National Academies Study on Future Products of Biotechnology – First Public Meeting

Robbie Barbero
Assistant Director for Biological Innovation
White House Office of Science and Technology Policy
April 18, 2016

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Overview of Agency Protection Goals

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Overview of Agency Protection Goals

Modernizing the Regulatory System for Biotechnology Products – Background

- June 1986: White House Office of Science and Technology Policy (OSTP) issued 51 FR 23302, The Coordinated Framework for the Regulation of Biotechnology
- February 1992: OSTP issued 57 FR 6753, an update to the Coordinated Framework
- January 2011: Executive Order 13563---Improving Regulation and Regulatory Review
- July 2015: Executive Office of the President (EOP) issued an memorandum directing US Environmental Protection Agency (EPA), US Food and Drug Administration (FDA), and US Department of Agriculture (USDA) to—
  - update the Coordinated Framework for the Regulation of Biotechnology by clarifying current roles and responsibilities;
  - commission an expert analysis of the future landscape of biotechnology products to support this effort; and
  - develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology.

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Overview of Agency Protection Goals

2015 Memorandum on Modernizing the Regulatory System for Biotechnology Products

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.

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Overview of Agency Protection Goals

Principles Guiding the Regulation of Biotechnology Products

from the 1986 Coordinated Framework for the Regulation of Biotechnology and the 1992 update

- The process used to make a product does not determine the safety of or risk posed by the product; rather it is the characteristics of the organism, the environment into which it will be introduced, and the application of the organism that determine risk (or lack thereof) of a biotechnology product
- A risk-based approach to regulation should distinguish between those organisms that require a certain level of federal action and those that do not
- A risk-based approach properly protects public health and the environment against risk, and avoids hindering safe innovations
- Each agency will use its existing statutory authorities and regulatory programs to help ensure the safety of the biotechnology products
- Federal statutes and implementing regulations regulate products based on specific uses, which allows similar products (whether made using biotechnology or not) to be treated similarly by regulatory agencies
- Agencies should seek to operate their programs in an integrated and coordinated fashion
- Although there is some inconsistency in statutory nomenclature, reviews conducted by each regulatory agency is of comparable rigor
- Future scientific developments will lead to further refinements of Federal policies

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Overview of Agency Protection Goals

(1) Update the Coordinated Framework

- Clarify which biotechnology product areas are within the authority and responsibility of each agency;
- Clarify 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;
- Clarify 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
- Clarify the mechanism and timeline for regularly reviewing, and updating as appropriate, 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.

(2) Long-term strategy

- Increase Transparency
  - Establish 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;
  - Coordinate the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system;
  - Initiate 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
  - Proactively engage 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.

(2) Long-term strategy

- Support the science that underpins the regulatory system
  - Work with other Federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities;
- Predictability and Efficiency
  - Develop a plan for periodic formal horizon-scanning assessments of new biotechnology products;
  - Identify 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; and
  - Ensure 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.

(3) Expert analysis of future landscape of biotechnology products

- The EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify
  - potential new risks and frameworks for risk assessment and
  - 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.

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Overview of Agency Protection Goals

Modernizing the Regulatory System for Biotechnology Products: Progress Update

- July 2015: Formed the Biotechnology Working Group under the auspices of the Emerging Technologies Interagency Policy Coordination (ETIPC) Committee
- October – November 2015: Request for Information (RFI) posted on the Federal Register
  - –903 comments received
- November 2015-Present: USDA, EPA, FDA, and EOP reviewed the public responses to RFI

Modernizing the Regulatory System for Biotechnology Products: Progress Update

- October 30, 2015: First public meeting – Silver Spring, MD
  - Discussed overview of Federal regulation of biotechnology products
  - Over 300 registered participants in-person or via webcast
- March 7, 2016: Administration releases draft documents for discussion at public meetings
  - Case studies of hypothetical products
  - Table of authorities related to biotechnology products
- March 9, 2016: Second public meeting – Dallas, TX
  - Focused on clarifying current roles and responsibilities by discussing case studies of hypothetical products
  - Over 150 registered participants in-person or via webcast

Modernizing the Regulatory System for Biotechnology Products: Progress Update

- March 30, 2016: Third public meeting – Davis, CA
  - –Focused on:
    - Clarifying current roles and responsibilities by discussing case studies of hypothetical products,
    - And, discussion of three general thematic areas relevant to tasks assigned in July 2, 2015 memo
      - –Governance
      - –Education, communication, and outreach
      - –Improving regulatory certainty
  - –Over 300 registered participants in-person or via webcast

Modernizing the Regulatory System for Biotechnology Products: Progress Update

- Ongoing: Updating Coordinated Framework and developing long-term strategy

- Spring/Summer 2016: Update to Coordinated Framework will be made available for public comment

Modernizing the Regulatory System for Biotechnology Products: Progress Update

- January 2016: National Academies of Science announces study "Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System"
  - Major advances and potential new types of biotech products over the next 5–10 years,
  - Whether potential future products could pose different types of risk relative to existing products and organisms,
  - Areas in which the risks or lack of risk relating to biotechnology are well understood, and
  - What scientific capabilities, tools, and expertise may be useful to the regulatory agencies to support oversight of potential future products of biotechnology
- March 2016:
  - Website established: www.nas.edu/biotech
  - Study committee announced
- April 2016
  - First public meeting

Agenda

- Modernizing the Regulatory System for Biotechnology
  - Background
  - Goals and Guidance
  - Principles
  - Tasks
- Progress Update
- Introduction to Agency Protection Goals

Agency Protection Goals for the Regulation of Biotechnology Products

Agency	Statute	Protection Goals
USDA/APHIS	Animal Health Protection Act (AHPA)	Protect livestock from animal pests and disease risks
USDA/APHIS	Plant Protection Act (PPA)	Protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks
EPA	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	Eliminate unreasonable adverse effects upon man and the environment • For environmental and occupational risks, this involves comparing economic, social, and environmental risks and benefits associated with pesticide use • For dietary or residential human health effects, the sole standard is the safety of exposure
EPA	Food, Drug, and Cosmetics Act (FD&C Act)	Ensure dietary exposure to pesticide chemical residues in or on food are safe
EPA	Toxic Substances Control Act (TSCA)	Ensure the manufacture, processing, distribution in commerce, use, or disposal of chemical substances, or any combination of such activities with such substances does not present unreasonable risk of injury to health or the environment
FDA	FD&C Act Public Health Service Act	Ensure food is safe, sanitary, and properly labeled Ensure human and veterinary drugs are safe and effective Ensure there is a reasonable assurance of safety and effectiveness of devices intended for human use Ensure cosmetics are safe and properly labeled Ensure public health and safety are protected from electronic product radiation Regulate tobacco products

USDA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FDA
U.S Food and Drug Administration

ADDITIONAL INFORMATION

Additional Information

- 1986 Coordinated Framework for Regulation of Biotechnology
  - https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
- 1992 Update to Coordinated Framework: Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment
  - https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf
- 2015 EOP Memo and Blog post: Modernizing the Regulatory System for Biotechnology Products
  - https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf
  - https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology
- Other Relevant Policy Documents
  - "Improving Regulation and Regulatory Review", Executive Order 13563, January 18, 2011.
    - http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf
  - "Principles for Regulation and Oversight of Emerging Technologies", Memorandum for the Heads of Departments and Agencies, March 11, 2011.
    - https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf
  - "Identifying and Reducing Regulatory Burdens", Executive Order 13610, January 10, 2012.
    - https://www.whitehouse.gov/sites/default/files/docs/microsites/omb/eo_13610_identifying_and_reducing_regulatory_burdens.pdf