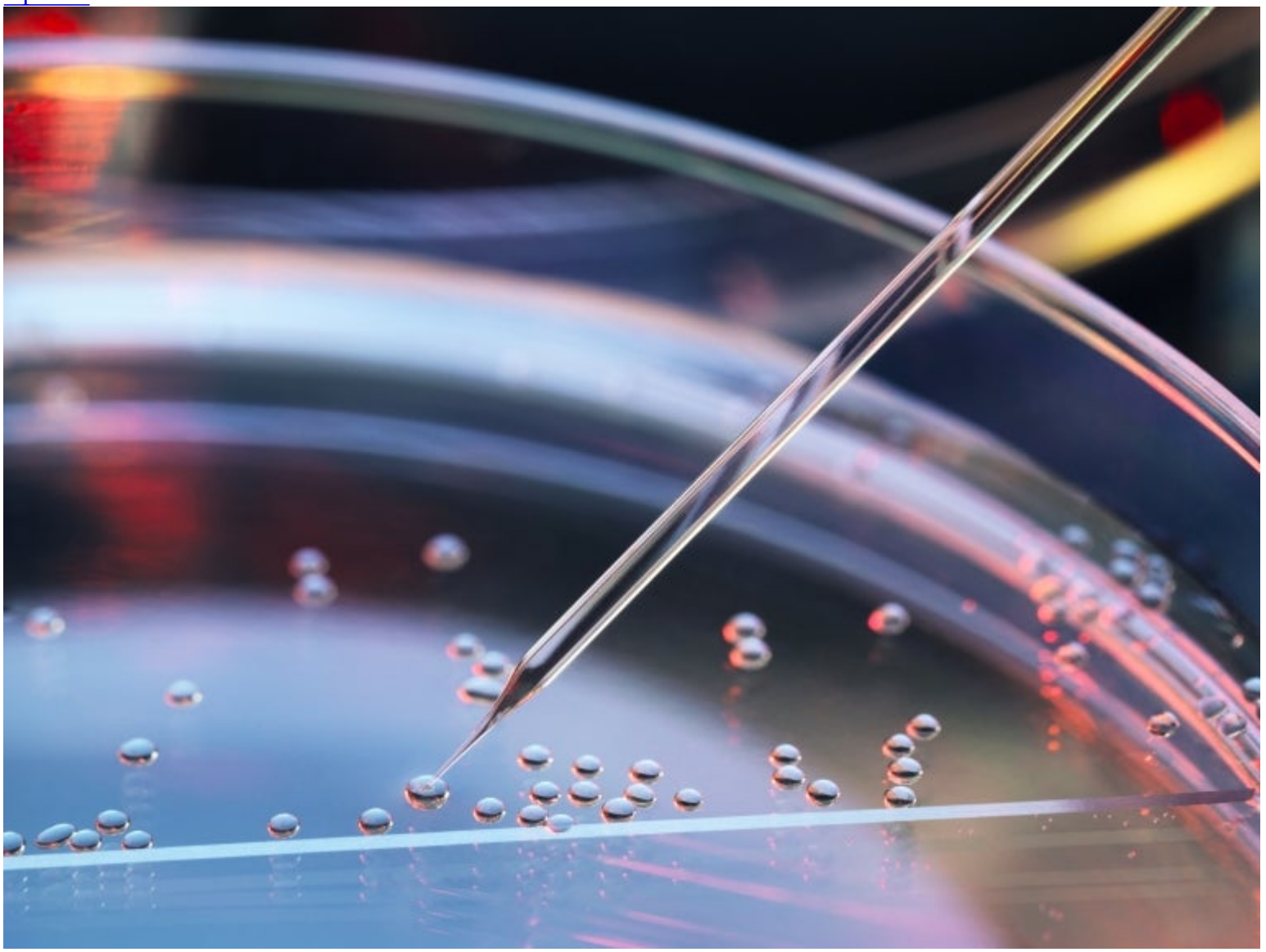
Updates



In a recently published Request for Information (RFI), the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) seeks public comment on options to potentially streamline and reduce the regulatory burden for modified microbes consistent with current APHIS regulations at 7 C.F.R. Part 340 covering the movement of organisms modified or produced through genetic engineering. The agency is currently accepting comments until September 3, 2024.

How the U.S. Government Regulates Biotechnology

The federal government regulates biotechnology products under the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework). First established in 1986, with updates in 1992 and 2017, the

Coordinated Framework outlines a comprehensive federal regulatory policy for oversight of biotechnology products under existing federal statutes implemented by the U.S. Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), and USDA. The Coordinated Framework describes the roles and responsibilities of each agency based upon a product's particular use and sets out key principles for regulatory oversight, with the overarching goal of facilitating the protection of public health and the environment while simultaneously promoting innovation.

