National Strategy for Modernizing the Regulatory System for Biotechnology Products

Establishes a long-term strategy to ensure that the Federal regulatory system is equipped to assess the risks of future biotechnology products.


WHAT IT DOES

The National Strategy for Modernizing the Regulatory System for Biotechnology Products ("Strategy") provides a review of existing mechanisms and future activities that ensure effective risk-assessment of future biotechnology products by the three agencies most involved in their regulation—the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA). The Strategy aims to balance this risk-assessment with support for innovation, protection of health and the environment, promotion of public confidence in the regulatory process, an increase in transparency and predictability, and a reduction in unnecessary costs and burdens.

The Strategy specifically outlines the efforts already underway and future activities that could further the following three goals and objectives:

1. Increasing transparency;
2. Increasing predictability and efficiency; and
3. Supporting the science that underpins the regulatory system.

In order to increase transparency, each of the three agencies (FDA, EPA, USDA) have developed communication mechanisms and processes to both connect the public with information on relevant regulations and guidelines and to enrich the agencies themselves through public input.

Examples of existing mechanisms and activities:

- Public meetings (FDA meeting, EPA meeting, USDA meeting) that clarified each agencies' roles and responsibilities regarding biotechnology regulation;
- Workshops for small businesses to learn how to navigate the regulatory system (e.g., USDA’s Specialty Crops Regulatory Assistance Workshop);
- Websites to exchange information both with developers and the general public (e.g., USDA’s BiotechQuery, EPA’s BPPDQuestions, FDA’s openFDA);
- Attendance at international fora to promote worldwide scientific competency and regulatory compatibility; and
- Agency-specific activities for relevant audiences.

Examples of future activities:

- Exploration of new opportunities to connect industry, consumers, and stakeholders with the agencies; and
- Review and potential revision of existing communication tools.

In order to increase predictability and efficiency, the Strategy reaffirms the risk-based, science-based regulatory approach established by the 1992 Update to the Coordinated Framework to ensure that regulatory oversight accomplishes the greatest protection of health and the environment while minimally inhibiting innovation, stigmatizing new technologies, or creating trade barriers. Each of the three agencies have developed numerous activities to learn about new technologies and trends in
biotechnology.

Examples of existing mechanisms and activities:

- Employment of experts from a variety of scientific disciplines;
- Participation in scientific and trade fora;
- Membership in interagency, national, and international organizations;
- Commission of an independent study by the National Academy of Sciences about future biotechnology;
- Development of an assessment system of biotechnology products in other countries;
- Frequent interaction with product developers; and
- Commitments to use the best available science.

Examples of future activities:

- Interagency communication to help with timely decisions about regulatory jurisdiction so as to expedite clarification of agency roles;
- Exploration of ways to enhance interagency collaborations;
- Examination of regulatory structures to clarify regulation of genetically engineered insects;
- Clarification of regulations for products derived from genome editing techniques; and
- Commission of the Emerging Sciences Working Group to identify relevant science and technology trends.

In order to support the science that underpins the regulatory system, each of the three agencies have committed to basing regulatory reviews and decisions on the best available science by engaging with organizations and institutions both internal and external to the Federal government.

Examples of existing mechanisms and activities:

- Development of the FDA's Strategic Priorities 2014-2018 and the Strategic Plan for Regulatory Sciences;
- Addressing scientific gaps and developing new methods, models, and approaches to inform regulatory policy;
- Engagement with academic institutions through the Centers of Excellence in Regulatory Sciences and Innovation (CERSI);
- Engagement with Federal research agencies, such as the Agricultural Research Service (ARS) and the National Institute of Food and Agriculture (NIFA.)

Example of future activities:

- Exploration of mechanisms to enhance coordination and collaboration with Federal research agencies to promote agencies' regulatory science.

RELEVANT SCIENCE

Biotechnology refers to a range of tools that use or alter living systems to create products for specific applications in medicine, agriculture, energy, manufacturing, and environmental protection. In the Strategy, biotechnology products refer to those developed through genetic engineering—the manipulation of genetic information of organisms, including plants, animals, and microbes. This definition also includes some products produced by or derived from genetically engineered plants, animals, and microbes.

One of the most common techniques used in genetic engineering is recombinant DNA technology. This technology can be used to join together, or recombine, two DNA segments from separate species in a cell-free system (i.e. in a test tube, not in living cells or organisms). Under appropriate conditions, a recombinant DNA molecule can then be introduced into a host cell and allowed to copy itself. This allows for highly specific DNA mutations to be made and reinserted into a living organism.
Biotechnology has an ancient history, beginning with the development of hybrid plants through selective breeding by the earliest farmers. Later technological developments in the Industrial Revolution led to increased abilities to select and manufacture specific characteristics. Breeds of cotton were pioneered in the 1870s, and the first hybrid corn was commercialized in the early 1930s. After the 1928 discovery of *Penicillium* mold, biotechnology enabled the synthetic production of antibiotics including penicillin. The modern field of biotechnology is generally recognized as beginning in 1971 with successes in gene splicing experiments conducted at Stanford University.

