

# Welcome

to the

# BRS Stakeholder Meeting



**AGENDA**



**RESOURCES  
ONE-PAGER**



# Welcome!

Amanda Kenney, Ph.D.

Senior Biological Scientist



# Opening Remarks

Dudley Hoskins, J.D., USDA MRP Under Secretary

Kelly Moore, M.A., USDA APHIS Acting Administrator



# FY 25 Program Highlights

Donna Lalli, Ph.D.

BRS Deputy Administrator

# A Tale of Two Rules in FY 25



2020-2024  
SECURE  
Rule

Original  
Rule



# Quick Service Restoration under the Original Rule

# Am I Regulated (AIR) Inquiries



Restarted AIR process in **17 days**



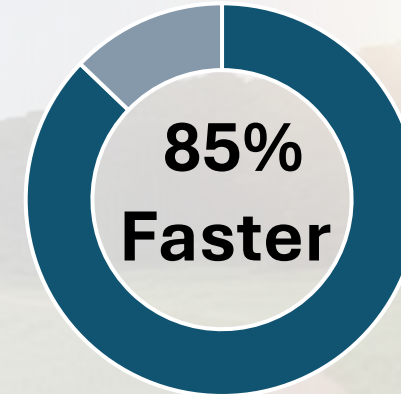
**Target:** Respond to Am I Regulated (AIR) inquiries **35% faster**



Issued 69 AIR responses –  
A **360% increase in responses**

## AIR Accomplishment

FY 25 Average:  
**28 Days**



Historic  
Average:  
**190 days**

2025 Days

Historic Average Days

Am I  
Regulated?

# Authorizations for Regulated Activities



Restarted **permit process in 17 days** and **notifications process in 52 days**



**Target: Issue 95% within regulatory timeframe**



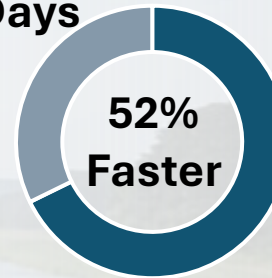
**Target exceeded** with roughly **42% faster service**



