure of information, and, for petroleum refineries, attributes of goal-setting regulatory approaches.

CSB's full set of recommendations for the PSM regulatory program is available [online](#), as is CSB's [Most Wanted Page](#).

OSHA Issues Safety Bulletin On Fracking Hazards: On December 4, 2014, OSHA circulated a 24-page safety alert on hazards associated with hydraulic fracturing operations. According to OSHA, each year, an estimated 35,000 wells are hydraulically-fractured in the U.S. More workers are potentially exposed to the hazards created by hydraulic fracturing and flowback operations due to the large increase in the number of these operations in the past decade. OSHA determined that additional information concerning hydraulic fracturing and flowback operations hazards should be provided to educate and protect workers, which is why it prepared the bulletin. OSHA examines in the bulletin hazards associated with work stages in the fracking process. Section I covers transportation as well as setting up and breaking down the on-site equipment. The hazards during these processes are primarily traffic- and construction-related. Section II explains hazards and control measures present when mixing chemicals into the fracking fluid and injecting the fluid underground. Hazards explored here are predominantly health-related. Section III addresses pressure pumping and Section IV examines flowback operations. The OSHA safety alert on fracking hazards other than silica exposure is available at <https://www.osha.gov/Publications/OSHA3763.pdf>.

LEGISLATIVE DEVELOPMENTS

Lawmakers Pass \$1.1 Trillion Spending Package: The Senate worked late into a Saturday night and on December 13, 2014, voted 56-40 to pass a \$1.1 trillion spending package that funds most of the government through next September. The bill (H.R. 83) was passed by the House late December 11, 2014, by a 219-206 vote. The Senate vote capped a week of acrimonious sniping and sends the spending bill to President Obama's desk for a signature, who has stated he will sign the bill. The package includes 11 appropriations bills that fund most of the government through September 30, 2015. EPA's funding coffers will take a big hit: the bill cuts EPA's funding by \$60 million below the fiscal year 2014 funding level, providing a total of \$8.1 billion for the Agency. Overall, EPA funding has been reduced by \$2.2 billion -- or 21% -- since 2010. The bill also continues reductions to EPA staff: EPA's staffing level will be at its lowest level since 1989. The bill also contains several environmental policy provisions. Some of the provisions include a prohibition on funding for EPA to regulate lead content in ammunition and fishing tackle under TSCA, exemptions from EPA's greenhouse gas emission regulations for livestock producers, and a requirement that the White House report to Congress on federal agency obligations and expenditures on climate change programs.

Keystone XL Pipeline Bill Fails In Senate: On November 18, 2014, legislation to approve construction of the Keystone XL oil pipeline failed in the Senate, less than a week after the House had passed the bill. The measure was defeated 59-41, falling a single vote short of the 60 votes necessary for passage. Fifteen Democrats voted for the bill; the no votes came from Democrats and one Independent. The vote was likely welcome news at the White House, which did not have to issue an explicit veto threat if the bill passed, although it is clear that President Obama opposed the measure. The bill is certain to be taken up again when the 114th Congress -- and its GOP majority in both houses -- is sworn into office.

Carbon Fee Bill Introduced In Senate: Senator Sheldon Whitehouse (D-RI) on November 19, 2014, unveiled legislation that he claims would reduce carbon pollution and generate as much as \$2 trillion dollars over ten years. The American Opportunity Carbon Fee Act would require companies in certain industries that emit carbon to pay a fee for every ton of carbon pollution they emit. The fee would start at \$42 per ton in 2015 and increase annually by an inflation-adjusted 2 percent. The price of the fee follows the Obama Administration's central estimate of the "social cost of carbon," the value of the harms caused by carbon pollution, including falling agricultural productivity, human health hazards, and property damages from flooding. The fee would be assessed on all coal, oil, and natural gas produced in or imported to the U.S. and cover large emitters of non-carbon greenhouse gases and carbon dioxide from non-fossil-fuel sources.

