

President Biden Signs Executive Order 14081 to Promote Biotechnology and Biomanufacturing

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In the latest of a series of Presidential actions intended to promote biotechnology and confirm the continued support of advances in biotechnology as official policy of the United States, on September 12, 2022, President Joe Biden signed Executive Order 14081 that will build on and expand biotech-promoting policies of the Obama and Trump Administrations. President Biden's September 12 Executive Order, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy* (EO 14081), is intended, *inter alia*, to "accelerate biotechnology innovation and grow America's bioeconomy across multiple sectors, including a range of industries, including health, agriculture, and energy."¹

Since the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) was first issued in 1986, it has been the asserted policy of the United States to promote the beneficial utilization of biotechnology. In 2015, President Obama initiated a significant effort to update and modernize the Coordinated Framework to make it more useful and efficient in the face of the ever-increasing pace of technological advances in genetic engineering.² The Trump Administration followed this with Executive Order 13874, which required the Coordinated Framework agencies to continue the work started during the Obama Administration to update the regulatory policies and procedures applicable to biotech products.³ President Biden's EO 14081 constitutes a significant step forward to require U.S. federal agencies to take positive steps to translate biotechnology innovations into actual manufacturing and economic developments.

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EO 14081 announces the initiation of a “whole-of-government approach” to launch a National Biotechnology and Biomanufacturing Initiative (the Initiative) that will engage numerous federal agencies in the development of policies that can support the bioeconomy. This will include the development of a number of reports by various agencies to “further societal goals related to health, climate change and energy, food and agricultural innovation, resilient supply chains, and cross-cutting scientific advances.”⁴ The agencies required to submit reports include the U.S. Department of Health and Human Services (HHS), the U.S. Department of Energy (DOE), the U.S. Department of Agriculture (USDA), the U.S. Department of Commerce (DOC), and the National Science Foundation (but not, interestingly, the U.S. Environmental Protection Agency, although EPA will presumably be identified by USDA as an “appropriate agency” to consult with in developing the USDA report).

Section 8 of EO 14081 addresses the regulations applicable to biotechnology, and, as the basis for justifying action, states “[t]he complexity of the current regulatory system for biotechnology products can be confusing and create challenges for businesses to navigate.” To address this regulatory complexity, uncertainty, and confusion, the EO requires USDA, EPA, and FDA to identify “areas of ambiguity, gaps, or uncertainties” in the updated Coordinated Framework or in policy changes made pursuant to Executive Order 13874. The agencies are then to provide a plan to implement regulatory reforms that will provide more streamlined processes and greater clarity to the regulated biotechnology community. The goal is that improvements to the applicable regulatory processes will help to bring biotech products to market more efficiently.

In addition, the EO requires federal agencies to implement policies that focus on expansion of “biomanufacturing.” This is to be accomplished by “improving processes and developing infrastructure.” Specifically, agencies are to focus on advancing emerging technologies, addressing supply chain development challenges, creating incentives for the expansion of industrial biomanufacturing capacity in the defense sector, and supporting and accelerating “bioenergy” and bioscience advances.

On September 14, the White House hosted a briefing to discuss and expand on the multi-faceted approach to promoting and expanding the U.S. bioeconomy and the \$2 billion investment that the administration intends to make in biotechnology and biomanufacturing. During the briefing, Deputy Secretary of Agriculture Jewel Bronaugh provided examples of actions that USDA will take to further the goals of President Biden’s policy initiative. These USDA actions will include developing a partnership for “climate-smart” commodities that will invest in commodities and create climate-smart market opportunities for agricultural producers; investing \$68 million to train the next generation of ag researchers, educators, and extension professionals; expanding the BioPreferred Program to further promote the development, marketing, and use of biobased products; and, critically, a \$500 million investment to support the development of innovative, sustainable American fertilizer. Deputy Secretary Bronaugh also committed USDA to developing new regulatory processes to promote the safe innovation of agriculture and alternative foods.

The above summary barely skims the surface of the comprehensive action plan set forth in the EO. The initiatives and federal actions announced in EO 14081 constitute the most comprehensive, coordinated, and committed action plan ever devised by a U.S. administration to promote the development of the U.S. biotech economy and manufacturing base. Of particular importance will be the development of new regulatory

policies that will facilitate agricultural biotech and chemicals manufacturing. Wiley's Environment and Product Regulation group will closely monitor the evolution of the applicable regulatory processes to ensure that our clients can navigate these new processes most effectively. Also, an upcoming edition of the Wiley podcast, Keith Matthews and Chris Wozniak: Talking Ag Biotech, will focus on an in-depth discussion of the Executive Order and what it could mean for ag biotech in the United States.

1 <https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/12/fact-sheet-president-biden-to-launch-a-national-biotechnology-and-biomanufacturing-initiative/>

2 <https://obamawhitehouse.archives.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology>

3 <https://trumpwhitehouse.archives.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>

4 Section 3.