**Trend – FY 21 – FY 25: Permit applications for modified microbes increased greater than two-fold**

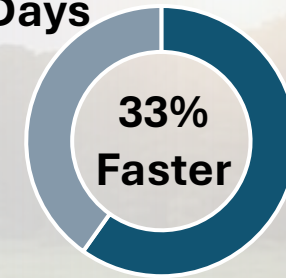
## Movement Permits

20 Days



## Release Permits

45 Days



■ 2025 Days ■ Historic Average Days

Permits/  
Notifications

# Compliance Oversight

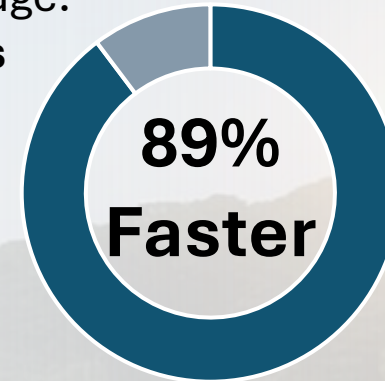


**Target: Issue noncompliance notices within 14 days**



**Issued 93% of noncompliance notices within 14 days**

FY 25 Average:  
**11 Days**



2025 Days

Historic Average Days

Regulatory  
Operations

# Petitions



Restarted **accepting petitions** in **87 days**

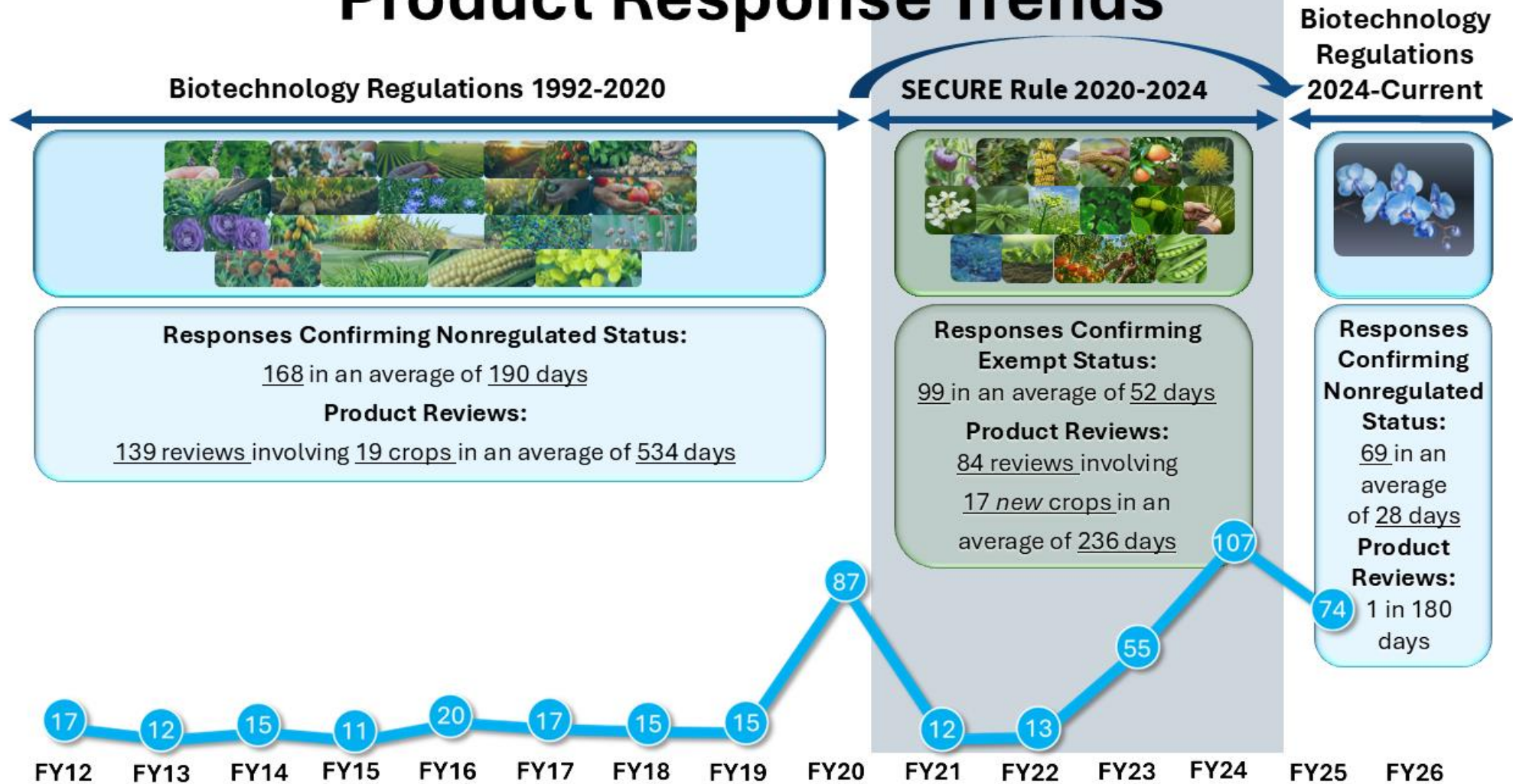


Issued our first **petition** (orchid) within the 180-day regulatory timeframe



Petitions

# Product Response Trends



# Looking Forward: The Proposed Efficiency Rule

## Current State

- Petition for every new transformation event
- Duplicative regulation for products regulated by EPA and USDA
- Prescriptive shipping requirements
- Limited duration movement permits

## Efficiency Rule Impact

### Regulatory Streamlining

- ✓ Movement exclusions for low risk/common lab organisms
- ✓ Reduces rigid shipping requirements
- ✓ Multiyear movement permits

### Regulatory Relief

- Deregulation applies to future transformation events eliminating re-review of the same product.
- USDA regulatory relief when a product is registered or permitted by EPA.



