Modernizing the Regulatory System for Biotechnology Products: An Update to the Coordinated Framework for the Regulation of Biotechnology

Clarifies the current roles and responsibilities of the primary agencies involved in the regulation of biotechnology products.

Updated last October 17, 2016
for the Update posted in the Federal Register on 09/22/2016.

WHAT IT DOES

The proposed Update to the Coordinated Framework for the Regulation of Biotechnology ("proposed Update") provides a summary of the roles and responsibilities of the three primary agencies with regulatory authority over biotechnology products—the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA). The proposed Update does not create new authorities, processes, or regulatory proposals. It simply aims to clarify the current practices of the primary agencies to inform the public on how biotechnology products are evaluated, help businesses and academic institutions navigate the regulatory process, support biotechnology innovation, protect health and the environment, and promote public trust in the biotechnology product regulatory system.

The proposed Update is a sequel to the 1986 Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework") and the 1992 Update to the Coordinated Framework ("1992 Update"). It relies on the same guiding principles for biotechnology regulation established in those documents. Notable principles include:

- Regulatory oversight is based on specific product uses, allowing multiple products with the same use to go through the same regulatory process;
- Product, application, and environment characteristics determine a product’s risk (or lack thereof); and
- Level of agency oversight depends on the associated risk of introduction, not on any process or technique used to create or alter the product.

The proposed Update outlined four objectives:

- Clarify agency authority and responsibility for biotechnology product areas;
- Clarify agency roles for different product areas, particularly for areas within the responsibility of multiple agencies;
- Clarify the standard mechanism for communication and coordination among agencies; and
- Clarify the mechanism and timeline for reviewing and updating the Coordinated Framework to minimize delays, support innovation, protect health and the environment, and promote the public trust in the regulatory systems for biotechnology products.

To achieve these objectives, the proposed Update presents information about agency roles and responsibilities in several forms, including illustrative graphics, product development case studies, and a comprehensive table of statutory authorities. This information was previously scattered among statutes, regulatory guidance documents, and agency websites (FDA Biotechnology Guidance, FDA Food, FDA Animals, EPA, USDA). The proposed Update concludes with a summary of public comments solicited during the drafting process and a table of key terms and definitions within the various statutes discussed. A summary of the stated roles and responsibilities follows.

EPA regulates biotechnology product areas including pesticides, plant-incorporated protectants, and microorganisms and biochemicals. EPA authority to regulate these products arises from the Federal Insecticide, Fungicide, and Rodenticide Act, the FD&C Act, and the Toxic Substances Control Act. EPA responsibilities under these statutes include the following:
• Regulation and pre-market registration of plant-incorporated protectants;
• Regulation and pre-market registration of microbial pesticides; and
• Premanufacturing review and approval of GE microorganisms and new biochemicals.

Notably, EPA has oversight for a wide range of commercial, industrial, and consumer applications of microbial biotechnology under the Toxic Substances Control Act.

FDA regulates a wide variety of biotechnology product areas including human and animal foods derived from genetically-engineered (GE) plants, GE animals, as well as drugs, biological products, and medical devices for both humans and animals that are derived from a GE source. FDA authority to regulate these products arises under several provisions of the Food, Drug, and Cosmetic (FD&C) Act and other statutes. FDA has the following responsibilities under the Act for biotechnology products:

• Regulation and market removal of adulterated food and ingredients;
• Regulation and premarket approval of food additives;
• Premarket consultation for foods derived from new plant varieties;
• Regulation of the safety and effectiveness as well as premarket approval of new animal drugs (and GE animals themselves); and
• Regulation of the safety and effectiveness as well as premarket approval of new human drugs, biological products, and medical devices.

Notably, FDA regulates GE animals under the new animal drug provisions of the FD&C Act because the regulated article is the recombinant DNA construct inserted into a specific site in the genome of the animal.

USDA has two divisions engaged in biotechnology product regulation, the Animal and Plant Health Inspection Service (APHIS), and the Food Safety and Inspection Service (FSIS). APHIS regulates any biotechnology product that may risk agricultural plant and animal health including products with plant pesticide components, GE animals, and products with animal pathogens. APHIS authority to regulate these products primarily arises out of the Plant Protection Act, the Animal Health Protection Act, and the Virus-Serum-Toxin Act. APHIS has the following responsibilities under these statutes:

• Licensing and permitting of the import, transport, and dissemination of pests or diseases harmful to livestock and organisms that may transmit pests or diseases to livestock;
• Regulation and authorization of plant pests; and
• Regulation and authorization of veterinary biological products used to prevent, diagnose, or treat animal diseases.

FSIS ensures the safety and correct labeling of the commercial food supply, specifically for meat, poultry, and egg products derived from GE sources. FSIS authority to regulate these products arises under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS has the following responsibilities under these statutes:

• Inspection and assessment of all meat, poultry, and processed egg products in interstate commerce; and
• Preapproval for product labels.

The three agencies also operate under a set of formal Memoranda of Understanding (MOUs) to enhance and coordinate interagency information exchange. Each principal agency also calls upon other secondary agencies on a case-by-case basis to obtain the necessary expertise to conduct a full biotechnology product assessment.

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 proposed Update, 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
One of the most common techniques used in genetic engineering is the use of 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 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. This tool, known as the “Swiss army knife of genetic engineering” enables scientists to target specific genes in a DNA strand, cut, and remove (or replace) 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 removing the affected DNA from the human cell. 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 leading to a complex regulatory process with overlapping roles and responsibilities among the primary agencies.
This fragmentation prompted the July 2015 call for the proposed Update to clarify ongoing agency activities.

ENDORSEMENTS & OPPOSITION

To date, there are no direct, publicly stated endorsements of or opposition to the proposed Update. 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.

The proposed Update is expected to assist biotechnology product manufacturers, especially small and mid-size businesses and new market entrants, in navigating the regulatory process. The charts, tables, and case studies centralize complex information that was formerly scattered throughout various agency websites and regulatory guidance documents.

However, some scholars have expressed disappointment that the proposed Update only clarifies current agency roles which remain “diffuse, outdated, and confusing, especially for newer biotechnology products.” The proposed Update lacks guidance or case studies addressing the newest emerging products that could pose challenges for agency coordination and review.

STATUS

The Administration released the proposed Update to the Coordinated Framework on September 16, 2016. The OSTP posted a Notice of Request for Public Comment on the proposed Update on September 22, 2016. The public may submit comments through November 1, 2016. The Office particularly seeks comments regarding additional clarification on:

- Agency statutory authorities for biotechnology product areas;
- Agency roles for biotechnology product areas, especially those falling within the responsibility of multiple agencies;
- Communication tools and coordination among agencies; and
- Mechanism and timeline for regular review and update of the Coordinated Framework.

RELATED POLICIES

The heads of EPA, FDA, and USDA began the process to update the Coordinated Framework in response to a July 2, 2015 memorandum from the Executive Office of the President (EOP). The memo also asked the agencies to (1) develop a long-term national strategy for the biotechnology regulatory system and (2) commission a study of the future biotechnology product landscape. The study, conducted by the National Academy of Sciences (NAS), is slated for release at the end of 2016. NAS is accepting comments throughout the course of the study.

To support all of these activities, 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. Each agency also conducted a joint public meeting with OSTP to inform the public and invite oral comments (FDA meeting, EPA meeting, USDA meeting).

POLICY HISTORY

The proposed Update is a sequel to the 1986 Coordinated Framework for the Regulation of Biotechnology and the 1992 Update to the Coordinated Framework.

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