Congress Passes Bill Extending CFATS Program: The Senate passed on December 10, 2014, legislation (H.R. 4007) reauthorizing the Department of Homeland Security's (DHS) Chemical Facility Anti-Terrorism Standards (CFATS) program for an additional five years. The House passed the legislation on December 11, 2014. The bill now moves to the White House for

approval; President Obama is expected to sign the legislation. The Protecting and Securing Chemical Facilities from Terrorist Attacks Act (H.R. 4007) requires DHS to establish risk-based performance standards designed to protect chemical facilities from acts of terrorism and other security risks. It also requires such facilities to submit security vulnerability assessments and develop and implement site security plans. DHS would also be authorized to approve an alternative security program established by a private sector entity or a federal, state, or local authority that meets the requirements of the bill. DHS must review site vulnerability assessments, audit and inspect regulated chemical facilities, and conduct other oversight and implementation duties. DHS must also carry out a Personnel Surety Program that provides a participating facility owner or operator with feedback about individuals based on vetting against the terrorist screening database. Regulated entities may use this federal screening program to satisfy the requirements of a risk-based performance standard that address personnel surety.

House Passes EPA Science Advisory Board Reform Act: On November 18, 2014, the House passed H.R. 1422, the EPA Science Advisory Board Reform Act. The bill would amend the Environmental Research, Development, and Demonstration Authorization Act of 1978 to provide for more transparency in EPA SAB deliberations. The bill passed the chamber by a vote of 229-191. It specifically would revise the process of selecting members of the SAB, guidelines for participation in SAB advisory activities, and terms of office. Under the bill, federally registered lobbyists would be prohibited from being appointed to the SAB. The legislation would also revise the procedures for providing advice and comments to EPA by: (1) including risk or hazard assessments in the regulatory proposals and documents made available to the SAB, and (2) requiring advice and comments to be included in the record regarding any such proposal and published in the *Federal Register*. In a move to ensure transparency in SAB deliberations, the bill would also require that SAB members operate in accordance with the membership, participation, and policy requirements (including new requirements for public participation in advisory activities) contained in the bill. H.R. 1422 would also deny SAB members from making any decisions on behalf of the board and prohibit direct reporting to EPA.

Legislation Would Revise Unfunded Mandates Reform Act: A bill introduced by Senators Rob Portman (R-OH) and Mike Crapo (R-ID) would revise the Unfunded Mandates Reform Act (UMRA). Under the Unfunded Mandates Accountability Act of 2014 (S. 2931), federal agencies would for the first time be required specifically to assess the potential impact of any new major regulation (rules with an annual effect of \$100 million or more) on job creation or job loss, and quantify that impact to the extent feasible. The bill also requires agencies to consider reasonable alternatives that require no action by the federal government, use incentives and market-based solutions, and/or “permit the greatest flexibility” in achieving the goals of the statute authorizing the regulation. Currently, the UMRA states that agencies must select the “least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule” unless the agency explains why it did not select that alternative. This bill eliminates that exception. An agency would be required to follow the least onerous regulatory course to achieve the policy goals set out by Congress. Agencies will, however, continue to have latitude to interpret

statutory objectives. The bill would require a cost-benefit analysis to any new rule, which is currently not the case. The bill would permit judicial review of an agency's compliance with UMRA as part of any challenge to the rule brought under the Administrative Procedure Act. Each agency's cost-benefit analysis, as well as its approach to less onerous regulatory alternatives, would be reviewed under the arbitrary and capricious standard. Review would be deferential, but it would require an agency to provide a reasoned explanation of how its adoption of a particular regulatory means is consistent with UMRA. An agency that relies on an irrational or otherwise deficient cost-benefit analysis, or adopts a needlessly burdensome option, would risk remand or vacatur of its regulation. The Senate is unlikely to pass the legislation before the end of the 113th Congress, and even if it did so, President Obama is certain to veto the legislation.

House Passes Promoting New Manufacturing Act: The House on November 20, 2014, passed H.R. 4795, the Promoting New Manufacturing Act. The bill is intended to provide for greater transparency and timeliness in obtaining necessary permits from EPA and state environmental agencies. The legislation would direct EPA to expedite preconstruction permits issued under the CAA, which are required for major stationary sources that emit air pollution. The bill would also require EPA to publish implementing guidance for revised ambient air quality standards at the same time it publishes the final standards. EPA also would be required to put out an annual count of the preconstruction permits it issues and the time it took to issue each one.