# For More Information

## Contact Us:



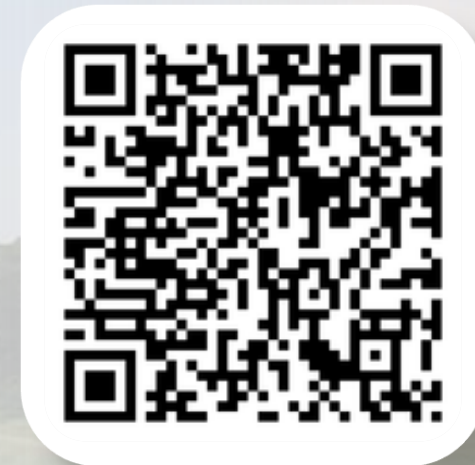
<https://www.aphis.usda.gov/contact/biotechnology>

## BRS Website:



<https://www.aphis.usda.gov/biotechnology>

## Subscribe:



<https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new>

# Coming Up

**Regulatory  
Operations**

**International  
Engagement**

**Microbe  
Efforts**

**Permits/  
Notifications**

**Organizational  
Updates**

**Petitions**

**Am I  
Regulated?**



# Thank You!

Donna Lalli, Ph.D.

BRS Deputy Administrator



# Organizational Updates

Michael Stulberg, Ph.D.

BRS Associate Deputy Administrator

A wooden sign on a post, placed on a dirt path in a rural landscape. The sign is weathered and has the text 'Organizational Updates' written on it in a bold, sans-serif font. The background shows a dirt path curving through a green field towards a river and a wooden bridge, with a sun setting behind a line of trees in the distance.

Organizational  
Updates



# FY 25 New Staff Members



**Jennifer Nelson**

Branch Chief  
Resource Management Services



**Donna Lalli, Ph.D.**

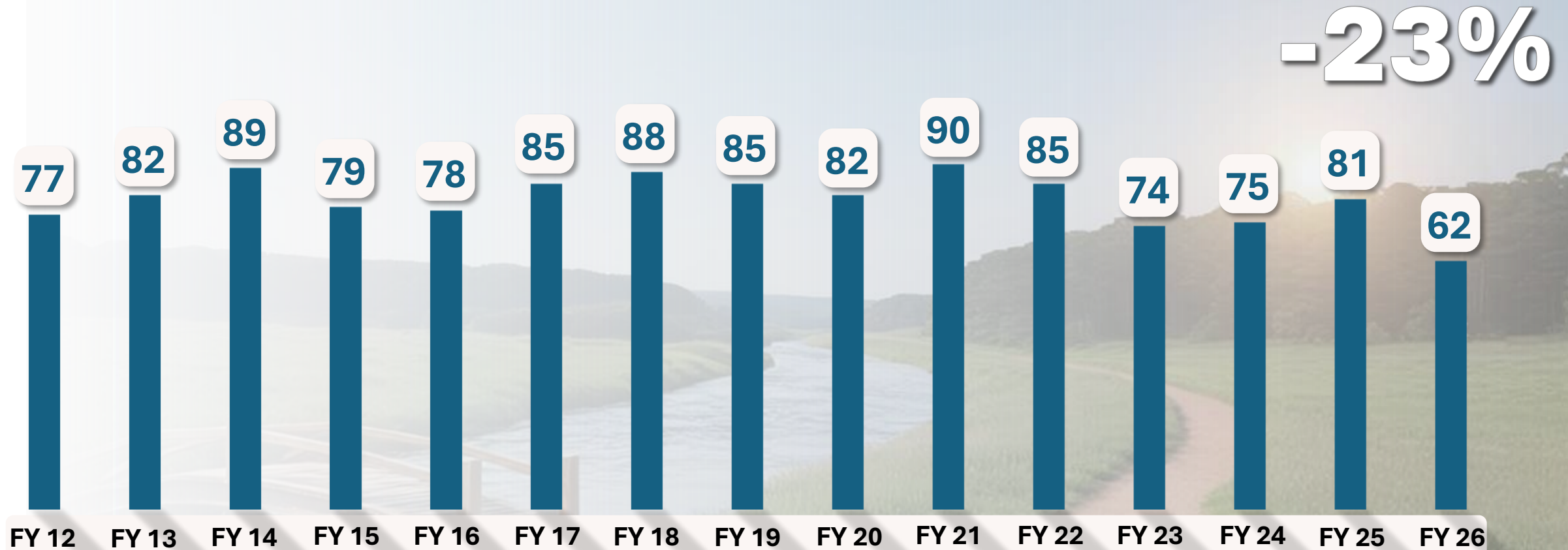
Deputy Administrator  
Office of the Deputy Administrator



