



United States Department of Agriculture

USDA-APHIS Biotechnology Regulatory Services

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USDA APHIS BRS Mission

To protect and enhance U.S. agricultural and natural resources using a science- and risk-based regulatory framework to ensure the safe importation, interstate movement, and confined environmental release of regulated genetically engineered (GE) organisms.



Three Discussion Areas

- Current APHIS BRS Program
- APHIS Effort to Revise 7 CFR 340
- USG Effort to Modernize the Regulatory System



Our Regulatory Framework

Statutory Authority: Plant Protection Act

Regulatory Authority: 7 CFR 340

Protection Goal: Protect plants and plant products from plant pests.

GE Organisms can include: plants and plant pests – bacteria, fungi, viruses, and invertebrate animals such as insects, arachnids, and nematodes

The Plant Protection Act

- APHIS-BRS conducts its regulatory activities under the authority of the Plant Protection Act of 2000
- The Plant Protection Act provides two authorities that could be used in regulating GE organisms:
 - **Plant Pest Authority** – Basis of current APHIS regulations (7 CFR part 340)
 - **Noxious Weed Authority** – Proposed by APHIS in the 2008 draft rule; remains under consideration for revised regulations

What Does APHIS Regulate?

- “Regulated articles” (7 CFR part 340)
 - If the organism has been altered or produced through genetic engineering,
 - and**
 - If the GE organism could pose a plant pest risk:
 - Donor, recipient, or vector organism is a plant pest, or
 - Plant pests (defined by statute): organisms that can directly or indirectly injure, cause damage to, or cause disease in or to any plant or plant product

Genetic Engineering

“The genetic modification of an organism by recombinant DNA techniques.” (7CFR340.1)

Other terms:

- Products of Biotechnology
- Genetically Modified Organisms
- Transgenic, Recombinant, Transformed Organisms

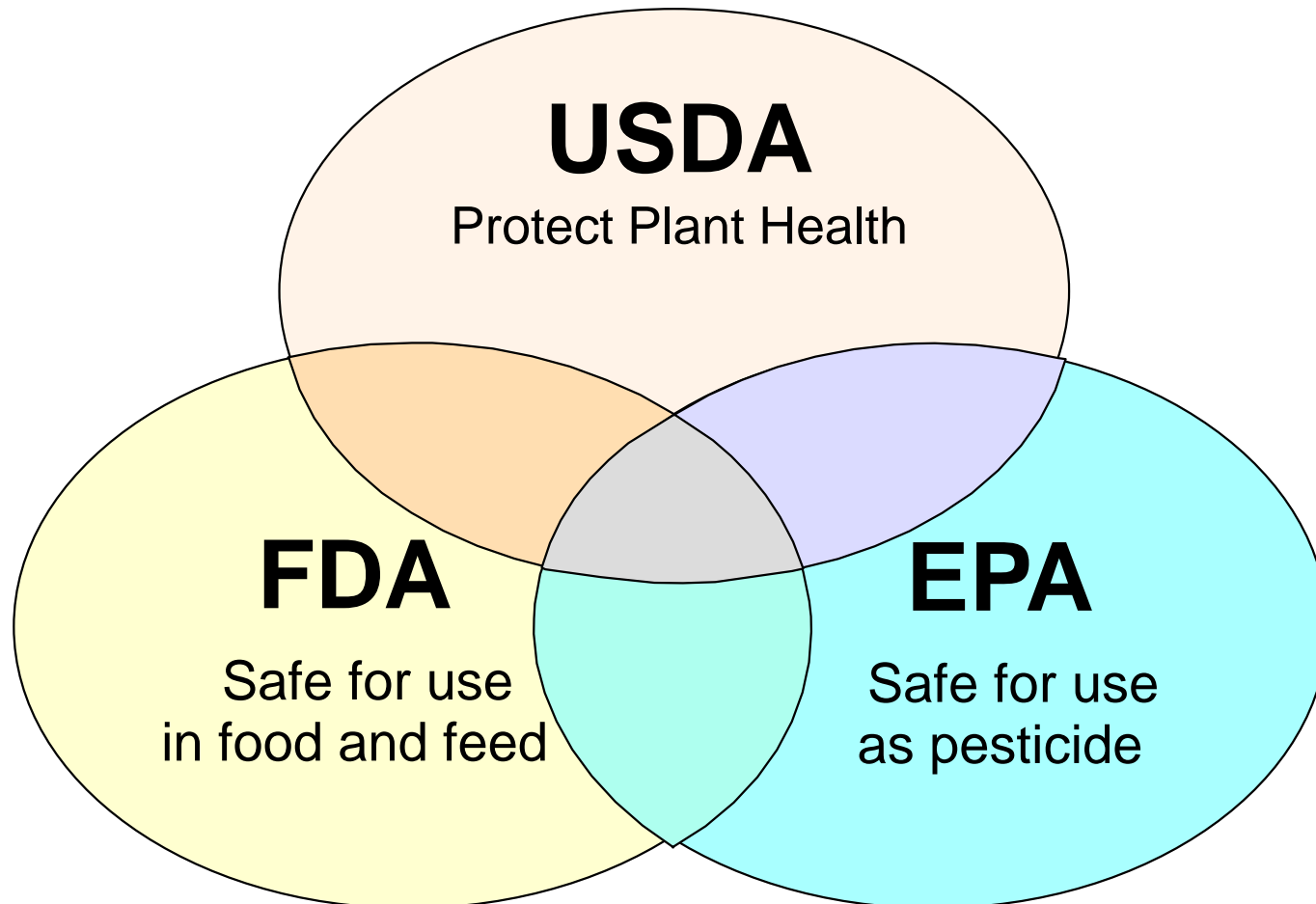
Product Types Regulated by the Federal Government

