On February 28, 2020, the U.S. Environmental Protection Agency (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 also 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.

**Madison Le Will Be Director Of EPA’s Chemical Control Division**

Effective **March 15, 2020**, Madison Le will join the U.S. Environmental Protection Agency’s (EPA) Office of Pollution Prevention and Toxics (OPPT) as Director of the Chemical Control Division (CCD). Ms. Le will replace Acting Director Lynn Vendinello. Ms. Le is currently Director of the Fuels Compliance Policy Center within the Office of Air and Radiation. In that capacity, Ms. Le manages the implementation of EPA’s national fuels programs, including the Renewable Fuel Standard Program, Tier 3 Gasoline, Ultra-Low Sulfur Diesel, and Fuels and Fuel Additives Registration. Prior to working for EPA, Ms. Le worked for California’s Los Angeles County on engineering design projects for municipal solid waste landfills and wastewater treatment plants, including air quality modeling and permitting for stationary and mobile sources. Ms. Le holds an M.S. and B.S. in Environmental Engineering from the University of Southern California.

**DOE Announces Biomass R&D Technical Advisory Committee Meeting**

On March 2, 2020, the U.S. Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy (EERE) announced open meetings of the Biomass Research and Development (R&D) Technical Advisory Committee. Occurring on **March 24, 2020, from 8:00 a.m. to 5:00 p.m. (EDT)** and **March 25, 2020, from 1:00 p.m. to 4:30 p.m. (EDT)**, both meetings will take place in Arlington, VA. The purpose of the meetings is to develop advice and guidance that promotes R&D leading to the production of biobased fuels and biobased products. Parties interested in participating in the meeting and/or making oral statements must contact **Dr. Ian Rowe** five days prior to the meetings.

**Helsinki Announces Energy Challenge**

On February 26, 2020, the city of Helsinki announced the opening of applications for the Helsinki Energy Challenge (HEC), which aims to address challenges associated with urban heating produced with coal. According to its press release, Helsinki is one of the leading cities in the transition toward a sustainable future. Its aim is to achieve carbon neutrality by **2035**. Currently, however, Helsinki needs solutions to meet its heat demand. Given Finland’s coal ban starting in **2029**, Helsinki is seeking heating solutions that go beyond coal and beyond burning biomass. Helsinki Mayor,
Jan Vapaavuori, stated that “[s]olving the urban heating challenge is crucial to reach global climate goals. Cities have a key role to play in the transition to a low carbon economy, and Helsinki is now taking an initiative to lead the way.” The city is inviting innovators from around the world to use Helsinki as a test bed to develop fossil-free and sustainable solutions in the fight against global warming.

Proposed solutions will be evaluated based on:

- Climate impact;
- Impact on natural resources;
- Implementation schedule and feasibility;
- Reliability and security of supply; and
- Capacity.

HEC is open globally to consortiums, start-ups, established companies, research institutions, universities, research groups, and individual experts. Applications will be accepted until May 31, 2020. Finalists will be invited to a co-creation phase in early July 2020, which will include a 3-day boot camp, where they will be provided support to develop their proposals. After the boot camp, finalists will present their proposals to an international jury of experts, who will name the winner or winners. To be presented in November 2020, the winning solution will be awarded one million euros.

**USPTO Announces Nominations Opportunity For NMTI**

On February 25, 2020, the U.S. Patent and Trademark Office (USPTO) announced that nominations are now open for the 2020 National Medal of Technology and Innovation (NMTI) to recognize those who have worked to advance U.S. competitiveness and quality of life and who have strengthened the workforce through technological innovations. The award is presented annually by the President of the United States to leading technological honorees. Applications will be accepted until April 3, 2020, for individuals, teams (up to four individuals), companies, and company divisions that have contributed to the U.S. economic, environmental, and social well-being. Nominees will be considered for up to three consecutive years. Initial selections will be made by the NMTI Nomination Evaluation Committee, which reviews applications and makes recommendations to the U.S. Secretary of Commerce. The committee will then make recommendations to the President for final selection. Further information is available in this recorded webinar.