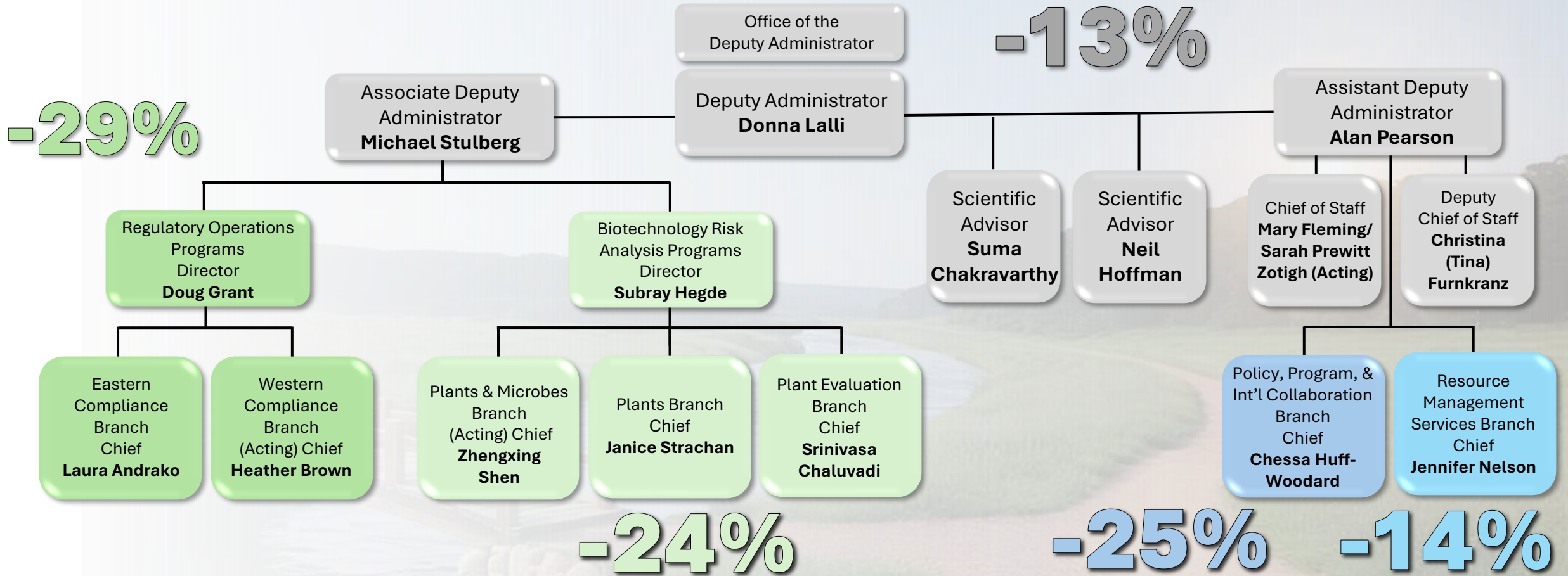
**Christina (Tina) Furnkranz**

Deputy Chief of Staff  
Office of the Deputy Administrator

# Staffing Levels since FY 12



# BRS Organization





# APHIS Headquarters Move

Riverdale, MD



Spring 2025

Beltsville, MD





# Thank You!

Michael Stulberg, Ph.D.

BRS Associate Deputy Administrator

A wooden sign on a post, placed on a dirt path. The sign is rectangular with a weathered, light-brown wood texture and contains the text 'Organizational Updates' in a bold, black, sans-serif font. The background of the slide is a scenic landscape with a river, a wooden bridge, a dirt path, and a sun setting behind a line of trees.



# Am I Regulated (AIR)?

Rebecca Fletcher, Ph.D.