House Bill Seeks To Protect Drinking Water From Cyanotoxins: Representative Bob Latta (R-OH) on November 20, 2014, introduced legislation to help protect drinking water from harmful algae blooms known as cyanotoxins. Latta authored the legislation in response to Toledo, Ohio's, August water emergency caused by the increased presence of harmful algal blooms in Lake Erie. H.R. 5753, the Drinking Water Protection Act, requires EPA to develop and submit a strategic plan to Congress for assessing and managing the risk associated with cyanotoxins in drinking water.

House Passes Secret Science Reform Act: On November 19, 2014, the House passed the Secret Science Reform Act (H.R. 4012), a bill that would ban EPA from promulgating regulations unless it makes public all scientific and technical information it used to develop them. The bill, introduced by Representative David Schweikert (R-AZ), is not expected to be taken up in the Senate before the 114th Congress takes over on **January 6, 2015**.

Committee On Environment And Public Works Holds Hearing On Super Pollutants Act: On December 2, 2014, the Senate Committee on Environment and Public Works (EPW) held a hearing on the Super Pollutants Act (S. 2911). Introduced by Senator Christopher Murphy (D-CT), the bill aims to promote interagency cooperation in regard to so-called "super pollutants," which include methane, black carbon, and hydrofluorocarbons (HFC), and to help prioritize emissions reduction strategies using existing federal authority and programs. The bill would enable federal agencies to work with business and non-profit communities to speed the adoption

of super pollutant-reducing technologies and policies, while supporting U.S. technology innovations and investments to reduce these pollutants. S. 2911 would also establish an interagency task force to review policies and measures to promote, and to develop best practices for, the reduction of these super pollutants. The task force would coordinate and optimize the federal government's existing efforts to address these super pollutants; reduce overlap and duplication of such efforts; and encourage federal operations, programs, policies, and initiatives to reduce super pollutants. Testifying at the hearing were Durwood Zaelke, Institute for Governance and Sustainable Development; Stephen Moore, Heritage Foundation; Kevin Fay, The Alliance for Responsible Atmospheric Policy; Drew Shindell, Duke University Nicholas School of the Environment; and Benny Peiser, The Global Warming Policy Foundation. Witness testimony and a webcast of the hearing are available [online](#).

House Passes Pest Management Records Modernization Act: On December 2, 2014, the House passed a bill that would allow commercial pesticide applicators to retain and submit their records in electronic form. The bill, the Pest Management Records Modernization Act (H.R. 5714), was introduced on November 14, 2014, by Representative Kurt Schrader (D-OR), and passed by voice vote.

Bill Would Authorize States To Impose Carbon Tax To Meet EPA Requirements For Greenhouse Gas Emissions: On December 5, 2014, Representative John Delaney (D-MD) introduced a bill that would authorize states to tax carbon dioxide-emitting industries to meet EPA's proposed Clean Power Plan requirements for cutting emissions of greenhouse gases. The State's Choice Act (H.R. 5796) would specifically give states the option of using an excise tax as a compliance option to meet the EPA requirements for greenhouse gas emissions. The carbon tax rate must be no less than \$20 per metric ton of carbon dioxide or carbon dioxide equivalent in 2015 and must increase each subsequent year by a rate that is no less than 4% above inflation. The bill would require that the tax rate be evaluated in 2025 to ensure that each state that has implemented a tax is on track to achieve their emissions reduction goal by 2030.

Bill Would Authorize Electronic HazMat Shipping Papers: On December 9, 2014, Representative Daniel Lipinski (D-IL) introduced legislation that seeks to authorize the use of electronic shipping papers for hazardous materials transportation. The bill (H.R. 5822) would establish a Hazardous Materials Information Advisory Committee to develop standards for the use of electronic shipping papers for the transportation of hazardous materials, and for other purposes. The bill was referred to the Committee on Transportation and Infrastructure.

Senate Committees Hold Hearing Executive Order On Improving Chemical Facility Safety And Security: On December 11, 2014, the Senate Committees on EPW and Health, Education, Labor, and Pensions held a joint hearing entitled "Oversight of the Implementation of the President's Executive Order on Improving Chemical Facility Safety and Security." Testifying at the hearing were David Michaels, Assistant Secretary of Labor for Occupational Safety and Health, and Mathy Stanislaus, EPA Assistant Administrator for the Office of Solid Waste and

