



Policy Update: White House Announces Executive Order to Decrease Regulatory Burden on Agricultural Biotechnology

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On June 11, President Trump announced a new executive order (EO), “Modernizing the Regulatory Framework for Agricultural Biotechnology Products,” intended to enhance coordination across relevant agencies and decrease the regulatory burden associated with agricultural biotechnology. The EO directs the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to streamline regulations and promote innovation and public confidence in both regulations and products. The EO defines agricultural biotechnology as a plant, animal or derived product developed through genetic engineering or through “targeted in vivo or in vitro manipulation of genetic information, with the exception of plants or animals, or the products thereof, developed for non agricultural [sic] purposes, such as to produce pharmaceutical or industrial compounds.”

The EO recommends that agencies base decisions on scientific and technical evidence, to review applications in a timely and efficient process, ensure “transparency, predictability, and consistency of the regulation of products of agricultural biotechnology,” make regulatory determinations based on “risks associated with the product” and “intended use,” and urge trade partners to “adopt science- and risk-based regulatory approaches.” Agency leadership has been given 180 days to identify regulations that can be streamlined and to use existing authority to exempt “low-risk” products from undue regulation. The EO builds on the recommendations released by the Interagency Task Force on Agriculture and Rural Prosperity in January 2018.

EPA, FDA, and USDA currently steward the Coordinated Framework for the Regulation of Biotechnology, which was established in 1986 and gives distinct roles to each agency in the oversight of products encompassing human, animal, plant, and environmental health. These roles and associated reporting requirements can often be complex for stakeholders attempting to certify new products. As such, the EO also tasks the agencies with the creation of an online portal that can more easily connect researchers and product developers with relevant resources. Additionally, the EO charges the agencies with developing a domestic engagement strategy to build public trust in biotechnology that supports research and education on effective science communication, integrates biotechnology into science education, creates “consumer facing web content,” and develops materials that communicate the safety and benefits of biotechnology. This strategy will involve coordination between USDA and state level agriculture departments.

Sources and Additional Information:

- The “Modernizing the Regulatory Framework for Agricultural Biotechnology Products” Executive Order can be found at <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>.
- A White House press release on the EO is available at <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-is-unleashing-innovation-for-american-farmers/>.

- More information on the Coordinated Framework for the Regulation of Biotechnology can be found at https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.
- Secretary Purdue's statement on the EO can be found at <https://www.usda.gov/media/press-releases/2019/06/11/secretary-perdue-statement-president-trumps-biotech-eo>.