Senior Biological Scientist

*Biotechnology Risk*

*Analysis Programs (BRAP)*



# What is the AIR process?



Voluntary and nonregulatory process



Developers submit a letter of inquiry describing their modified organism



BRS issues a response letter confirming that the organism does not meet, or meets, the definition of “regulated article”



Not a risk assessment

# What is a Regulated Article?



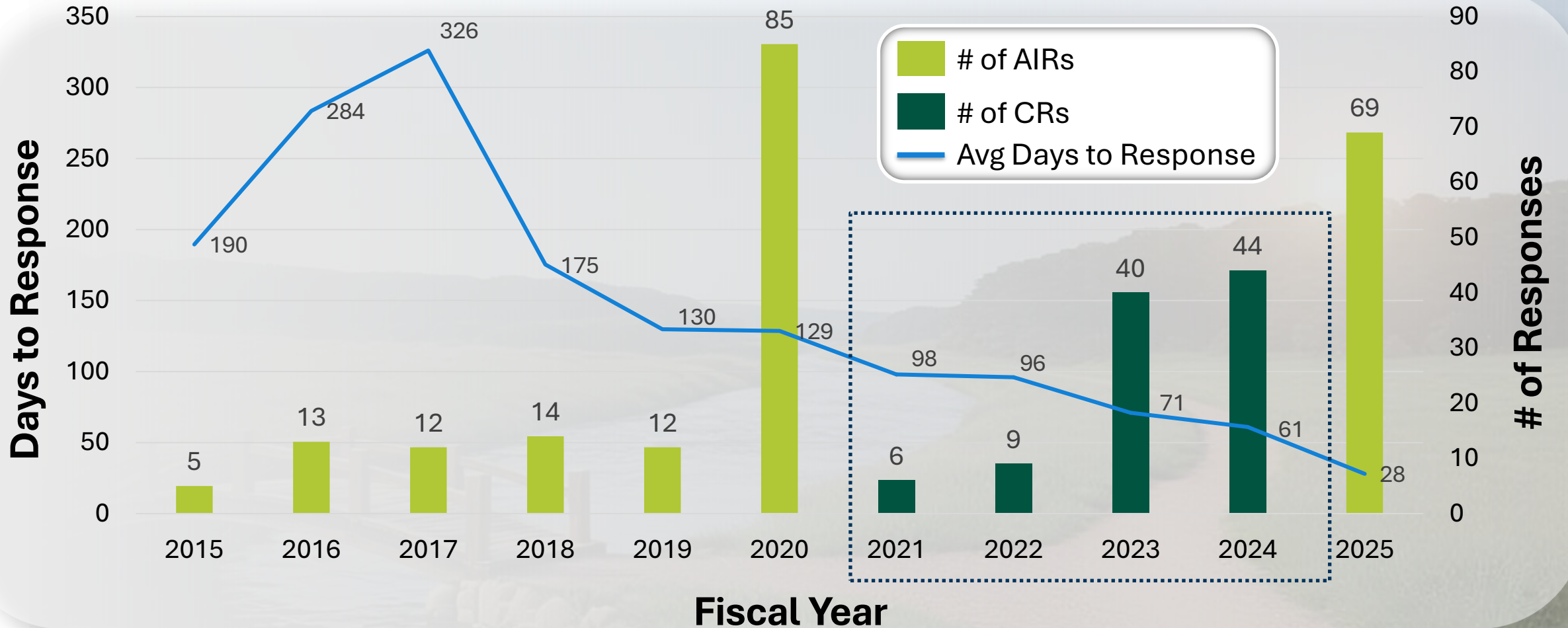
A regulated article is an organism that has been altered or produced using genetic engineering and that:

has one or more of its components derived from a plant pest or an unclassified or unknown organism;