Not Regulated	Regulated
Classical Breeding	Genetic Engineering
Cell Fusion	
Chemical Mutants X-Ray Mutants	

The Coordinated Framework for the Regulation of Biotechnology (1986)

- The risks of GE organisms are not fundamentally different from risks posed by non-GE organisms with similar traits.
- The existing laws provide adequate authority.
- Regulation should be science-based and conducted on a case-by-case basis.

Regulation Under the Coordinated Framework



Agency **Authorities** & Responsibilities

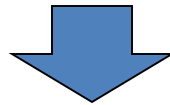
- **USDA APHIS**
 - **Plant Protection Act (PPA) of 2000**
 - **Plant Pest Potential - evaluate safety for agriculture and environment**
- **U.S. EPA**
 - **Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)**
 - **Federal Food, Drug, and Cosmetic Act (FFDCA)**
 - **Plant Incorporated Protectants (PIPs) – regulated as bio-pesticides**
 - **New herbicide uses**
- **FDA**
 - **Federal Food, Drug, and Cosmetic Act (FFDCA)**
 - **Food, food additives, and feed**
 - **Veterinary and human drugs, and human biologics**

GE Plant Development

LABORATORY / GREENHOUSE
(mostly/not regulated by APHIS)



FIELD TESTING
(regulated by APHIS)



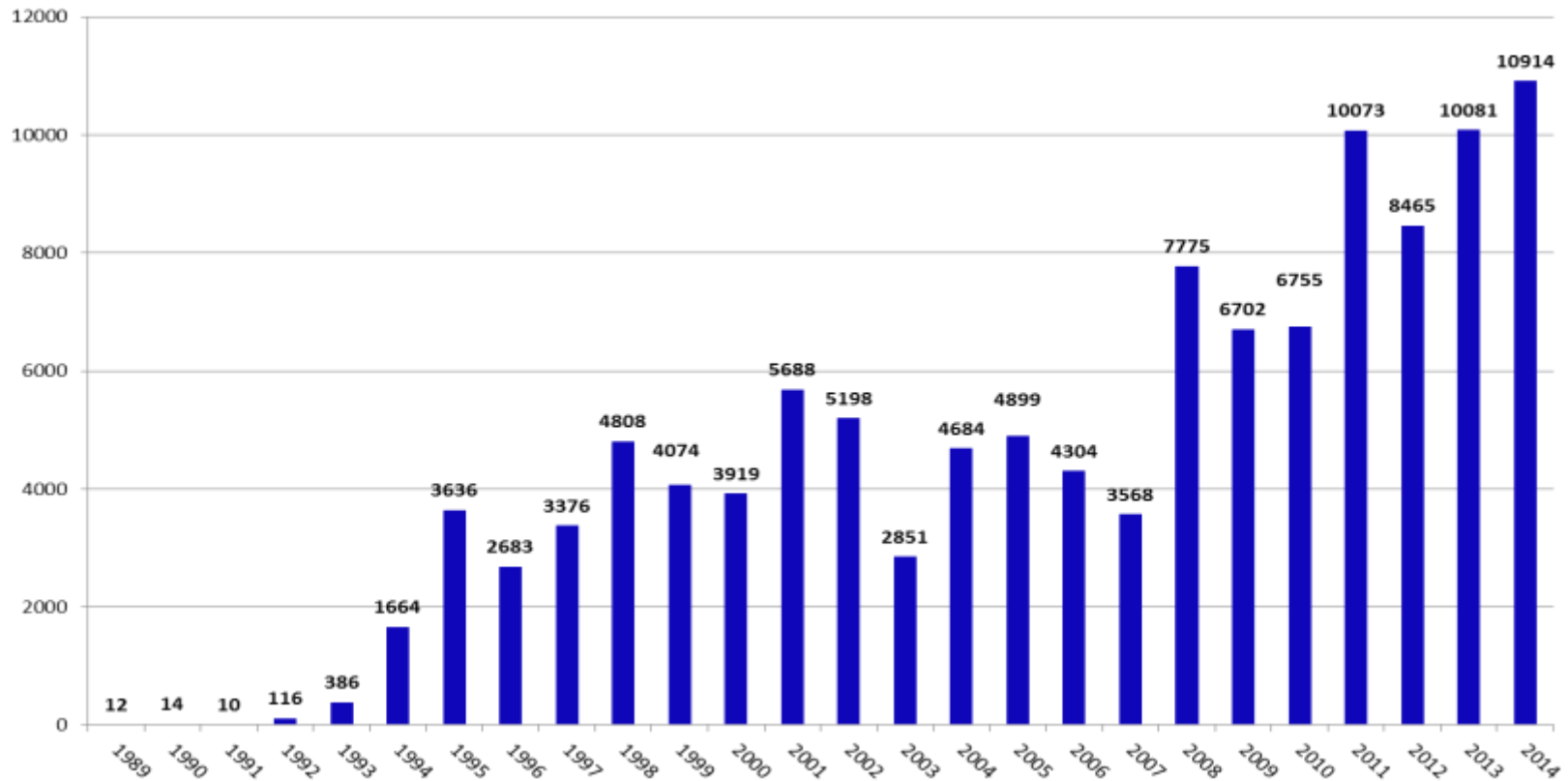
COMMERCIALIZATION
(not regulated by APHIS)

