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July 2, 2015

MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION,  
ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE

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SUBJECT: Modernizing the Regulatory System for Biotechnology Products<sup>1</sup>

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.<sup>2</sup> This memorandum initiates a process to modernize the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system. The objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and

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<sup>1</sup> For the purpose of this memo, “biotechnology products” refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in this memo.

<sup>2</sup> “Improving Regulation and Regulatory Review”, Executive Order 13563, January 18, 2011.

efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

This memorandum shall be implemented consistent with applicable law, Executive Order 13563, Executive Order 13610, and the 2011 “Principles for Regulation and Oversight of Emerging Technologies” memorandum.<sup>2,3,4</sup> Through those policies, this Administration has sought regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. These principles must now be applied to updating the regulatory framework and systems that regulate the products of biotechnology.

## **Background**

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF),<sup>5</sup> which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation. In 1992, OSTP issued an update to the CF<sup>6</sup> that sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment. The update affirmed that Federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, rather than the process by which the product is created.

Each of the Federal regulatory agencies with jurisdiction over the products of biotechnology has developed regulations and guidance documents to implement its authority under existing laws, resulting in a complex system for assessing and managing health and environmental risks of the products of biotechnology. While the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of small and mid-sized companies to navigate the regulatory process and of the public to understand easily how the safety of these products is assured; and, accordingly, they have the potential to reduce economic growth, innovation, and competitiveness.

Advances in science and technology, moreover, have dramatically altered the biotechnology landscape since the 1992 update of the CF. Such advances can enable the development of products that were not previously possible. A further update of the CF is needed to facilitate the appropriate Federal oversight by the regulatory system and increase transparency, while continuing to provide a framework for advancing innovation.

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<sup>3</sup> “Identifying and Reducing Regulatory Barriers”, Executive Order 13610, January 10, 2012.

<sup>4</sup> “Principles for Regulation and Oversight of Emerging Technologies”, Memorandum for the Heads of Departments and Agencies, March 11, 2011.

<sup>5</sup> [http://www.aphis.usda.gov/brs/fedregister/coordinated\\_framework.pdf](http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf)

<sup>6</sup> [https://www.whitehouse.gov/sites/default/files/microsites/ostp/57\\_fed\\_reg\\_6753\\_1992.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753_1992.pdf)

## Goals and Guidance

Federal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements. It is critical that these improvements:

- maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
- promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

This memo initiates a process to help advance these aims, beginning with the following one-year objectives: (1) development of an updated CF to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology; (2) formulation of a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and (3) commissioning an external, independent analysis of the future landscape of biotechnology products.

The following elements will support the process to achieve these objectives:

Section I. Biotechnology Working Group Under the Emerging Technologies Interagency Policy Coordination Committee. The new Biotechnology Working Group under the Emerging Technologies Interagency Policy Coordination Committee (ETIPC) will include representatives from the Executive Office of the President, as well as the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and United States Department of Agriculture (USDA). The working group shall coordinate with other Federal agencies and offices as necessary.

Section II. Mission and Function of the Working Group. Within one year of the date of this memorandum, the working group shall take steps detailed below and others, as appropriate, to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology. Specifically, the working group shall:

- (a) update the CF to clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology, after input from the public, by clarifying:
  - (i) which biotechnology product areas are within the authority and responsibility of each agency;
  - (ii) the roles that each agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies,

- and how those roles relate to each other in the course of a regulatory assessment;
- (iii) a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and
  - (iv) the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products; and
- (b) develop a long-term strategy to ensure that the Federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens by:
- (i) developing a plan for periodic formal horizon-scanning assessments of new biotechnology products to ensure that regulatory agencies are prepared for future products well before they reach the regulatory system;
  - (ii) working with other Federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities with regard to the assessment of biotechnology products, and to reflect these priorities in agency budget submissions starting with the fiscal year (FY) 2017 budget;
  - (iii) ensuring that product evaluations are risk-based and grounded in the best science available, including regularly adjusting regulatory activities based on experience with specific products and the environments into which those products have been introduced;
  - (iv) establishing a timetable and mechanisms to work with stakeholders to identify impediments to innovation, focusing on building new, and augmenting existing, stakeholder collaborations to inform efforts, increase transparency, streamline processes, reduce costs and response times, and ensure the protection of health and the environment;
  - (v) coordinating the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system;
  - (vi) identifying changes to authorities, regulations, and policies, if any, that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products;
  - (vii) initiating development of a modernized, user-friendly set of tools for presenting the regulatory agencies' authorities, practices, and bases for decision making for the regulation of biotechnology products to the

public, including digital services to improve the interactions between the FDA, EPA, USDA, the general public, and product developers and updating these tools and practices regularly to ensure optimal transparency; and

- (viii) proactively engaging with the public to discuss how the Federal government uses a risk-based, scientifically sound approach to regulating the products of biotechnology, and clearly communicating to the public which types of products are regulated, which types of products are not regulated, and why.

Sec. III. Independent Assessment. The EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify (1) potential new risks and frameworks for risk assessment and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood. The review will help inform future policy making. Due to the rapid pace of change in this arena, an external analysis should be completed at least every five years.

Sec. IV. Budgeting for Efficiency. The EPA, FDA, and USDA shall work with OSTP and OMB, within the annual President's budget formulation process, to develop a plan for supporting the implementation of this memo in Agency FY 2017 budget requests and, as appropriate, in future budget submissions.

Sec. V. Annual Reporting. For at least five years, starting one year after the release of the strategy described in Section II, the working group will produce an annual report on specific steps that agencies are taking to implement that strategy and any other steps that the agencies are taking to improve the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products. This report will be made available to the public by the Executive Office of the President.

Sec. VI. General Provisions. Nothing in this memorandum shall be construed to impair or otherwise affect:

- (a) the mission as established by law for any agency;
- (b) the authority granted by law to any agency or the head thereof; or
- (c) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, regulatory, or legislative proposals.

Nothing in this memorandum shall be construed to require the disclosure of confidential business information or trade secrets, classified information, law enforcement sensitive information, or other information that must be protected in the interest of national security or public safety.

This memorandum 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.