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# Presidential Documents

**Title 3—**

## The President

**Executive Order 13874 of June 11, 2019**

## Modernizing the Regulatory Framework for Agricultural Biotechnology Products

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to conduct Federal oversight of agricultural biotechnology products that is science-based, timely, efficient, and transparent, it is hereby ordered as follows:

**Section 1**. *Purpose.* Recent advances in biotechnology have the potential to revolutionize agriculture and thereby enhance rural prosperity and improve the quality of American lives. Biotechnology can help the Nation meet its food production needs, raise the productivity of the American farmer, improve crop and animal characteristics, increase the nutritional value of crop and animal products, and enhance food safety. In order to realize these potential benefits, however, the United States must employ a science-based regulatory system that evaluates products based on human health and safety and potential benefits and risks to the environment. Such a system must both foster public confidence in biotechnology and avoid undue regulatory burdens.

The September 2016 National Strategy for Modernizing the Regulatory System for Biotechnology Products (National Strategy) and the January 2017 Update to the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) were important steps in clarifying Federal regulatory roles and responsibilities with respect to agricultural biotechnology. The Agriculture and Rural Prosperity Task Force established in April 2017 recommended additional steps to further modernize the regulatory framework for agricultural biotechnology products so as to facilitate innovation, ensure coordination across regulatory agencies, and safely enable billions of people across America and the world to reap the benefits of such products. The directives below are intended to implement those recommendations.

**Sec. 2**. *Definition.* For the purposes of this order, the term ''product of agricultural biotechnology'' refers to a plant or animal, or a product of such a plant or animal, developed through genetic engineering or through the 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 purposes, such as to produce pharmaceutical or industrial compounds.

**Sec. 3**. *Policy.* It is the policy of the Federal Government to protect public health and the environment by adopting regulatory approaches for the products of agricultural biotechnology that are proportionate responses to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies. Any regulatory regime for products of agricultural biotechnology should ensure public confidence in the oversight of such products and also promote future innovation and competitiveness. To support these goals, the Federal Government shall:

(a) base regulatory decisions on scientific and technical evidence, and take into account, as appropriate and consistent with applicable law, economic factors;

(b) review regulatory applications for products of agricultural biotechnology in a timely and efficient manner;

(c) ensure the transparency, predictability, and consistency of the regulation of products of agricultural biotechnology, to the extent permitted by law;

(d) as appropriate and consistent with applicable law, develop regulations and guidance through processes that provide fair notice to the public and allow for its participation;

(e) make regulatory determinations based on risks associated with the product and its intended end use; and

(f) promote trade in products of agricultural biotechnology by urging trading partners to adopt science- and risk-based regulatory approaches.

**Sec. 4**. *Regulatory Streamlining.* The Secretary of Agriculture (Secretary), the Administrator of the Environmental Protection Agency (Administrator), and the Commissioner of Food and Drugs (Commissioner), to the extent consistent with law and the principles set forth in section 3 of this order, shall:

(a) within 180 days of the date of this order, identify relevant regulations and guidance documents within their respective jurisdictions that can be streamlined to ensure that products of agricultural biotechnology are regulated in accordance with the policy set forth in section 3 of this order and take the steps appropriate and necessary to accomplish such streamlining; and

(b) use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation.

**Sec. 5**. *Unified Biotechnology Web-based Platform.* To ensure that innovators can easily navigate the regulatory system for products of agricultural biotechnology, the Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration (collectively, the ''agencies'') shall, within 180 days of the date of this order, work together to design a plan to establish a web-based platform that contains and provides links to relevant United States Government regulatory information. This web-based platform shall allow developers of products of agricultural biotechnology to submit inquiries about a particular product and promptly receive from the agencies 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. The web-based platform shall be funded by the Department of Agriculture, with the other agencies providing support, to the extent consistent with applicable law and within existing appropriations, through appropriate interagency agreements, including agreements under the Economy Act.

**Sec. 6**. *Review of Current Authorities, Regulations, and Guidance.* (a) Each of the agencies shall, as appropriate, conduct a review of its regulations and guidance that may apply to genome-edited-specialty-crop-plant products designed to have significant health, agricultural, or environmental benefits, in particular those that are likely to benefit rural communities significantly. Based on the findings of its review, each of the agencies shall take steps to update its regulations and guidance, as necessary and appropriate, to remove undue barriers that impede small, private United States developers, the United States Government, and academic institutions from bringing innovative and safe genome-edited-specialty-crop-plant products to the marketplace.

(b) Every 90 days after the date of this order, for a period of 2 years, each of the agencies shall provide an update regarding its progress in implementing section 6 of this order to the Director of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the Assistant to the President for Economic Policy, and the Assistant to the President for Domestic Policy.

**Sec. 7**. *Domestic Engagement Strategy.* (a) Within 180 days of the date of this order, the Secretary, in coordination with the Administrator, the Commissioner, and any other Administration officials that the Secretary deems appropriate, shall develop an action plan to facilitate engagement with consumers in order to build public confidence in, and acceptance of, the use of safe biotechnology in agriculture and the food system.

(b) In developing the plan described in subsection (a) of this section, the following shall be considered: supporting research and education on effective science communication; developing educational materials that integrate agricultural biotechnology into science education; creating consumer-facing web content; and developing other outreach materials that clearly communicate the demonstrated benefits of agricultural biotechnology, the safety record of the regulatory system, and how biotechnology can address agricultural challenges. The strategy shall take into account the ongoing work of the Agricultural Biotechnology Education and Outreach Initiative, which calls on the Food and Drug Administration to work with the Department of Agriculture to conduct public education and outreach on agricultural biotechnology and food and animal-feed ingredients derived from such technology. The Secretary shall coordinate with State leaders in the fields of public health and agriculture as part of this strategy.

**Sec. 8**. *International Outreach.* Within 120 days of the date of this order, the Secretary and the Secretary of State (collectively, the ''Secretaries''), in consultation with the United States Trade Representative, the Administrator, the Commissioner, and any other Administration officials that the Secretaries deem appropriate, shall develop an international communications and outreach strategy to facilitate engagement abroad with policymakers, consumers, industry, and other stakeholders. The goal of the strategy shall be to increase international acceptance of products of agricultural biotechnology in order to open and maintain markets for United States agricultural exports abroad.

**Sec. 9**. *International Trade Strategy.* Within 120 days of the date of this order, the United States Trade Representative, in consultation with the Secretaries and the Trade Policy Staff Committee, shall develop an international strategy to remove unjustified trade barriers and expand markets for products of agricultural biotechnology.

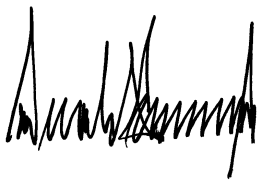
**Sec. 10**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
*June 11, 2019.*

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