



Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Plants: The Regulatory Frontier

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Deputy Administrator

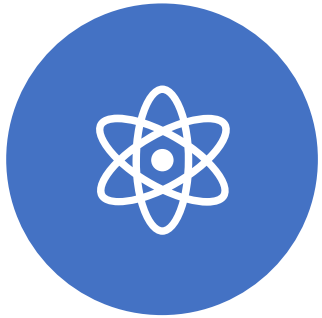
Animal and Plant Health Inspection Service (APHIS)

Biotechnology Regulatory Services (BRS)

February 23, 2023



Modernizing the Regulations



Based advances on science, technology, and experience



Clear, consistent, science-based and risk-based framework



Focus on areas of plausible risk to plant health and ease burden in well-understood areas



Nearly two years of experience with the revised regulations (since May 18, 2020)

Three Key Components

1

EXEMPTIONS and CONFIRMING EXEMPT STATUS (only plants)

2

REGULATORY STATUS REVIEW (only plants)

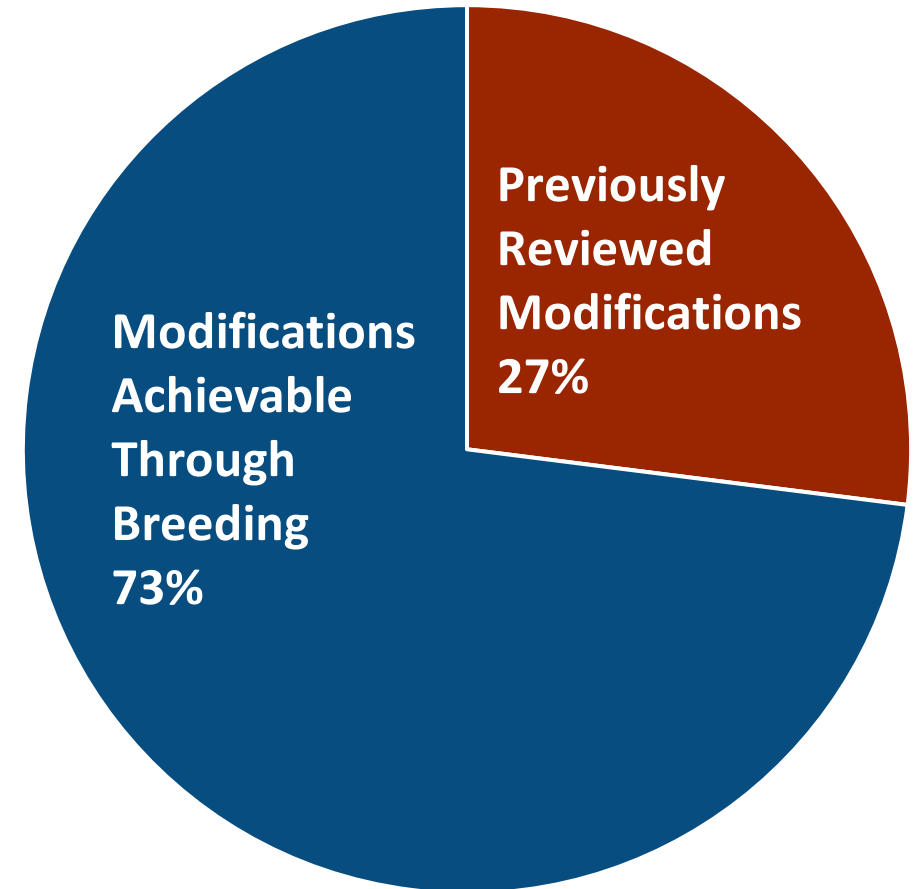
3

PERMITTING



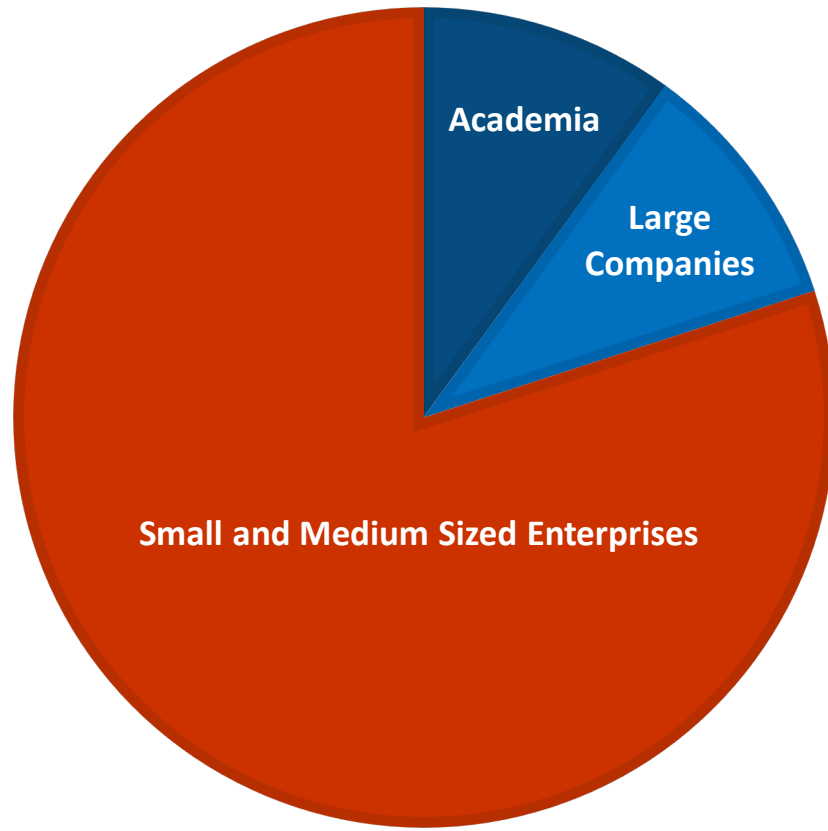
Regulatory Exemptions

- Certain modifications achievable through conventional breeding
- Same plant-trait-mechanism of action combination previously reviewed and found not regulated
- 30 letters confirming a modified plant's exempt status (on average, within 41 days of receiving a complete submission)