**or**

that APHIS determines is a plant pest or has reason to believe is a plant pest

# AIR Trends: Process Efficiency



# FY 25: Varieties of Organisms and Traits

## 20 plant species & 9 microbes

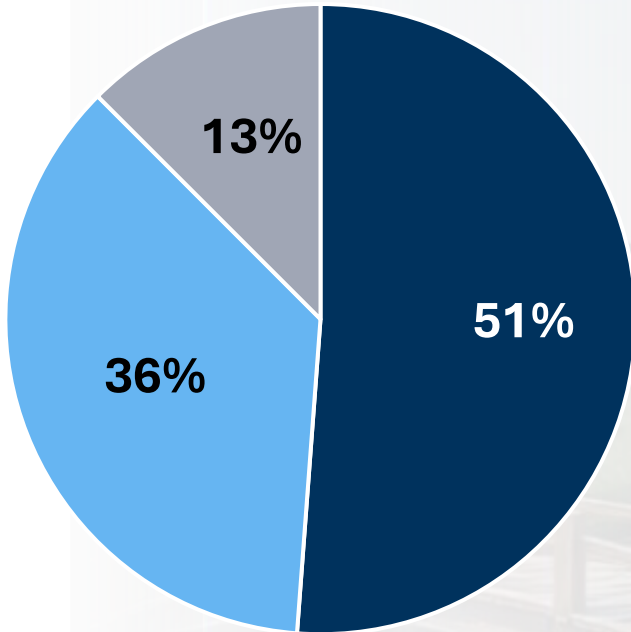


## Example traits and phenotypes

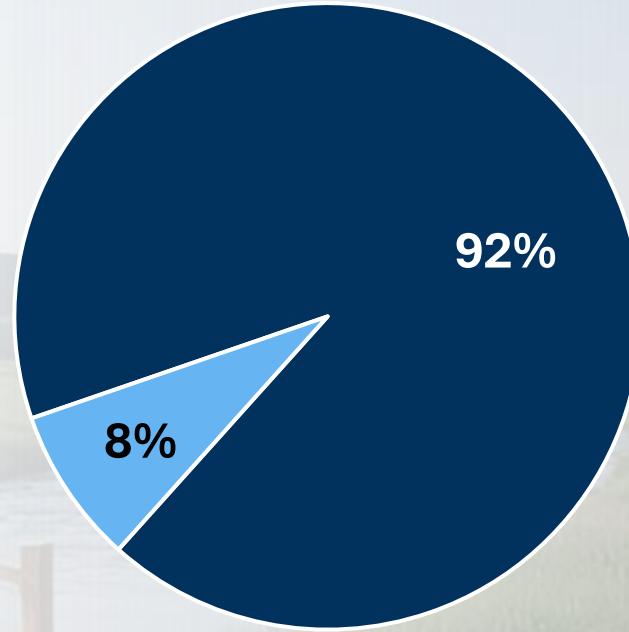
Herbicide Resistance  
 Altered Plant Architecture  
 Reduced Browning Altered Maturation  
 Waxy Tubers Altered Seed Characteristics  
**Altered Root Architecture**  
 Reduced Stature  
**Altered Fruit Quality**  
 Altered Product Quality Water Use Efficiency  
 Male Sterility Increased Biomass  
**Disease Resistance**  
 Drought Tolerance  
 Altered Ear Morphology  
 Improved Heat Tolerance **Increased Yield**

# Modification Category

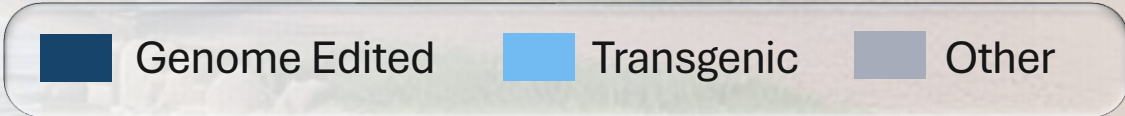
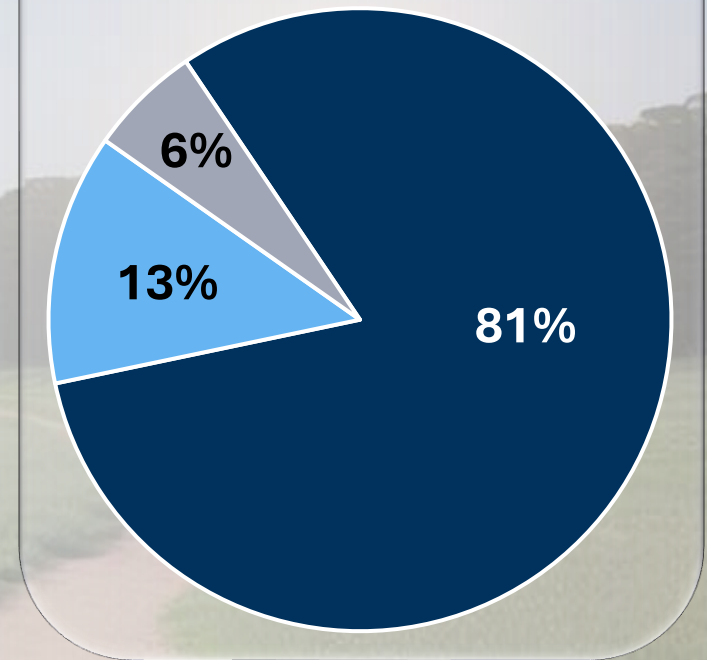
**AIRs FY 11-FY 20**  
(N=168)