Regulated Activities

If a GE organism is regulated, a Permit or Notification is required for the following activities:

- Importation
- Interstate movement
- Environmental release (field trial)

BRS-Authorized Field Release Sites for GE Plants



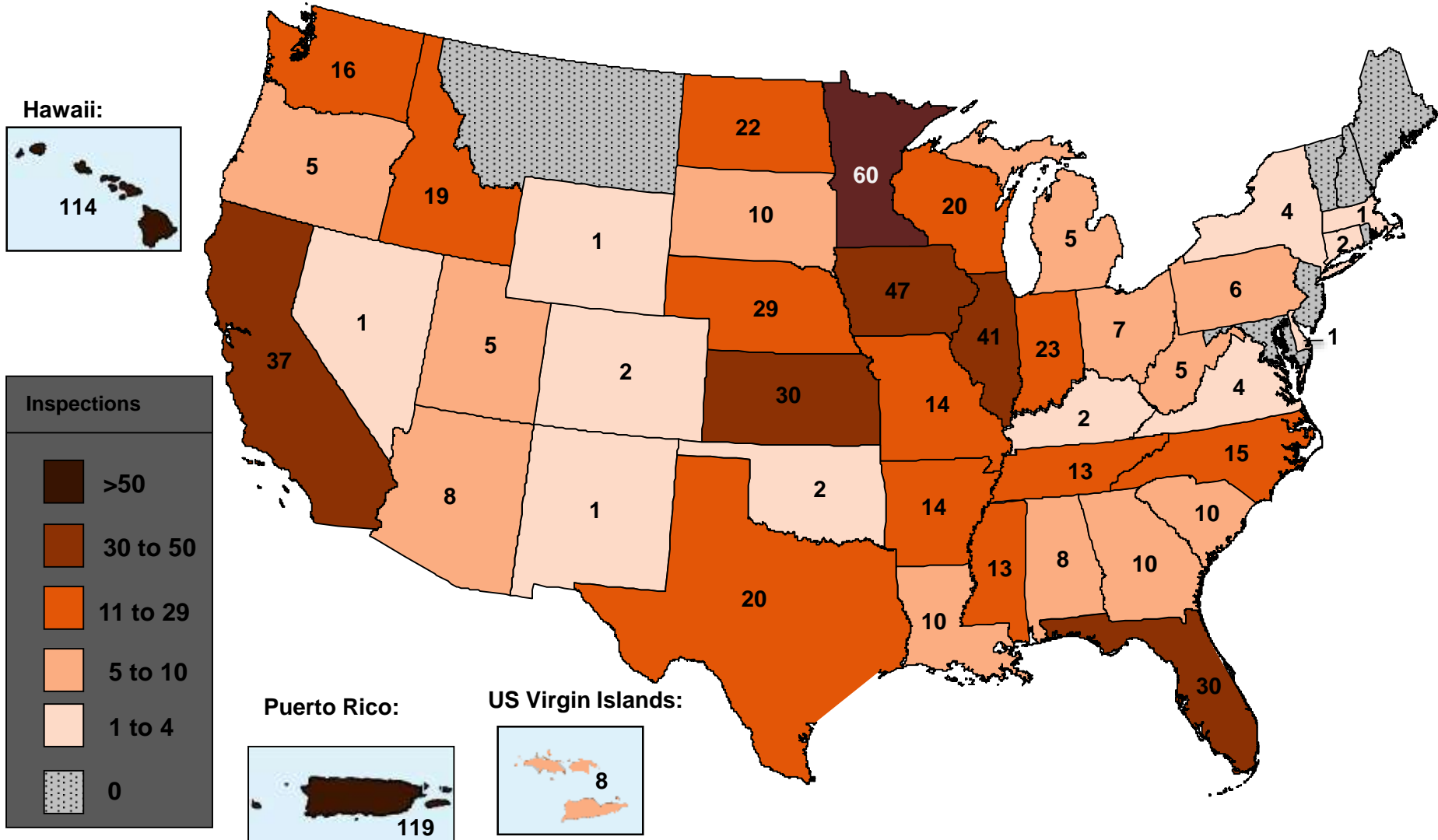
Compliance and Inspections:

all release sites eligible

verify compliance
with regulations



Biotech Inspections FY14 Total = 797



Petition for Nonregulated Status

After safety has been established through field testing and other research activities, a developer may petition APHIS to grant “nonregulated status”

- No longer a regulated article
- Free to be moved and planted without permits or further APHIS oversight.
- Actual commercialization of GE plants with nonregulated status is determined by market demand, not the APHIS decision.

GE Plants with Nonregulated Status under 7 CFR part 340

- ❖ Alfalfa – HR, PQ
- ❖ Canola – HR, AP, PQ
- ❖ Corn – HR, IR, AP, PQ
- ❖ Cotton – HR, IR
- ❖ Papaya – VR
- ❖ Soybean – HR, IR, AP, PQ
- ❖ Sugar Beet – HR
- ❖ Rose – PQ
- ❖ Squash – VR
- ❖ Tobacco – PQ
- ❖ Apple – PQ
- ❖ Chicory – AP
- ❖ Flax – HR
- ❖ Plum – VR
- ❖ Potato – IR, VR, PQ, FR
- ❖ Rice – HR
- ❖ Tomato – PQ

 Major Commercial Production
 Minor Commercial Production
 No Known Commercial Production

HR – Herbicide Resistant
 IR – Insect Resistant
 VR – Virus Resistant
 AP – Agronomic Properties
 PQ – Product Quality
 FR – Fungal Resistant

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New 7 CFR 340 Regulations

Current thinking ...



New 7 CFR 340 Regulations

- The United States' current process has been successful in protecting public health, welfare, safety, and the environment, while promoting innovation and growth.
- Current regulations developed in 1987 - The science has and continues to change rapidly.
- The revised 340 regulations will focus on those organisms that present a risk to plant health.
- Balance regulatory oversight with risk by shifting from “regulate first/analyze later” to upfront analysis that brings us to a place where we “analyze first/regulate when and how appropriate.”

New 7 CFR 340 Regulations

- Withdrew 2008 Proposed Rule
 - Enables fresh dialogue with stakeholders
- Conducted three public webinars (196 comment documents/220 K Commenters)
 - Gathers new ideas and input

New 7 CFR 340 Regulations

- Proposed Rule – the new proposed regulatory language by end of summer, 2016.
 - Current thinking
- EIS – Draft PEIS around time of Proposed Rule.
 - Notice of Intent

New 7 CFR 340 Regulations

CURRENT THINKING

- Noxious weed authority
- Scope around Products of Biotechnology
- Analyze first and regulate when appropriate
 - New Weed Risk Assessment Tool
 - Adjust the plant pest regulatory trigger
 - Issue regulatory status documentation
 - Regulatory Status Register online

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Modernizing the Regulatory System



Modernizing the Regulatory System for Biotechnology Products

- July 2 memo from EOP to the Regulatory Agencies
- Collaborative USG effort
 - Creates the Biotechnology Working Group
 - USDA/APHIS, EPA, and FDA

Separate and compatible efforts:

- Revision of 7 CFR 340 – how APHIS implements its statutory authority under the Plant Protection Act
- Modernizing Coordinated Framework – how the USG Federal agencies work together to regulate the products of biotechnology



Three Focus Areas

- Update the Coordinated Framework
 - Develop long-term strategy
 - Commission an external analysis
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- ❖ Ensure public confidence, prevent unnecessary barriers to innovation and competitiveness, improve coordination and efficiency, periodic updates, horizon scanning...public service

Public Meetings

- October 30, 2015 – FDA Facility in MD
- 2016 – two more meetings in the Central and Western United States (late Winter)
 - Comment period
 - Webinars
 - Gather public input



For More Information

USDA-APHIS-BRS:

<http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology>