**FDA Requests Comments On Its Licensed Biological Products Database**

On March 5, 2020, FDA opened a public docket for comments on its enhancement of the Purple Book, which is otherwise known as FDA’s “Database of FDA-Licensed Biological Products.” As reported in B&C’s biobased products blog on February 28, 2020, FDA is working to expand the Purple Book by transitioning from its current table list format to a searchable online database for all approved biosimilar
products and their reference products. These upgrades will be released in multiple phases. FDA has now completed phase I, which consists of the full search functionality of the database. Subsequent phases will include the expansion of the number of FDA-licensed biological products included in the Purple Book online database until the final release, which will include information about all FDA-licensed biological products.

The first phase of the upgrade includes information about a product’s proprietary and proper names, the full product label, dosage form, route of administration, strength, and marketing status, among other information. Given its completion, FDA is now requesting comments from stakeholders until May 4, 2020.

**FDA Announces Educational Initiative To Inform Consumers Of GE Foods**

On March 4, 2020, the U.S. Food and Drug Administration (FDA), in collaboration with EPA and the U.S. Department of Agriculture (USDA), launched a new initiative called “Feed Your Mind” to help consumers better understand genetically engineered (GE) foods. Consisting of science-based information, the initiative’s features include a wide range of resources designed to teach consumers, health care professionals, and students about what a genetically modified organism (GMO) is, how GMOs are created and grown, the types of crops that can be GE, and to address questions about the health and safety of GMOs. “Feed Your Mind” also includes an explanation of how GMOs are regulated in the United States. Materials available through the initiative include new web content, videos, graphics, fact sheets, and stories, which include historical information on GMOs in agriculture. The initiative is launching in phases, and FDA expects that more resources will become available later in 2020 and 2021, including professional learning series for dietitians and a supplemental science curriculum for high schools. According to the three agencies, the materials available are based on extensive formative research after input from stakeholders and experts in biotechnology, education, and communications.

**Guidance On Biological Product Transition Issued By FDA**

On March 4, 2020, FDA announced that it has issued in final a guidance for industry titled “The ‘Deemed to be a License’ Provision of the BPCI Act: Questions and Answers,” which addresses FDA’s “transition” provision of the BPCI Act. Established in 2009, the Biologics Price Competition and Innovation Act (BPCI Act) deemed applications for an approved biological product under Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to be a license for the biological product under Section 351 of the Public Health Service Act (PHS Act) as of March 23, 2020. Aiming to make the BPCI Act implementation process smoother, FDA has published the guidance for industry as part of the “transition” provision of the Act. The transition of biological products currently regulated under the FD&C Act to the PHS Act will allow for the submission and approval of marketing applications for new biosimilar or interchangeable biological products. The guidance follows FDA’s recent issue of the new definition of the term “biological product,” announced on February 21, 2020, per Bergeson & Campbell, P.C.’s (B&C®) February 28, 2020, blog item.
IEDA Opens Applications For Renewable Chemicals Production Tax Credit

The Iowa Economic Development Authority (IEDA) is offering the first Renewable Chemicals Production (RCP) Tax Credit in the United States. What does this mean? It means that the program provides an opportunity for industry stakeholders to advance Iowa’s economy through a focus on biomass as a feedstock for the production of renewable chemicals. As an attempt to incentivize the production of 30 high-value chemicals derived from biomass feedstocks, IEDA developed the RCP Tax Credit program to “capitalize on its resources and infrastructure and to capture the renewable chemical manufacturing industry.” IEDA is offering tax credit of $0.05 per pound of renewable chemical produced. Start-ups can receive up to $1 million in credit, and established businesses can earn up to $500,000. Applications are open until March 15, 2020, for chemicals produced in 2019.

USDA Requests Comments On Updates To Technical Guidelines For GHG Quantification And Carbon Sequestration

On March 4, 2020, USDA announced that it is now accepting comments on its technical guidelines and science-based methods to quantify greenhouse gas (GHG) sources and sinks from the agriculture and forest sectors at the entity-scale. USDA intends to update the technical guidelines based on newly available data and methodologies within the next three years. Interested parties must submit comments on or prior to April 20, 2020.

©2020 Bergeson & Campbell, P.C.

Source URL: https://www.natlawreview.com/article/brag-biobased-products-blog-march-6-2020