Emergency Response (OSWER). Witness testimony and an archive of the hearing are available [online](#). The hearing was intended to provide the Obama Administration with the opportunity to update the Committees on the steps they have taken to implement Executive Order (EO) 13650 -- *Improving Chemical Facility and Security*. Messrs. Michaels and Stanislaus offered little new information about their respective agencies' efforts to implement the EO, although Michaels did stress the need to modernize the OSHA PSM standard as a means to achieve greater safety at chemical facilities. EPW Chair Barbara Boxer (CA) and fellow Democrat Edward Markey (MA) criticized federal efforts to improve chemical facility safety. Boxer stated that she is "[v]ery concerned that despite the clear risks posed by our nation's chemical facilities, very little progress has been made to improve safety," adding that "[n]o agency has proposed changes to its chemical safety program, and not a single facility faces new federal requirements to adopt safety precautions to reduce chemical hazards." She and Markey argued that hundreds of accidents have occurred at industrial facilities since the West, Texas, explosion that killed a dozen people at a fertilizer plant. They urged Michaels and Stanislaus to tighten regulations to address risks from hazardous chemicals. The lawmakers specifically reiterated their calls for EPA to add ammonium nitrate to the CAA's Risk Management Plan. Markey also criticized federal agencies for doing nothing to reduce risks from chlorine used in wastewater treatment plants. Republican Senators, however, argued that EPA is moving too quickly and could impose changes that would weaken safety at chemical facilities. Ranking EPW member David Vitter (R-LA) stated that the actions EPA and OSHA are considering in response to the EO may actually result in "outcomes contrary to our collective goals, and more specifically may result in less compliance with the law and less safety at these already highly regulated facilities." He noted that EPA has set tighter deadlines for regulatory decisions than OSHA, failing the EO's call for federal agencies to harmonize regulations.

Bill Reauthorizing Great Lakes Restoration Program Clears House: The House of Representatives on December 9, 2014, passed legislation that reauthorizes EPA's Great Lakes Restoration Program (GLRP). The Great Lakes Restoration Initiative Act (H.R. 5764) was sponsored by David Joyce (R-OH) and would fund the program at \$1.5 billion annually for five years. EPA's GLRP funds the remediation of toxic substances and areas of concern, prevention and control of invasive species and their impacts, protection and restoration of near-shore health as well as prevention and mitigation of nonpoint source pollution, and habitat and wildlife protection and restoration. The bill prohibits EPA or any other agency from using the funds authorized for this program for any water infrastructure project save those using green infrastructure techniques. The bill now moves to the Senate for consideration.

MISCELLANEOUS

EPA Revises Draft Guidelines For Ecolabels And Private Performance Standards In Purchasing: On December 1, 2014, EPA revised its draft guidelines for using private sector environmental performance standards and ecolabels in federal purchasing. Changes have been made to a section of the guidelines on environmental effectiveness, which examines the criteria

in environmental standards or ecolabels that support their environmental claims. EPA reportedly is waiting for the White House OMB to update one of its policies before potentially revising other sections of the draft guidelines. The draft guidelines are intended to assist federal procurement officers determine which product environmental standards and ecolabels, among hundreds worldwide, that they should use to meet their sustainability goals. EPA clarified several portions of the environmental effectiveness section of the guidelines, and its position on how product standards should address lifecycle thinking, multiple environmental impacts and where a product could have significant impacts. EPA also, in response to comments, eliminated wording in the section that stated the standards and ecolabels must require that a product's functional performance is consistent with comparable conventional products or standard industry test methods. EPA's response to public comments on its draft guidelines is available at <http://www.epa.gov/epp/draftGuidelines/responses.html>.

EPA Clarifies How Advisers May Address Media: On December 1, 2014, EPA issued guidance on how members of its scientific advisory panels may speak with the media or the public about their recommendations and activities without prior Agency clearance except during panel deliberations. The independent panels include the SAB, the Clean Air Scientific Advisory Committee, and the Advisory Council on Clean Air Compliance Analysis. The policy, *Clarifying EPA Policy regarding Communications between Members of Scientific and Technical Federal Advisory Committees and Outside Parties*, states that advisory committee members are free to respond to broader inquiries as private citizens and are expected to be available to respond to press inquiries except during the deliberative phase of activities when the panels are preparing their advice to the Agency. During deliberations, members of the independent panels should speak with a designated federal official before speaking to the media or public to ensure federal recordkeeping and other requirements are met. The policy clarification on interacting with the media is available at <http://1.usa.gov/1v5Lpie>.

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