In 1980, the U.S. Supreme Court ruled that biotechnology products could be patented in *Diamond v. Chakrabarty*. This led to the birth and global expansion of the biotechnology industry. One of the most recent breakthroughs in the field lies in the development of CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)/Cas9. There are many Cas (CRISPR associated) proteins, but Cas9 is currently the most commonly used for biotechnology. This tool, known as the “Swiss army knife of genetic engineering”, enables scientists to target specific genes in a DNA strand, cut both DNA strands, and remove, replace, or disrupt those genes. This tool has already been used to modify crop genomes, with the first ever meal from these plants served to a reporter in September 2016. In the future, scientists hope this tool could be used to cure genetic diseases by altering the mutated DNA in human cells. Federal regulation of these tools, techniques, and products addresses concerns that the genetic modifications could result in harm to individuals and the environment.

**RELEVANT EXPERTS**

Jennifer Kuzma, PhD, NC State University; relevant publications include:


**BACKGROUND**

In 1986, the White House Office of Science and Technology Policy (OSTP) issued the *Coordinated Framework for the Regulation of Biotechnology* (“Coordinated Framework”), which outlined a risk-based approach to federal policy regarding the safety of biotechnology products. The Coordinated Framework sought to balance achievement of health, environment, and safety goals with sufficient regulatory flexibility to avoid impeding innovation. The policy established the interagency Biotechnology Science Coordinating Committee (BSCC) to coordinate the regulatory activities of the FDA, EPA, USDA, and Occupational Safety and Health Administration, as well as the research activities of EPA, USDA, the National Institutes of Health, and the National Science Foundation.

The 1992 Update to the Coordinated Framework (“1992 Update”) affirmed the risk-based approach to regulatory oversight of the introduction of biotechnology products into the environment. The 1992 Update clarified that federal oversight focused on product characteristics, intended use, and similarity to previously released products. Regulatory concern therefore shifted away from the processes by which these products were created and allowed agencies to exempt certain product categories from federal oversight.

Since its establishment in 1986, the BSCC morphed into various ad hoc committees or working groups. When agency representatives were unable to agree on policy measures, each agency issued its own guidance under the Coordinated Framework. This eventually led to a complex regulatory process with overlapping roles and responsibilities among the primary agencies. This fragmentation prompted the *July 2015 Executive Office of the President Memorandum* (“EOP memorandum”). The memorandum called for the clarification of ongoing agency activities through a proposed Update to the Coordinated Framework ("proposed Update"); SciPol brief available), a long-term national strategy for the future of biotechnology regulation (the Strategy), and a study into the future of the biotechnology product landscape. The study is currently being conducted by the National Academy of Sciences (NAS) and is slated for release at the end of 2016; the NAS is accepting comments throughout the course of the study.
This Strategy was created as the second of three tasks outlined in the EOP memorandum. All three tasks work in tandem to:

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

Despite all the attention the federal government affords biotechnology risk assessment, interest in the topic spans international boundaries. Though not officially sponsored by the U.S. government, an international summit on human gene editing was held in Washington D.C. in December 2015, after CRISPR/Cas9 technologies became applicable to human health considerations. The summit included experts from around the world, including the U.S. NAS, the U.K.’s Royal Society, and the Chinese Academy of Science. The summit concluded by issuing a statement on the ethical, scientific, and governance issues of human gene editing research.

ENDORSEMENTS & OPPOSITION

To date, there are no direct, publicly stated endorsements of or opposition to the Strategy. Comments have not yet been filed on the agency docket. There is bipartisan support for the proposed Update and reform efforts consistent with the underlying policies of the 1986 Coordinated Framework.

In implementing the Strategy, the EPA, FDA, and USDA intend to consider relevant public opinion concerning the proposed Update and the NAS study of the future biotechnology landscape. Most available opinions concern the proposed Update and make only brief mention of the Strategy. However, some agriculture organizations and scholars believe both fall short of what they believe to be proper regulation and guidance.

STATUS

The Emerging Technologies Interagency Policy Coordination Committee released the Strategy on September 29th, 2016. Starting one year after its release, the EPA, FDA, and USDA are tasked with producing an annual report on the steps they have taken to implement the policy, every year for at least five years, as instructed by the July 2015 EOP memorandum.

RELATED POLICIES

To support the three tasks from the EOP Memorandum, which include the present Strategy, the agencies sought guidance through a Notice of Request for Information issued jointly by OSTP and the National Science and Technology Council. Comments were received from a wide array of industry groups, non-profit organizations, individual scholars, and university groups.

POLICY HISTORY

The Strategy works in tandem with the proposed Update, which was the sequel to the 1986 Coordinated Framework for the Regulation of Biotechnology and the related 1992 Update to the Coordinated Framework.

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