

Recent Federal Developments - Nanotechnology & Biobased Products - March 2020

Article By:

Lynn L. Bergeson

NANOTECHNOLOGY

Germany Publishes English Translation Of TRGS 527: Activities With Nanomaterials: The Federal Institute for Occupational Safety and Health (BAuA) has published an English translation of [Technical Rules for Hazardous Substances \(TRGS\) 527: “Activities with nanomaterials.”](#) TRGS 527 contains rules for protection of employees at the workplace during activities with substances, mixtures, and products consisting of or containing nanomaterials. More information is available in our March 2, 2020, [blog item](#).

EU Publishes NanoDefine Methods Manual: On January 28, 2020, the European Union (EU) published [The NanoDefine Methods Manual](#), a collection of three Joint Research Center (JRC) reports developed within the NanoDefine project “Development of an integrated approach based on validated and standardized methods to support the implementation of the European Commission (EC) recommendation for a definition of nanomaterial.” The Manual consists of three parts:

- Part 1: The NanoDefiner Framework and Tools;
- Part 2: Evaluation of Methods; and
- Part 3: Standard Operating Procedures.

NIOSH Publishes Science Blog Item On Nano- And Microplastics In The Workplace: On February 19, 2020, the National Institute for Occupational Safety and Health (NIOSH) posted a Science Blog item entitled [“Are There Nano- and Microplastics in the Workplace?”](#) that reviews workplace exposure to microplastics and nanoplastics. According to NIOSH, its Nanotechnology Research Center (NTRC) has developed approaches for exposure measurement, assessment and mitigation, and hazard characterization for nanomaterials, and many of these approaches would also be applicable to characterize and minimize risk of nano- and microplastics in the workplace. In the absence of occupational exposure limits for nano- and microplastics, NIOSH states that workplace safety efforts should focus on minimizing potential exposure through appropriate engineering controls such as isolation cabinets, exhaust ventilation, and utilizing good industrial hygiene practices.

ECHA Urges Companies To Provide More Data On Nanoforms: The European Chemicals Agency (ECHA) issued a [press release](#) on February 24, 2020, stating that it has received only 95 unique submissions for 36 substances covering nanoforms according to the updated Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation requirements. According to the press release, ECHA is working closely with key industry associations and Member States to understand better the additional actions needed to raise awareness on the legal obligations. ECHA reminds companies that without a valid registration, nanomaterials that fall within the scope of REACH are currently illegally on the market.

EPA Extends Comment Period For Proposed Registration Decision For New Nanosilver Product: According to a February 27, 2020, [memorandum](#) placed in [Docket ID EPA-HQ-OPP-2020-0043](#), EPA received a request to extend the comment period 30 days on a proposal to incorporate a new nanosilver pesticide product into textiles to allow additional time to review the documentation contained in the docket. The memorandum states that EPA “feels that 15 additional days should be sufficient to allow for adequate review of the Proposed Decision and supporting documentation.” As reported in our February 13, 2020 [blog item](#), EPA [announced](#) on February 12, 2020, that it is seeking public input on a proposal to incorporate a new nanosilver pesticide product into textiles to combat odors, discoloration, and other signs of wear. Comments are now due **March 30, 2020**.

ISO Standard Specifies Characteristics And Measurement Methods For Carbon Nanotube Suspensions: The International Organization for Standardization (ISO) has published standard ISO/TS 19808:2020, “[Nanotechnologies -- Carbon nanotube suspensions -- Specification of characteristics and measurement methods](#).” The standard specifies the characteristics to be measured of suspensions containing multi-walled carbon nanotubes (carbon nanotube suspensions). The standard includes the essential and additional characteristics of the carbon nanotube suspension, and the corresponding measurement methods. ISO notes that characteristics specific to health, environmental, and safety issues are excluded from the standard.

SCCS Guidance On Safety Assessment Of Nanomaterials In Cosmetics Published In Regulatory Toxicology And Pharmacology: The EC’s Scientific Committee on Consumer Safety (SCCS) announced on March 3, 2020, that the April 2020 issue of *Regulatory Toxicology and Pharmacology* includes “[The SCCS guidance on the safety assessment of nanomaterials in cosmetics](#).” The article is available for purchase through the *Regulatory Toxicology and Pharmacology* website.

