Overview of the Coordinated Framework

The Future of Microbial Biotechnology: From Research to Regulation

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Presentation Outline

- Coordinated Framework
- Principles
- Agencies
- Regulatory Website

U.S. Coordinated Framework for Regulation of the Products of Biotechnology

- Proposed by Office of Science and Technology Policy (OSTP)
- Describes federal regulatory system for evaluating products of biotechnology
- Based on existing laws that provide basic network of agency jurisdiction
- Established formal policy in 1986; updated in 1992 and 2017

The Coordinated Framework for the Regulation of Biotechnology (1986)

- The existing laws provide adequate authority to address safety
- Regulation based on the end use of the product
- The product, not the process, should be regulated
- Regulation should be science-based and conducted on a case-by-case basis
- Broad spectrum of products that cut across many uses regulated by different agencies
- Lead agencies will coordinate as needed among other relevant agencies.

National Research Council (1987)

- Products of biotechnology ***do not differ fundamentally*** from unmodified organisms or from conventional products;
- There is ***no evidence that unique hazards exist*** either in the use of rDNA techniques or in the transfer of genes between unrelated organisms.

- The ***risks associated with the introduction*** **of rDNA** engineered organisms ***are the same in kind*** as those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques.

1992 Update to the Coordinated Framework

- ***Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment***
- Clarify roles and responsibilities of the primary agencies involved in the regulation of biotechnology products
- Reaffirmed --Federal oversight "focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created"
- Described a risk based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment.

Modernizing the Coordinated Framework

July 2015 White House Memo
"Modernizing the Regulatory System for Biotechnology Products"

U.S. Policy Principles for Regulation of Biotechnology Products

- Federal statutes and regulations regulate products based on specific uses
- The characteristics of the product, the environment into which it will be introduced, and the product application determine its risk (or lack thereof)
- Regulatory oversight should be commensurate with risk posed by the product, and not that it has been created by a particular process or technique
- Following a risk-based approach, the regulatory system should distinguish between those products that require oversight and those that do not.

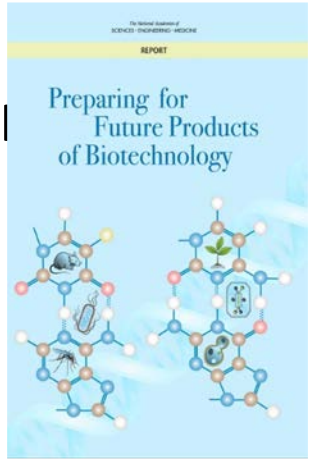
- **Ref: *2017 Update to the Coordinated Framework***

Coordinated Framework Documents

- National Strategy for Modernizing the Regulatory System for Biotechnology Products – September 2016.
  - https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf

- 2017 Update of the Coordinated Framework – January 2017.
  - https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf

- Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System – National Academy of Sciences – March 2017
  - http://nas-sites.org/biotech/



Statutes versus Regulations

Statutes: THE LAW --- passed by Congress and signed by the President

Regulations: Implements the law --- written by the Agency and approved by the Executive Branch

Guidance: Agency interpretation of the Regulations for compliance

Regulation of Organisms Developed Using Genetic Engineering Under the Coordinated Framework

- **Department of Agriculture (USDA-APHIS)**
  - Plant Protection Act (PPA)
  - Animal Health Protection Act (AHPA)
- **Environmental Protection Agency (EPA)**
  - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):
  - Federal Food Drug and Cosmetic Act (FFDCA)
  - Toxic Substances Control Act (TSCA)
- **Food and Drug Administration (FDA)**
  - Federal Food, Drug and Cosmetics Act (FFDCA)

The Statutes governing oversight of biotechnology products have been in place for many years prior to GE techniques.

Protection Goals

- **USDA-Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS)**
  - **Protection of Plant Health**
  - **Safety of Veterinary Biologics**
  - **Safety of Meat, Poultry and Eggs**
- **U.S. Environmental Protection Agency (EPA)**
  - **Regulation of Plant Incorporated Protectants (PIPs) as bio-pesticides**
  - **Safe Use of New Pesticides**
  - **Safe Use of Chemicals**
- **U.S. Food and Drug Administration (FDA)**
  - **Safety of Food, Food Additives and Feed**
  - **Safety of Veterinary and Human Drugs, and Human Biologics**

Modernizing the Regulatory Framework for Agricultural Biotechnology Products

Executive Order 13874 June 11, 2019

- The President issued an Executive Order on modernizing regulatory systems for agricultural biotechnology products
- Regulatory approaches for agricultural biotechnology products should be proportional to the risks such products pose
- Regulatory decisions based on scientific and technical evidence
- Regulatory determinations based on risks associated with the product and its intended end use

Regulatory Cycle

Regulations are updated to keep pace with advancing technology

- Define clear objectives
- Developing/revising regulations
- Implementation
- Review and assessment
  - Effective
  - Efficient
  - Meeting legal and policy objectives

Best Information Available

Note: Folders & subfolders can be restricted to certain users only, as needed

Product Area: Pesticide

Source Organism: Genetically Engineered Microbe

EPA/OPP

If pesticide is a GE malmicrobe, EPA/OPP regulates the microbial pesticide for human and environmental safety, including the safety of dietary exposure to pesticide residues

EPA/OPPT

Evaluates and potentially regulates a living GE microbe used as a pesticide intermediate.

i.e., where the "pesticide" product is the dead microbe

FDA/CFSAN

If human food, FDA/CFSAN oversees non-EPA-regulated aspects of the food for safety for human consumption.

