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EPA Renews Biotechnology Innovation Efforts under New Executive Order

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On September 12, 2022, President Biden issued an <u>Executive Order (EO)</u> calling on his Administration to renew efforts to improve the clarity and efficiency of regulatory processes for biotechnology products. Launching a new "National Biotechnology and Biomanufacturing Initiative," the EO is intended to advance policies that promote innovative biotechnology and biomanufacturing solutions in "health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security."

Among its directives, the EO calls on the U.S. Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA) to identify areas of ambiguity, gaps, or uncertainties in the January 2017 Update to the Coordinated Framework for the Regulation of Biotechnology and EO 13874, Modernizing the Regulatory Framework for Agricultural Biotechnology Products. Specifically, the EO charges the agencies with:

- Providing plain-language information to the public regarding the regulatory roles, responsibilities, and processes of each agency as they relate to biotechnology products;
- Identifying regulations and guidance that they can update, streamline, or clarify; and
- Providing annual updates to identify gaps in statutory authority to address in order to improve the clarity and efficiency of the regulatory process for biotechnology products.

The EO also directs EPA, USDA, and FDA to build on the Unified Website for Biotechnology. The website update will allow developers of biotechnology products to inquire about a particular product and promptly receive a single, coordinated response providing information and informal guidance regarding the process that the developers must follow for Federal regulatory review.

In addition, the EO requires USDA to assess how to use biotechnology and biomanufacturing for food and agriculture innovation. Issues USDA will evaluate include improving sustainability and land conservation, increasing food quality and nutrition, increasing and protecting agricultural yields,



protecting against plant and animal pests and diseases, and cultivating alternative food sources.

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