EUON Publishes Nanopinion On Use Of The Term “Nanoplastics”: On March 3, 2020, the EU Observatory for Nanomaterials (EUON) published a Nanopinion entitled “[‘Nanoplastics’ -- it’s a name game](#).” Claire Skentelbery, Director General, Nanotechnology Industries Association (NIA), reviews the difference between engineered (manufactured) nanomaterials and naturally originating (incidental) nanomaterials. Rapid advances in characterizing and understanding engineered nanomaterials will help scientists worldwide to find, identify, and understand the biological interactions of incidental nanoplastics and address their impact on the environment. Skentelbery concludes that “[t]his can enable all measures necessary to reduce their occurrence, reaching back up through the long industrial and societal pathway through which they were produced.” B&C is a proud NIA member.

NIOSH CIB On Practices In Occupational Risk Assessment Addresses Nanomaterials: On March 4, 2020, NIOSH published a [Federal Register notice](#) announcing the availability of its [Current Intelligence Bulletin 69: NIOSH Practices in Occupational Risk Assessment](#). 85 Fed. Reg. 12786.

Appendix C of the Current Intelligence Bulletin (CIB) includes sections addressing nanomaterials risk assessment and alternative methods for nanomaterials. The CIB section on nanomaterials risk assessment includes subsections on dose normalization *in vitro* and *in vivo* and correlation of *in vitro* and *in vivo* responses. The section on alternative methods for nanomaterials includes subsections on comparative potency estimation, hazard classification/clustering, and validation. The CIB notes that a key challenge to using alternative test strategies data is the development and application of validation criteria. More information is available in our

LEGISLATIVE

Environmental Justice Legislation Introduced In The House: On February 27, 2020, Representatives Raúl M. Grijalva (D-AZ), Chair of the Natural Resources Committee, and A. Donald McEachin (D-VA) introduced the Environmental Justice for All Act at a press conference. According to Grijalva's February 27, 2020, [press release](#), the Act includes the following features:

- Creates a Federal Energy Transition Economic Development Assistance Fund -- paid for through new fees on oil, gas, and coal companies -- to support communities and workers as they transition away from greenhouse gas-dependent economies;
- Requires federal agencies to consider cumulative health impacts under the Clean Air Act (CAA) and Clean Water Act (CWA) in making permitting decisions and ensures that permits will not be issued if projects cannot demonstrate a reasonable certainty of no harm to human health;
- Strengthens the Civil Rights Act to permit private citizens and organizations facing discrimination to seek legal remedies, overturning the *Alexander v. Sandoval* ruling; and
- Provides \$75 million in annual grants for research and program development to reduce health disparities and improve public health in environmental justice communities.

House Subcommittee Holds Hearing On FY 2021 EPA Budget: The House Energy and Commerce Subcommittee on Environment and Climate Change [held a hearing](#) on February 27, 2020, on the fiscal year (FY) **2021** EPA budget. The February 24, 2020, [memorandum](#) from Representative Frank Pallone, Jr. (D-NJ), Chair of the Committee on Energy and Commerce, notes that President Trump's (R) FY **2021** budget requests \$6.658 billion for EPA, a \$2.399 billion (26 percent) decrease from the EPA's FY 2020 enacted appropriations. EPA's budget proposal outlines three overarching goals, each of which would be funded well below FY 2020 enacted levels:

- "A Cleaner, Healthier Environment" (including measures related to clean air, clean water, land contamination, and chemical safety) would incur a \$2.005 billion cut (29 percent) from the FY 2020 enacted level;
- "More Effective Partnerships" (including measures to improve cooperation with states and enhance public transparency) would incur an \$80.023 million cut (25 percent) from the FY 2020 enacted level; and
- "Greater Certainty, Compliance, and Effectiveness" (including measures to improve enforcement of environmental laws, permitting processes, efficiency of EPA's operations, and the use of science in policymaking) would incur a \$154.716 million cut (eight percent)

from the FY 2020 enacted level.

Bipartisan Energy Innovation Package Introduced In The Senate: On February 27, 2020, Senators Lisa Murkowski, (R-AK) and Joe Manchin (D-WV) [released the text](#) of the American Energy Innovation Act (AEIA), a bill intended to modernize domestic energy laws to ensure the United States remains a global energy leader while also strengthening national security, increasing international competitiveness, and investing in clean energy technologies. The key provisions in the AEIA focus on energy efficiency; renewable energy; energy storage; carbon capture, utilization, and storage; advanced nuclear; industrial and vehicle technologies; the Department of Energy; mineral security and cyber and grid security and modernization; and workforce development. The Senate Energy and Natural Resources Committee held legislative hearings and business meetings throughout 2019 and, following regular order, reported more than 50 energy-related bills to the full Senate on an individual basis. Most of those measures have now been compiled in the AEIA.