**CRs FY 21-FY 24**  
(N=99)

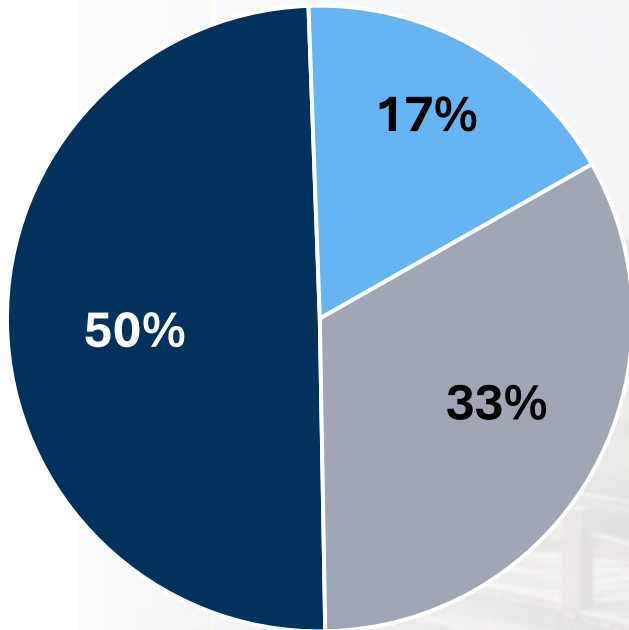


**AIR FY 25**  
(N=69)

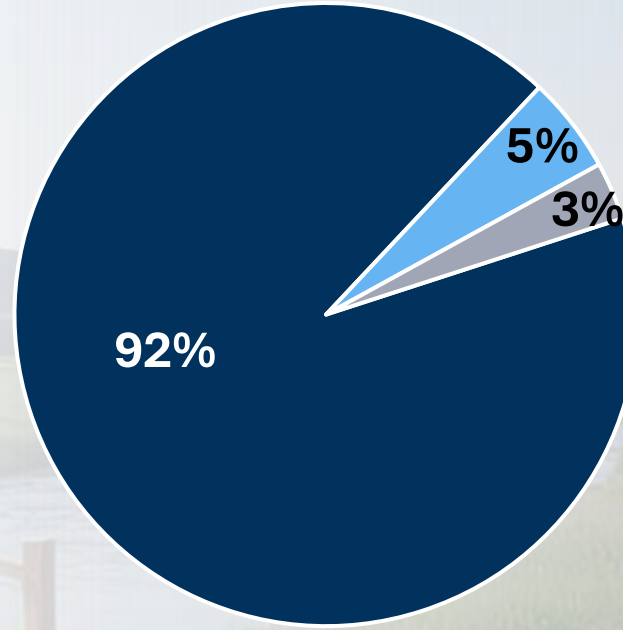


# Types of Organizations

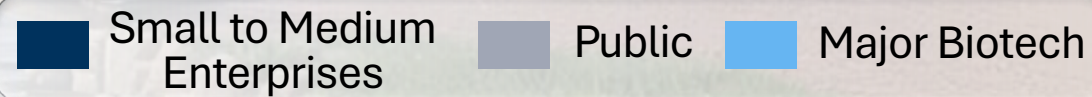
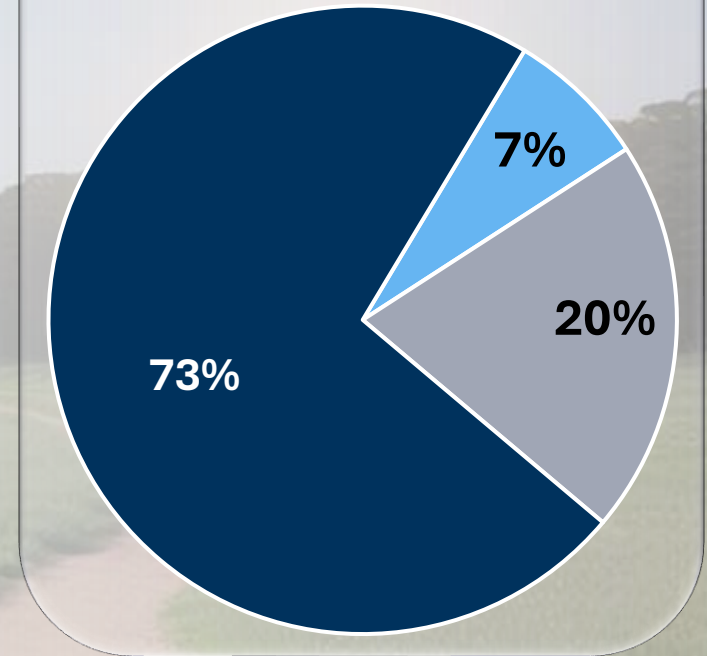
**AIRs FY 11-FY 20**  
(N=168)



**CRs FY 21-FY 24**  
(N=99)



**AIR FY 25**  
(N=69)





# Updates to the AIR Guide



Clarification on information requirements



Clarification that BRS does not conduct risk assessment through the AIR process



Administrative updates



# Resources

## AIR Guide:



<https://www.usda.gov/guidance-documents/biotechnology/aphis/am-i-regulated-air-process-guide-submission-air-inquiries>

## Public Table:



<https://www.aphis.usda.gov/biotechnology/regulated-article-inquiry>

## AIR Email Address:



[AIRinquiry@usda.gov](mailto:AIRinquiry@usda.gov)



# Thank You!

Rebecca Fletcher, Ph.D.

Senior Biological Scientist

*Biotechnology Risk*

*Analysis Programs (BRAP)*





# Petitions

Amanda Kenney, Ph.D.

Senior Biological Scientist

Subray Hegde, Ph.D.

Director

*Biotechnology Risk Analysis Programs (BRAP)*



# What is the Petition Process for Modified Plants under § 340.6?

Regulatory process to seek deregulation of a genetically engineered (modified) plant

- 1 Developers **submit** a written petition
- 2 APHIS **conducts** a plant pest risk assessment (PPRA)
- 3 APHIS **publishes** the petition and PPRA for public comment
- 4 APHIS **issues** a determination

