

# COORDINATED FRAMEWORK FOR THE REGULATION OF THE PRODUCTS OF BIOTECHNOLOGY-- 1986

## Four principles

- The products of recombinant DNA technology will not differ fundamentally from unmodified organisms or from conventional products
- Existing laws are adequate to regulate the products of this technology
- Product, not process, should be regulated, and regulation should be risk-based
- Regulation should be directed toward the intended end use for products, and should be conducted on a case-by-case basis

## Framework

The Coordinated Framework documented specific regulatory roles for:

### *Department of Agriculture*

- Animal and Plant Health Inspection Service
- Food Safety Inspection Service

### *Environmental Protection Agency*

### *Health and Human Services*

- National Institutes of Health
- Food and Drug Administration

The Coordinated Framework also directed each agency to focus on its existing regulations to ascertain their appropriateness to the products of biotechnology.

**PROVAL OF COMMERCIAL BIOTECHNOLOGY PRODUCTS**

From: Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment; 51 FR 23302-23393, June 26, 1986

Subject	Responsible agency(ies)
Foods/Food Additives.....	FDA,* FSIS. <sup>1</sup>
Human Drugs, Medical Devices and Biologics.....	FDA.
Animal Drugs.....	FDA.
Animal Biologics.....	APHIS.
Other Contained Uses.....	EPA.
Plants and Animals.....	APHIS,* FSIS. <sup>1</sup> FDA. <sup>1</sup>
Pesticide Microorganisms Released in the Environment All.	EPA,* APHIS. <sup>2</sup>
Other Uses (Microorganisms):	
Intergenic Combination.....	EPA,* APHIS. <sup>2</sup>
Intragenic Combination:	
Pathogenic Source Organism:	
1. Agricultural Use.....	APHIS.
2. Non-Agricultural use.....	EPA,** APHIS. <sup>2</sup>
No Pathogenic Source Organisms.....	EPA Report.
Nonengineered Pathogens:	
1. Agricultural Use.....	APHIS.
2. Non-agricultural Use.....	EPA, <sup>4</sup> APHIS. <sup>2</sup>
Nonengineered Nonpathogens.....	EPA Report.

\*Lead agency

<sup>1</sup>FSIS, Food Safety and Inspection Service, under the Assistant Secretary of Agriculture for Marketing and Inspection Services is responsible for food use.

<sup>2</sup>FDA is involved when in relation to a food use.

<sup>3</sup>APHIS, Animal and Plant Health Inspection Service, is involved when the microorganism is plant pest, animal pathogen or regulated article requiring a permit.

<sup>4</sup>EPA requirements will only apply to environmental release under a "significant new use rule" that EPA intends to propose

**CHART II.—COORDINATED FRAMEWORK—BIOTECHNOLOGY RESEARCH JURISDICTION**

Subject	Responsible agency(ies)
Contained Research, No Release in Environment:	
1. Federally Funded.....	Funding agency. <sup>1</sup>
2. Non-Federally Funded.....	NIH or S&E voluntary review. APHIS. <sup>2</sup>
Foods/Food Additives, Human Drugs, Medical Devices, Biologics, Animal Drugs:	
1. Federally Funded.....	FDA*, NIH guidelines & review.
2. Non-Federally Funded.....	FDA*, NIH voluntary review.
Plants, Animals and Animal Biologics:	
1. Federally Funded.....	Funding agency, <sup>1*</sup> APHIS. <sup>2</sup>
2. Non-Federally Funded.....	APHIS*, S&E voluntary review.

**Pesticide Microorganisms:**

**Genetically Engineered:**

**Intergenic.....**

EPA,\*  
APHIS,<sup>2</sup>  
S&E  
voluntary review.

**Pathogenic Intragenic.....**

EPA,\*  
APHIS,<sup>2</sup>  
S&E  
voluntary review.

**Intragenic Nonpathogen.....**

EPA,\* S&E  
voluntary review.

**Nonengineered:**

**Nonindigenous Pathogens.....**

EPA,\*  
APHIS.  
EPA,\*\*  
APHIS.  
EPA.\*

**Indigenous Pathogens.....**

**Nonindigenous Nonpathogen.....**

**Other Uses (Microorganisms) Released in the Environment:**

**Genetically Engineered:**

**Intergenic Organisms:**

  1. Federally Funded.....

Funding agency,<sup>1\*</sup>  
APHIS,<sup>2</sup>  
EPA.\*

  2. Commercially Funded.....

EPA, APHIS,  
S&E  
voluntary review.

**Intragenic Organisms:**

**Pathogenic Source Organism:**

  1. Federally Funded.....

Funding agency,<sup>1\*</sup>  
APHIS,<sup>2</sup>  
EPA.\*  
APHIS,<sup>2</sup>  
EPA (\* if non-agricul. USE).

  2. Commercially Funding.....

**Intragenic Combination:**

**No Pathogenic Source Organisms.....**

EPA Report.  
EPA Report,\*  
APHIS.<sup>2</sup>

**Nonengineered.....**

\* Lead Agency.

<sup>1</sup> Review and approval of research protocols conducted by NIH, S&E, or NSF.

<sup>2</sup> APHIS issues permits for the importation and domestic shipment of certain plants and animals, plant pests and animal pathogens, and for the shipment or release in the environment of regulated articles.

<sup>3</sup> EPA jurisdiction for research on a plot greater than 10 acres.

<sup>4</sup> EPA reviews federally funded environmental research only when it is for commercial purposes.