

Executive Order on Advancing Biotechnology and Biomanufacturing Innovation: Modernizing Regulation Under the Coordinated Framework

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On September 12, 2022, the Biden administration issued the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (Executive Order)¹. The Executive Order is important to regulated entities in this space because it may result in streamlining the existing Coordinated Framework for Biotechnology and thus ease the path to market for a range of innovative products using synthetic biology or genome editing.

The overall intent of the Executive Order is to bring a “whole-of-government” approach to the advancement of economic activity derived biotechnology and biomanufacturing (i.e., the bioeconomy) in the United States and to foster innovative solutions across health, climate change, energy, food security, agriculture, the supply chain, and national and economic security. The COVID-19 pandemic highlighted the critical role of biotechnology and biomanufacturing in addressing global healthcare needs. The Executive Order emphasizes the potential application of these industry sectors across the broader bioeconomy.

Of particular note for the biotechnology industry, the Executive Order aims to

- bolster federal investment in key research and development areas of biotechnology and biomanufacturing
- improve and expand domestic biomanufacturing production capacity and processes
- train and support a diverse, skilled workforce to advance biotechnology and biomanufacturing
- clarify and streamline regulations

Importantly, the Executive Order contains a promise to clarify — and potentially simplify — regulator pathways for genome-edited microorganisms used in fermentation and related manufacturing processes. The currently applicable regulatory framework, known as the Coordinated Framework, was established in 1986. Like the current Executive Order, the Coordinated Framework seeks to strike a balance between regulation that protects public health and the environment and allowing for flexibility to

avoid impeding innovation.

Based on an understanding of biotechnology as simply an extension of existing methods of production, the Coordinated Framework directed regulatory agencies, including the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and Department of Agriculture (USDA), to rely on existing statutory frameworks to regulate the products of biotechnology. As such, regulatory authority is distributed among multiple agencies depending on the nature of the product. This often results in multiple overlapping — and evolving — regulatory requirements for products relying on synthetic biology or genome editing, including fermentation-based products. Despite the fact that the Coordinated Framework was updated in 2017 to “to increase public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness,”² determining the appropriate route to market continues to be complex for those using fermentation processes.

The Executive Order also nods to the increasing importance of genomics data in the bioeconomy and promises support to ensure that such data is interoperable and available over the long term. Both of these reflect long-term goals of industry and academic researchers alike and stake the administration’s position on the importance of such data for ongoing U.S. innovation.

Regulatory Streamlining

As noted above, the Executive Order explicitly recognizes these challenges and calls for regulatory clarity and efficiency. This will all take place on a relatively short turnaround. The FDA Commissioner, USDA Secretary, and EPA Administrator are asked to engage with developers and external stakeholders to provide the administration, no later than 180 days from the date of the order (March 11, 2023), with information identifying ambiguity, gaps, or uncertainties in the Coordinated Framework and its related updates.

The Agencies are also instructed to provide to the general public, within 100 days thereafter, “plain-language information regarding the regulatory roles, responsibilities, and processes of each agency, including which agency or agencies are responsible for oversight of different types of products developed with biotechnology, with case studies, as appropriate.” To further facilitate innovation, the agencies must include this information on the existing Unified Website for Biotechnology Regulation³. Even more, the agencies are tasked to develop a one-stop shop for “developers of biotechnology products to submit inquiries about a particular product and promptly receive a single, coordinated response that provides, to the extent practicable, information and, when appropriate, informal guidance regarding the process that the developers must follow for Federal regulatory review[.]”

This is an important opportunity for regulators and industry alike to revisit the mechanisms being applied to the products and processes of fermentation-based production, including FDA’s General Recognition of Safety notification process; USDA’s Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) Rule; EPA’s regulation of biotechnology under the Toxic Substances Control Act (TSCA) Microbial Commercial Activities Notification (MCAN) process; the Federal Food, Drug and Cosmetic Act (FDCA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and other laws governing whether a biotechnology product could adversely affect human health or the environment. Stakeholders should use this unique opportunity to identify and advocate for clarity regarding the scope and applicability of these for their current and future innovations.

¹ [Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy](#) (Sept. 12, 2022).

² [Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology](#) (Jan. 2017).

³ [USDA, FDA, EPA, The Unified Website for Biotechnology Regulation](#).

CONTACTS

Emily Marden , Senior Counsel	+1 415 772 1235, <u>emarden@sidley.com</u>
Diane C. McEnroe , Partner	+1 212 839 5621, <u>dmcenroe@sidley.com</u>
Maureen F. Gorsen , Partner	+1 310 595 9644, <u>maureen.gorsen@sidley.com</u>
Kevin A. Sforza , Managing Associate	+1 202 736 8413, <u>ksforza@sidley.com</u>

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