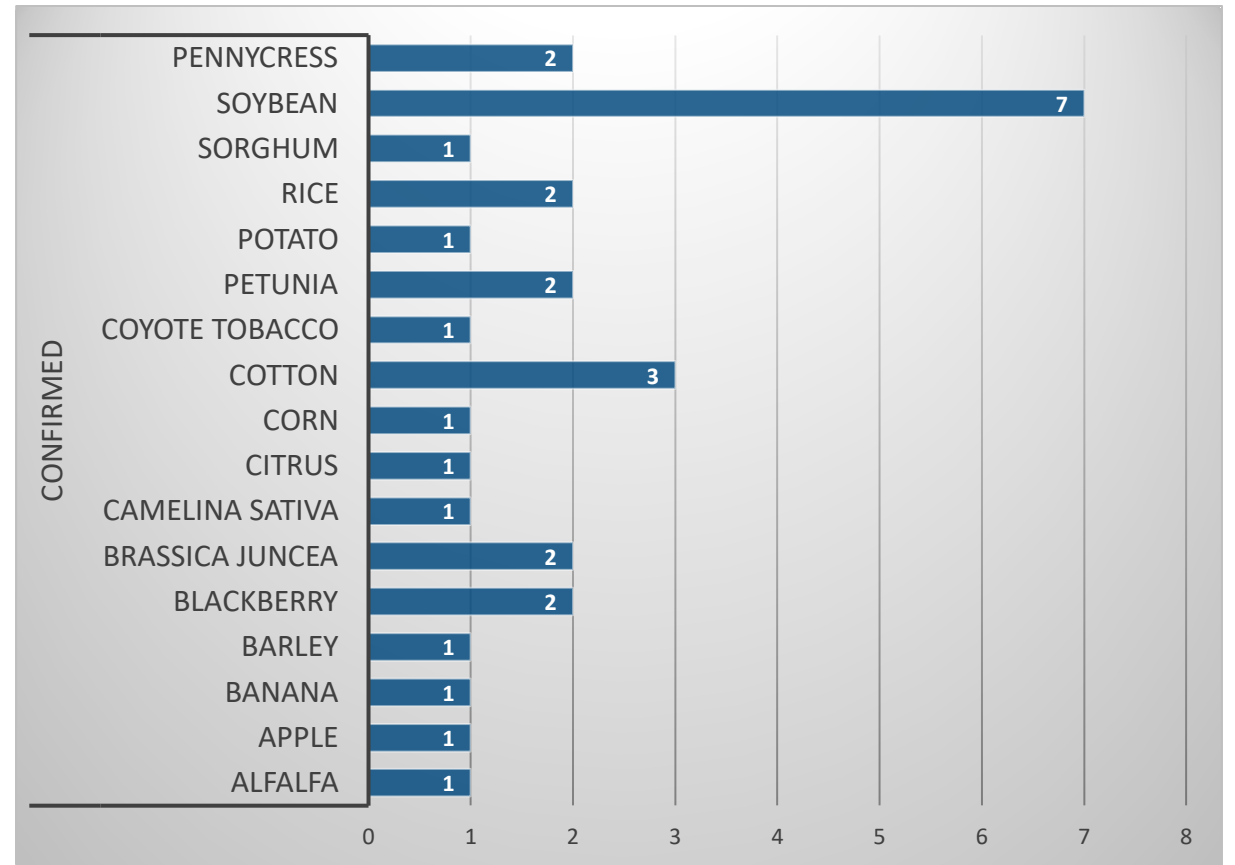




Institution Type



Plant Varieties



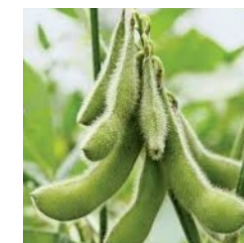
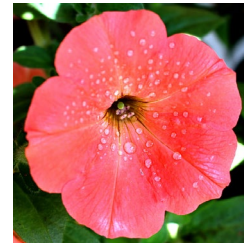
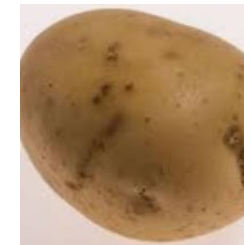
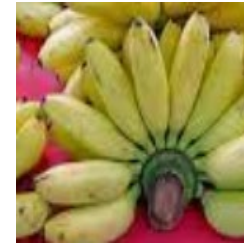


Confirmation Request – Traits

Herbicide, Insect, and Disease Resistance Traits



Product Quality Traits



Agricultural Production Traits



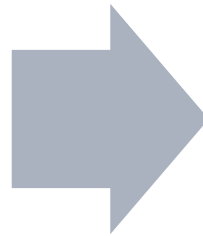
Other



Regulatory Status Review Process