On February 27, 2020, Senate Majority Leader Mitch McConnell (R-KY) filed cloture on the motion to proceed to S. 2657, a Murkowski-Manchin geothermal research and development bill that will serve as the legislative vehicle for the bipartisan energy innovation package. Murkowski filed a [modified substitute amendment](#) on March 5, 2020. Although Senators tried to attach more than 185 amendments to Murkowski's bill, the modified substitute amendment included the text of only 18 amendments -- nine from Senators on each side of the aisle -- that were filed during the floor debate that began on March 4, 2020. Senators John Kennedy (R-LA) and Tom Carper (D-DE) introduced an amendment that would direct EPA to implement a phase down of the production and consumption of hydrofluorocarbons (HFC) over the next 15 years. The amendment contains the text of American Innovation and Manufacturing (AIM) Act (S. 2754), which Kennedy introduced on October 30, 2019. Although the AIM Act has bipartisan support, the amendment was not among the 18 that Murkowski included. Senator John Barrasso (R-WY), Chair of the Senate Committee on Environment and Public Works, opposed the amendment, stating that it should have passed through the Committee. Kennedy has threatened to hold up the entire bill to include the proposal, while the White House stated that it "strongly objects" to the amendment. On March 9, 2020, the Senate failed to end debate on the AEIA and the package of amendments. Murkowski expressed frustration with both Kennedy and Barrasso. On March 11, 2020, the Senate Committee on Environment and Public Works announced that it would hold a legislative hearing on the AIM Act on **March 25, 2020**.

Carper Asks EPA OIG To Investigate Process Irregularities And Potential Illegalties Associated With The SAFE Vehicles And Secret Science Rules: Senator Tom Carper (D-DE), Ranking Minority Member of the Senate Environment and Public Works Committee, announced on March 2, 2020, that he asked the EPA OIG to open an investigation into "potentially unlawful efforts and procedural problems related to the preparation and review of both the draft final Safer Affordable Fuel-Efficient (SAFE) Vehicles rule and the draft supplemental proposal for the Strengthening Transparency in Regulatory Science rule (the so-called 'secret science' rule)." According to Carper's March 2, 2020, [press release](#), he made the request after his office "received reports of seemingly purposeful and potentially unlawful efforts on the part of EPA political officials to avoid the standard processes and statutory requirements associated with proposing and finalizing these two high-profile rules, including potential efforts to conceal documents that should eventually be made public."

Senate Committee Holds Hearing On Securing U.S. Leadership In The Bioeconomy: On March 3, 2020, the Senate Committee on Commerce, Science, and Transportation held a hearing on "[Securing U.S. Leadership in the Bioeconomy](#)." The hearing examined the bioeconomy, the federal

government's role in the bioeconomy, and the potential risks from such research. Witnesses also discussed the necessary policies and practices for the advancement of biotechnology.

House Committee Holds Hearing On Recycling And Waste Management And Its Impacts On Climate Change And The Environment: On March 4, 2020, the House Energy and Environment Subcommittee on Environment and Climate Change held a hearing on "[Reduce, Reuse, Recycle, Reform: Addressing America's Plastic Waste Crisis](#)." The Subcommittee heard testimony about recycling and waste management in the United States, including its impacts on climate and the environment.

Senate Committee Holds Hearing On Nomination Of Douglas Benevento To Be EPA Deputy Administrator: The Senate Committee on Environment and Public Works [held a hearing](#) on March 11, 2020, on several nominations, including the nomination of Douglas Benevento to be EPA Deputy Administrator. According to EPA's February 13, 2020, [press release](#) on the nomination, Mr. Benevento served as EPA Region 8 Administrator from October 2017 through March 2019. He then moved to EPA Headquarters where he has served as Senior Counselor for Regional Management and State Affairs and later as Associate Deputy Administrator. The press release states that he was previously executive director for the Colorado Department of Public Health and Environment, where he managed the state's environmental and public health programs. He also served as the Department's director of environmental programs, where he managed the state's air, water, waste, and consumer protection programs. The press release notes that from 2010 to 2017, Mr. Benevento was working on energy and environmental issues in the private sector at Xcel Energy in various roles, and practiced law at Greenberg Traurig.