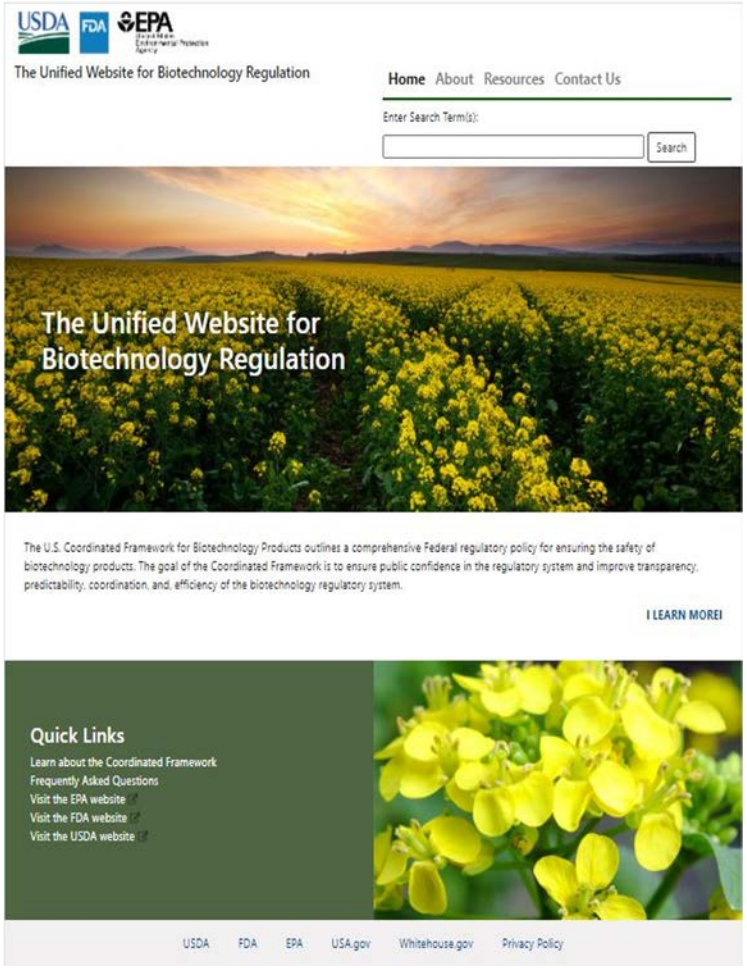
FDA/CVM

If animal food, FDA/CVM oversees non-EPA- regulated aspects of the food safety for animal consumption.

USDA/APHIS

If microbe poses a plant pest risk.

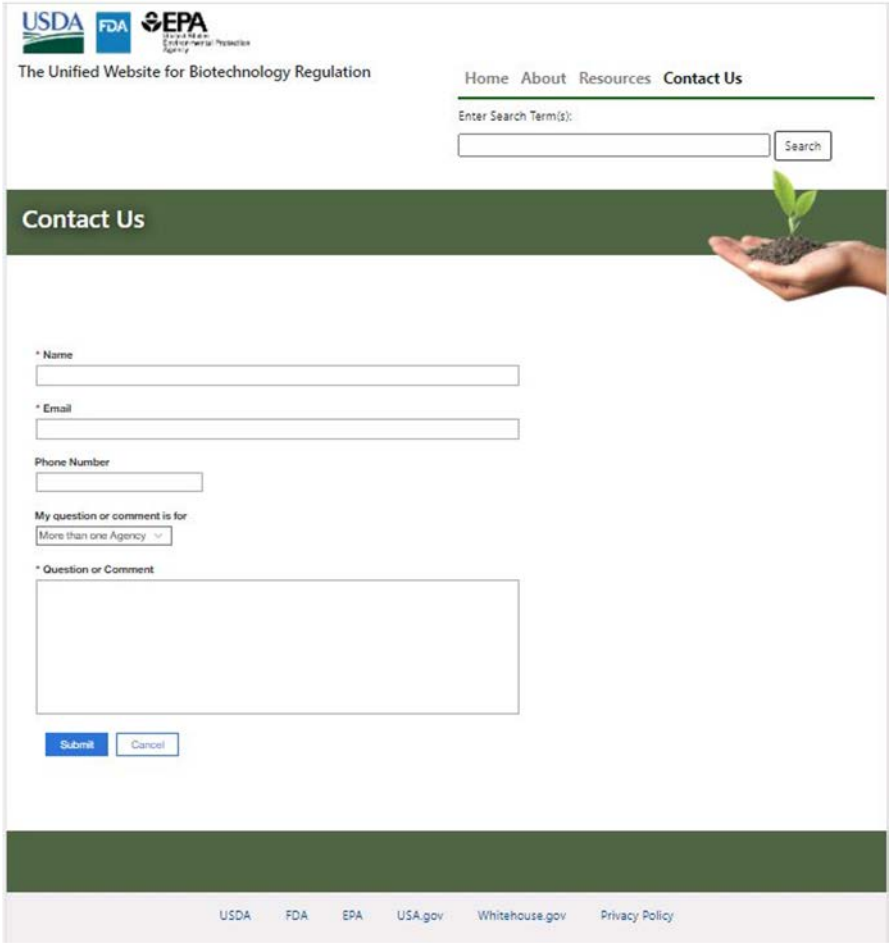
The Unified Website for Biotechnology Regulation



- Coordinated Framework
- Agency websites
  - EPA
  - FDA
  - USDA
- Frequently Asked Questions
- Contact Us

Contact Us

https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/contact-us



Thank you

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