1

Initial review problem formulation
to identify whether there are
plausible pathways to increased
plant pest risk

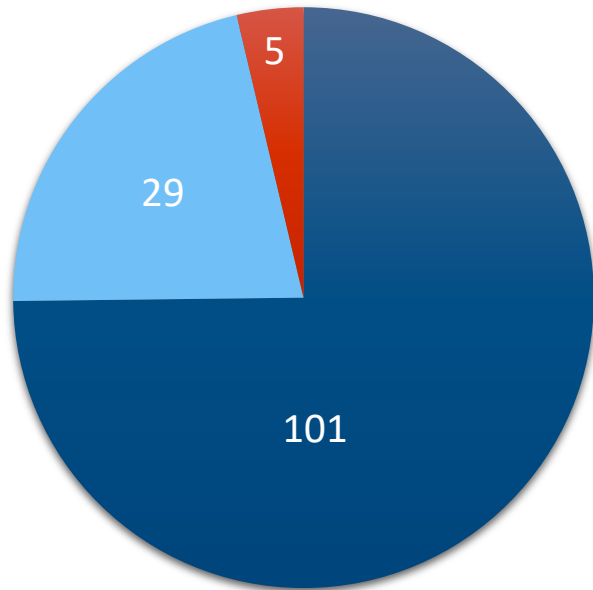


2

Plant Pest Risk Assessment (PPRA)
determines likelihood and
consequence of any plausible
pathways in the initial review

Impact of Revised Regulations

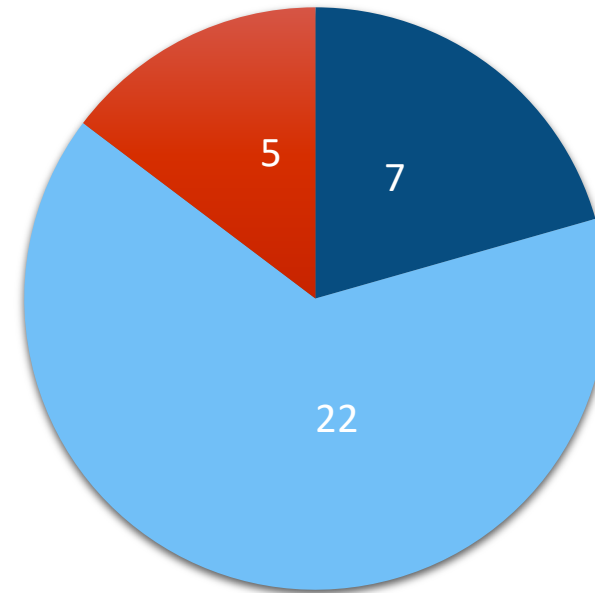
Completed Petitions



■ Major Biotech ■ Other Companies ■ Public

19 Crops
1992-2020

Regulatory Status Reviews (RSR)