Turning to USDA, in particular, APHIS administers the Animal Health Protection Act (AHPA) and the Plant Protection Act (PPA). Through these federal statutes and their implementing regulations, USDA regulates products of biotechnology that may pose a risk to agricultural plant and animal health. Additionally, pursuant to the Virus-Serum-Toxin Act (VSTA), USDA regulates products of biotechnology that are included in veterinary biologics and aims to ensure that veterinary biologics are pure, safe, potent, and effective.

Recent Developments

In December 2022, the Office of Science and Technology Policy (OSTP) issued a notice of request for information on the regulation of biotechnology on behalf of USDA, FDA, and EPA. The December 2022 RFI sought to identify regulatory ambiguities, gaps, inefficiencies, or uncertainties in the Coordinated Framework with a particular emphasis on new and emerging biotechnology products. APHIS's July 2024 RFI stems from responses to the December 2022 OSTP RFI. In particular, in response to the OSTP RFI, multiple commenters expressed a need for clear regulatory pathways to commercialization for modified microbes.

Additionally, in 2023, APHIS published a Draft Guide for Submitting Permit Applications for Microorganisms Developed using Genetic Engineering Under 7 CFR part 340 and, subsequently, a Revised Draft Guide. APHIS received comments to this Draft Guide similar to those received to the RFI related to potential pathways to commercialization for modified microbes. For example, some commenters noted that there were no processes for modified microbes similar to the up-front exemptions at § 340.1 and the Regulatory Status Review process at § 340.4 for modified plants. As such, APHIS is now requesting stakeholder comments regarding pathways to commercialization, including needs, ideas, and concerns, regarding possible APHIS risk-based deregulation of modified microbes and other potential regulatory and nonregulatory pathways to commercialization.

USDA's July 2024 RFI

APHIS explains that the requested information will help the agency to identify potential criteria and mechanisms for risk-based deregulation, develop a regulatory framework that could inform future rulemaking, and identify potentially viable nonregulatory solutions for APHIS Biotechnology Regulatory Services to improve coordination with APHIS's Plant Protection and Quarantine and the EPA.

APHIS specifically asks for feedback on the following six questions:

1. Describe new or emerging categories of biotechnology products that are relevant to the development and use of modified microorganisms. To assess new and emerging technologies with modified microbes, what expertise and resources are needed in the government to evaluate the overall plant pest risk of modified microbes?
2. Describe areas where the clarity and/or efficiency of regulations governing modified microorganisms could be improved (*e.g.*, definitions that need to be provided or revised, barriers to obtaining the data necessary to achieve commercialization).
3. Describe key elements of a regulatory framework that would enable a scientifically sound assessment of a modified microorganism's plant pest risk, in order to inform regulatory decision-making by APHIS.

    1. Describe any biological features of microorganisms that APHIS should consider when determining whether a modification changes the plant pest risk, and thus the regulatory status of a modified microorganism (*e.g.*, the potential for horizontal gene transfer, the production of airborne spores, its ecological role, or the ability to remain dormant for long periods of time).
    2. What criteria, data, and information should be considered when assessing a modified microorganism's plant pest risk?
    3. What should APHIS consider when determining whether modification of a biocontrol organism could result in it posing a plant pest risk? Provide scientific evidence to support which types of biocontrol organisms and methods could or could not pose a plant pest risk.
4. How should modified microorganisms with multiple uses (*e.g.*, developed for both biomedical or pharmaceutical purposes and agricultural purposes) be regulated and evaluated by APHIS? What steps should APHIS take to ensure efficient and appropriate oversight and evaluation when a product is subject to regulation and review by both USDA and another federal agency?
5. Should APHIS consider risk-based exemptions for certain types of microorganisms, or for certain modifications in microorganisms? If so, please provide examples of the types of modified microorganisms that should be exempt from regulation and provide scientific evidence to support which modifications and types of microorganisms should or should not be exempt.
6. Are there any other specific issues or topics APHIS should consider in developing a regulatory framework for assessing the plant pest risk of modified microorganisms, or possible pathways to commercialization for modified microorganisms?

This RFI provides developers and other interested stakeholders an opportunity to help shape a clearer and more streamlined regulatory pathway for modified microbes—an essential component to further promoting innovation in agricultural industries and beyond.

All comments should be received by APHIS on or before September 3, 2024.

Perkins Coie's Food & Beverage team includes a former USDA regulatory lawyer. We regularly interface with APHIS and provide strategic advice for navigating new and emerging rules and policies at APHIS and related agencies. If you have any questions concerning the material discussed in this Update, please contact the authors.

Authors

Brian P. Sylvester

Partner
BSylvester@perkinscoie.com 202.434.1669

Sichang (Cathie) Chen

Associate
SChen@perkinscoie.com

Explore more in

Food & Beverage Food & Consumer Packaged Goods Litigation

Related insights

Update

Wrapping Paper Series: Issues and Trends Facing the Retail Industry During the Holiday Season

Update

Privacy Law Recap 2024: Regulatory Enforcement