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Request for Information: Identifying Ambiguities, Gaps, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology

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WASHINGTON, December 20, 2022 – Today, the White House Office of Science and Technology Policy (OSTP)—in coordination with the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) requests relevant data and information, including case studies, to help identify regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework for Regulation of Biotechnology, particularly as related to new and emerging biotechnology products. Information provided will help regulatory agencies improve the clarity and efficiency of the regulatory processes for biotechnology products as described in Executive Order 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy.”

Executive Order 14081 promotes advancing biotechnology and biomanufacturing for innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security. It supports the just and equitable investment of resources to benefit all Americans, especially those in underserved communities, as well as the broader global community.

All information received in the docket by February 3, 2023, will be considered by EPA, FDA and USDA as part of their efforts to identify regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework.

The Request for Information (RFI) is available at: [Federal Register: Request for Information: Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology](#).

All comments should be received on or before February 3, 2023. Information can be submitted through either of the following methods (the eRulemaking Portal strongly preferred):

- Federal eRulemaking Portal: Go to [Regulations.gov](#). Enter APHIS-2022-0076 in the Search field. Select the Documents tab, then select the Comment button in the list of documents and follow the instructions to submit your comment.
- Postal Mail: Send your comment to Docket No. APHIS-2022-0076, APHIS, Biotechnology Regulatory Services, Unit Number 146, 4700 River Road, Riverdale. MD, 20737.
- Listening Session: OSTP will host a virtual public listening session on January 12, 2023. To register for the listening session and sign up to make a public comment, please go to https://www.zoomgov.com/webinar/register/WN_lhbckX4VTiacK0AsyiikKQ. A summary of the comments offered during the public listening session will be posted to the docket on [Regulations.gov](#).

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