House Subcommittee Holds Markup On CFATS And HFCS Legislation: On March 12, 2020, the House Energy Commerce Subcommittee on Environment and Climate Change [held a markup session](#) on legislation (H.R. 6160) to reauthorize the Chemical Facility Anti-Terrorism Standards (CFATS) program and on the American Innovation and Manufacturing Leadership Act of 2020 (H.R. 5544). The Subcommittee passed H.R. 6160, which would reauthorize the CFATS program for 18 months. Without the bill, CFATS will expire in April 2020. The Subcommittee also passed H.R. 5544, which would phase down HFCs over 15 years by limiting production and consumption of regulated HFCs to 15 percent of baseline levels beginning in **2036**. The legislation directs EPA to implement an allowance allocation and trading program to do so, and to establish standards governing the management of HFCs used as refrigerants, including to recover and reclaim used HFCs. It further authorizes EPA to establish schedules for specific sectors to transition to next-generation technologies. H.R. 5544 is a companion bill to S. 2754.

Senate Legislation Would Fund PFAS Cleanup: On March 12, 2020, Senator Jeanne Shaheen (D-NH) introduced legislation with Senators Tom Carper (D-DE) and Chuck Schumer (D-NY) to help communities combat per- and polyfluoroalkyl substances (PFAS) contamination and exposure in drinking water and groundwater. According to Shaheen's March 12, 2020, [press release](#), the Providing Financial Assistance to States (PFAS) for Testing and Treatment Act would provide substantial federal funding for PFAS remediation in drinking water, and groundwater, including private wells. The press release states that the legislation would:

- Increase funding for a newly created grant program within the SDWA State Revolving Loan Fund to \$1 billion per year over the next ten years to go towards the clean-up of PFAS and other emerging contaminants in drinking water. EPA is directed to prioritize this funding to states according to the prevalence and remediation costs associated with PFAS. The eligible use of funds is also extended to the testing and treatment of private wells, which supply

drinking water for over 43 million Americans; and

- Create a new grant program under the CWA that provides funding to states to help remediate groundwater contamination from PFOA and PFOS. This section of the bill requires that groundwater contamination be addressed in accordance with interim guidance issued by EPA in August 2018 or an applicable state, tribal, or other standard, where those exist. These interim requirements will remain in place until EPA acts to designate these chemicals as “hazardous substances” under Superfund. This program would be authorized at \$1 billion per year over the next ten years. EPA is directed to prioritize funding to states according to the prevalence and remediation costs associated with PFAS.

MISCELLANEOUS

CSB Promulgates Final Rule On Accidental Release Reporting: On February 21, 2020, the U.S. Chemical Safety Board and Hazard Investigation Board (CSB) promulgated a [final rule](#) on accidental release reporting. 85 Fed. Reg. 10074. The final rule describes when an owner or operator is required to file a report of an accidental release, and the required content of such a report. CSB states that the purpose of the rule is to ensure that CSB “receives rapid, accurate reports of any accidental release that meets established statutory criteria.” CSB notes that the accidental release reports will require only information that is already known or should be available to an owner/operator soon after an accidental release. To provide the owner/operator more time to gather the necessary information, the final rule has increased the reporting window from four to eight hours. CSB states that the required information is also limited in scope to critical information required for it to make informed decisions about its jurisdiction, interagency coordination, and deployment decision-making. The rule will be effective **March 23, 2020**.

Legislation Introduced To Repeal Safer Consumer Product Regulations: On February 21, 2020, California Assembly Member Laura Friedman (D) introduced legislation (A.B. 3354) that would repeal the provisions of the California Health and Safety Code requiring the California Department of Toxic Substances Control to adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern and to adopt regulations to establish a process for evaluating chemicals of concern in consumer products and their potential alternatives.

New Guidance Portal Provides Public Access To EPA Guidance Documents: On February 28, 2020, EPA [announced](#) that, in support of President Trump’s (R) Executive Order to promote transparency, EPA [launched a new guidance portal](#) that provides public access to its guidance documents. According to EPA, the new searchable database will make it easier for the regulated community to find and follow agency guidance. On October 9, 2019, President Trump issued Executive Order 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents, to promote transparency by ensuring that all active guidance documents are made available to the public. The portal provides an indexed database that allows the public to search for documents based on a range of criteria that include date of issuance, general subject matter, and summary of contents. EPA states that prior to the launch of the portal, it conducted an exhaustive review of its current guidance documents and withdrew those documents that it determined to be no longer relevant. The guidance portal provides a mechanism for the public to request modification or withdrawal of any documents. EPA notes that it uses guidance documents “to clarify existing obligations for interested parties, but not as a vehicle for implementing new, binding requirements on the public.” According to EPA, it will release by **August 28, 2020**, a regulation that establishes the processes and procedures

for issuance of new guidance documents.

