EPA, FDA, and USDA Release Tool to Help Biotechnology Developers Navigate Regulatory Landscape

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The U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) are releasing a new web-based tool on the Unified Website for Biotechnology Regulation for companies that develop microbial biotechnology products . Biotechnology products include plants, animals, and microorganisms developed through genetic engineering or the targeted manipulation of genetic information. The tool provides a starting point for researchers and developers, especially those new to biotechnology product development, to navigate the regulatory requirements for genetically modified microorganisms. This advancement helps meet the President’s goals, outlined in Executive Order 14081, of ensuring public confidence in the biotechnology regulatory system and improving its transparency, predictability, coordination, and efficiency.

The federal government established the Coordinated Framework for the Regulation of Biotechnology in 1986 and most recently updated it in 2017. It describes federal policy for ensuring the safe use of biotechnology products, including how EPA, FDA, and USDA share responsibility for regulating those products. Through a December 2022 Request for Information (RFI), stakeholders identified regulatory ambiguities, gaps, and inefficiencies within the framework. Commenters requested greater

coordination among the three agencies, and more assistance with the regulatory process for biotechnology products. The new tool is in response to this feedback, and part of a broader EPA, FDA, and USDA plan to modernize the Coordinated Framework.

The tool provides users, through a series of prompts, with information on regulatory requirements for biotechnology products developed using genetically modified microorganisms and the approval process across agencies. The tool reflects input from biotechnology organizations of varying sizes that were selected by the Science and Technology Policy Institute to participate in early testing in August 2024. As part of the agencies' commitment to continuous improvement, they will continue to expand the tool's utility, scope, and user base. A built-in feedback function allows all stakeholders to submit feedback directly to the agencies.

The three agencies are also undertaking other work to address the goals and directives in E.O. 14081. This includes aligning USDA and EPA data requirements to improve data transferability and reduce duplicative review of biotechnology products. Additionally, USDA recently issued a request for information to explore less burdensome pathways to commercializing genetically modified microbes.

View the new tool.