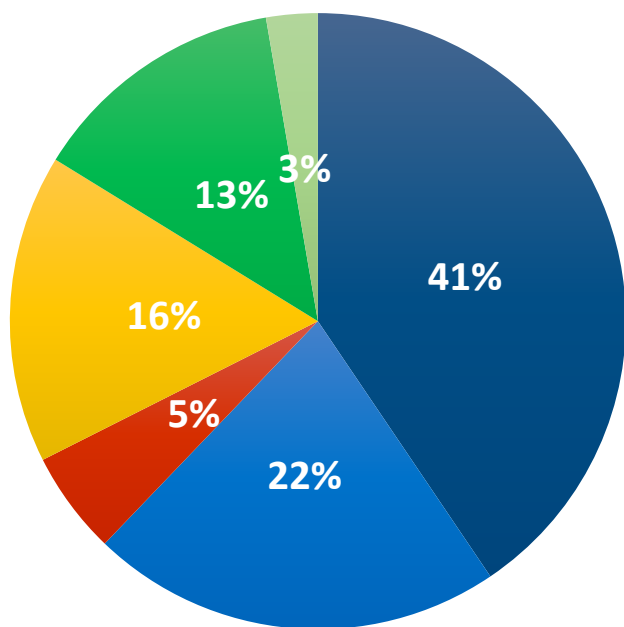


■ Major Biotech ■ Other Companies ■ Public

20 Crops
2020-Present

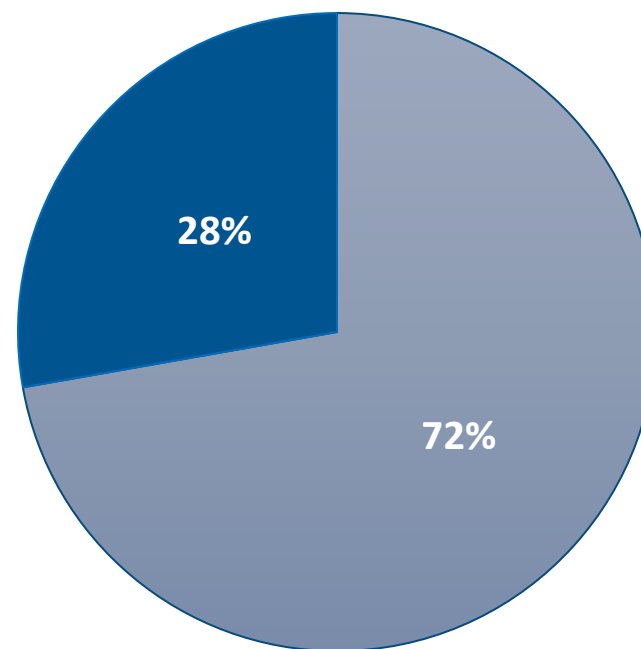
Impact of Revised Regulations

Crop/Plant categories



■ Annual/ Row crop ■ Vegetable/ Fruit
■ Ornamental ■ Tree
■ Oilseed/ Cover crop ■ Medicinal

Nature of modification



■ Transgenes ■ Genome edits



Completed Regulatory Status Reviews



Norfolk Tomato
Enhanced Nutrition



Agrivida Corn
Improved Digestion
for Feed



Toolgen Potato
Reduced Browning



Simplot Potato
Improved Product
Quality and Disease
Resistance



**Infinite Enzymes
Corn**
Enzyme for potential
detoxification



Zeakal Soybean
Increased Oil and
Protein



**Suntory Flowers
Limited
Chrysanthemum**
Altered Flower
Color

Next Steps: Improving Regulatory Processes

Regulatory Status Reviews

Firmly establish the RSR process and develop a trained cadre of risk assessors, enabling a high throughput of RSR reviews

Guidance

Provide developers with a guide for submitting inquiries and permits for modified microorganisms microbes

Regulatory Exemptions

Act on the notice proposing three new modifications a plant can contain and be exempt from regulation, and respond to comments proposing additional modifications for exemption.

Next Steps: Implementing Executive Order

Identify

Identify areas of ambiguity, gaps, or uncertainties in the Coordinated Framework (March 2023)

Improve

Improve the clarity of the regulatory processes and establish a plan for updating or streamlining regulations and guidance documents (June 2023)

Enhance

Enhance the Unified Website for Biotechnology Regulation (September 2024)

Emerging Themes from Comments

Regulatory Clarity

Guidance, plain language, clarifying agency roles

Regulatory Resources

Training on regulatory process, continued learning for staff

Regulatory Reform/Revision

Streamlining, gap filling, not over-extending scope/authority, labeling

Regulatory Coordination/Harmonization

Single intake, collaborative decision-making, consistent approaches, cross/inter-agency issues (calls for OSTP or other WH-led coordination)

THANK YOU!