EPA Releases Updated IRIS Program Outlook: On February 28, 2020, EPA announced the release of an updated [Integrated Risk Information System \(IRIS\) Program Outlook](#) on the IRIS website. The document describes assessments that are currently in development and their projected public milestones. EPA states that it identified these assessments as high priority needs. The anticipated dates of the IRIS activities communicated in the Outlook are based on several factors, including complexity of the assessment products and the availability of resources.

GAO Recommends Additional Action To Improve EPA Data On Informal Enforcement And Compliance Assistance Activities: On March 2, 2020, the U.S. Government Accountability Office (GAO) issued a report entitled [Environmental Protection: Additional Action Needed to Improve EPA Data on Informal Enforcement and Compliance Assistance Activities](#). GAO states that it was asked to review EPA's enforcement efforts. It examined, among other objectives, the types of information EPA collects on its compliance assistance, compliance monitoring, and enforcement actions. GAO notes that the Office of Enforcement and Compliance Assurance (OECA) does not require regional offices to collect data on compliance assistance or complete data on informal enforcement actions. According to GAO, "[h]aving complete information about its compliance assistance activities and informal enforcement is essential because EPA has elevated the role of such activities in its overall enforcement efforts. However, because EPA is not consistently collecting these data, the agency cannot be sure it is achieving its strategic objectives." GAO made three recommendations:

1. The OECA Assistant Administrator should clearly document in guidance to the regional offices how they should use the definition of informal enforcement actions to collect data on these actions;
2. The OECA Assistant Administrator should clearly document in guidance to the regional offices that they should collect data on compliance assistance activities and specify which mechanism to use to maintain the data, such as the Integrated Compliance Information System (ICIS); and
3. The OECA Assistant Administrator should include the known limitations of data in its annual reports and provide information on the intended use of EPA's data.

GAO states that EPA agreed with its recommendations and stated that the Agency has either begun to or plans to implement them.

Trump Announces Intent To Nominate Dr. Nancy Beck To Chair CPSC: President Trump announced on March 2, 2020, that he intends to nominate Dr. Nancy Beck, Principal Deputy Assistant Administrator for EPA's OCSPP, to be Chair and Commissioner of CPSC. Trump's [press release](#) notes that Dr. Beck has spent the majority of her career in the federal government, serving as a career employee under former Presidents Clinton (D), Bush (R), and Obama (D). Before joining the federal government, Dr. Beck worked for the Washington State Department of Health preparing health and exposure assessments for communities concerned about environmental exposures. Dr. Beck also has experience working in regulatory science policy for the American Chemistry Council. According to the press release, Dr. Beck has a B.S. from Cornell University and a M.S. and Ph.D. in environmental health from the University of Washington.

FTC And FDA Send Warning Letters To Seven Companies About Unsupported Claims That

Products Can Treat Or Prevent Coronavirus: On March 10, 2020, the Federal Trade Commission (FTC) and FDA [announced](#) that warning letters were sent to seven companies for allegedly selling unapproved products that may violate federal law by making deceptive or scientifically unsupported claims about their ability to treat coronavirus (COVID-19). The warning letters are the first issued by the Agencies alleging unapproved and/or unsupported claims that products can treat or prevent COVID-19/coronavirus. More information is available in our [blog](#).

OSHA Publishes Guidance On Preparing Workplaces For COVID-19: The Occupational Safety and Health Administration (OSHA) has published a document entitled [Guidance on Preparing Workplaces for COVID-19](#). OSHA states that it developed the COVID-19 planning guidance based on traditional infection prevention and industrial hygiene practices. The guidance focuses on the need for employers to implement engineering, administrative, and work practice controls and personal protective equipment (PPE), as well as considerations for doing so. OSHA intends the guidance for planning purposes. According to OSHA, employers and workers should use the planning guidance to help identify risk levels in workplace settings and to determine any appropriate control measures to implement. OSHA notes that additional guidance may be needed as COVID-19 outbreak conditions change, including as new information about the virus, its transmission, and impacts, becomes available. OSHA states that the guidance is advisory in nature and informational in content. It is not a standard or a regulation, and it neither creates new legal obligations nor alters existing obligations created by OSHA standards or the Occupational Safety and Health Act. The U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) provides the latest information about [COVID-19 and the global outbreak](#). The OSHA COVID-19 webpage offers [information specifically for workers and employers](#).

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