

BRAG Biobased Products Blog: October 11, 2019



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Friday, October 11, 2019

Negotiated Agreement On RFS

On October 4, 2019, U.S. Environmental Protection Agency (EPA) Administrator, Andrew Wheeler, and U.S. Department of Agriculture (USDA) Secretary, Sonny Perdue, [announced President Trump's negotiated agreement on the Renewable Fuel Standard \(RFS\)](#). Under the agreement, EPA and USDA will undertake the following actions:

- In a forthcoming supplemental notice building off the recently proposed **2020** Renewable Volume Standards and the Biomass-Based Diesel Volume for **2021**, EPA will propose and request public comment on expanding biofuel requirements beginning in **2020**.

- EPA will seek comment on actions to ensure that more than 15 billion gallons of conventional ethanol be blended into the nation's fuel supply beginning in **2020**, and that the volume obligation for biomass-based diesel is met. This will include accounting for relief expected to be provided for small refineries.
- EPA intends to take final action on this front **later this year**.
- In the most recent compliance year, EPA granted 31 small refinery exemptions.
- Building on the President's earlier decision to allow year-round sales of E15, EPA will initiate a rulemaking process to streamline labeling and remove other barriers to the sale of E15.
- EPA will continue to evaluate options for [renewable identification number] RIN market transparency and reform.
- USDA will seek opportunities through the budget process to consider infrastructure projects to facilitate higher biofuel blends.
- The Administration will continue to work to address ethanol and biodiesel trade issues.

EPA Administrator Wheeler commended Trump's leadership in this matter, stating that this agreement continues to promote domestic ethanol and biodiesel production in support of U.S. farmers. In addition, the agreement, according to USDA Secretary Perdue, found a way to pursue policy that promotes economic growth and energy security. A number of other elected officials also applauded Trump's agreement.

FDA Publishes Technical Specifications Guidance For Bioanalytical Methods Templates

On October 3, 2019, the U.S. Food and Drug Administration (FDA) announced that a [technical guidance for industry titled "Bioanalytical Methods Templates" is now available](#). The technical specifications guidance provides ready-to-use templates for sponsors to submit summaries of bioanalytical methods used in clinical pharmacology studies that require pharmacokinetic concentration evaluation. The templates provided are applicable to bioanalytical procedures such as chromatographic assays (CC) and ligand-binding assays (LBA) that quantitatively determine the levels of drugs and their metabolites and therapeutic proteins in biological matrices such as blood, serum, plasma, urine, and tissue such as skin. The templates in this guidance can be used for new drug applications (NDA), biologics license applications (BLA), and supplements to these applications to provide information regarding bioanalytical methods for pharmacokinetic assessments.

Government Of Quebec Publishes Draft Regulation On Renewable Fuel Minimum Volume

On October 2, 2019, the [government of Quebec, Canada, published in its *Official Gazette* a notice of a draft regulation setting standards for the integration of renewable fuels into gasoline and diesel fuel.](#) Under the draft regulation, the standards will apply on **July 1, 2021**, and will then increase. As of **July 1, 2025**, the integration of a minimum volume of ethanol of 15 percent into gasoline and a minimum volume of biobased diesel fuel of 4 percent into diesel fuel will be required. Given the evaluation by the Canadian government of this matter, the notice states that the proposed regulation would have no particular impact on small and medium-sized businesses because the petroleum products distribution sector is made up of large businesses. Also on **July 1, 2025**, enterprises subject to the regulation will invest a total of 110 million Canadian dollars in infrastructure to comply with the set standards for the integration of renewable fuels into gasoline and diesel fuel.

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