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EPA, FDA, and USDA issue joint regulatory plan for biotechnology

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To clarify and streamline regulatory oversight for genetically engineered plants, animals and microorganisms



In response to US President Biden's Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA), and the US Department of Agriculture (USDA) have developed a plan to update, streamline, and clarify their regulations and oversight mechanisms for products of biotechnology.

The plan helps meet the President's goals of ensuring public confidence in the biotechnology regulatory system and improving its transparency, predictability, coordination, and efficiency. Through engagement with developers and stakeholders, as well as horizon scanning for novel biotechnology products, the Agencies worked collaboratively to develop a cohesive plan.

It incorporates processes and timelines to implement regulatory reform, such as identifying guidance and regulations to update, streamline, or clarify, and identifying the potential need for new guidance or regulations. The plan supports a whole-of-government approach to the regulation of biotechnology products.

The agencies have identified five major areas of biotechnology product regulation where these actions will focus:

1. Modified plants
2. Modified animals
3. Modified microorganisms
4. Human drugs, biologics, and medical devices
5. Cross-cutting issues

EPA, the FDA and USDA intend to clarify and streamline regulatory oversight for genetically engineered (GE) plants, animals and microorganisms; update and expand their information sharing through an MoU to improve and broaden communication and coordination of oversight of modified microbes; and undertake a pilot project focused on modified microbes to explore and consider the feasibility and costs of developing a web-based tool that informs developers about which agency may regulate a given product category.