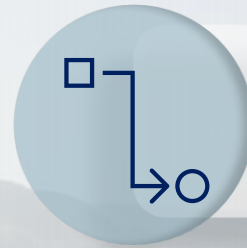
If deregulated, the modified plant may be moved and planted without BRS regulatory oversight\*

*\* Modified plants may be subject to regulatory review by other U.S. agencies*

# Petition Process Updates



Revised Petition User Guide



Better aligned petition process  
with the regulations



Shorter review time

# Required Information for a Petition

**Our risk assessment is comparative**



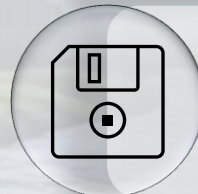
Biology of the nonmodified plant



Genotypic differences & mechanism of action (MOA)



Known and plausible phenotypic differences



Relevant experimental data and publications



List of authorizations

# Characteristics Relevant to 7 CFR 340

✓ Expression of the gene product, new phenotypes, or changes to plant metabolism
✓ Plant pest risk characteristics
✓ Disease and pest susceptibility
✓ Indirect plant pest susceptibility
✓ Effects of the regulatory event
✓ Weediness of the plant
✓ Impact on weediness
✓ Agricultural or cultural uses
✓ Transfer of genetic material
✓ Any other information that may be relevant

APHIS uses this information to conduct a **plant pest risk assessment (PPRA)** to evaluate whether a modified plant is unlikely to pose a **greater plant pest risk** than the nonmodified plant from which it was derived

# Types of Data and Information

Amount and type of **information needed depends** on the **plant** and the **trait**



Observational information



Experimental results



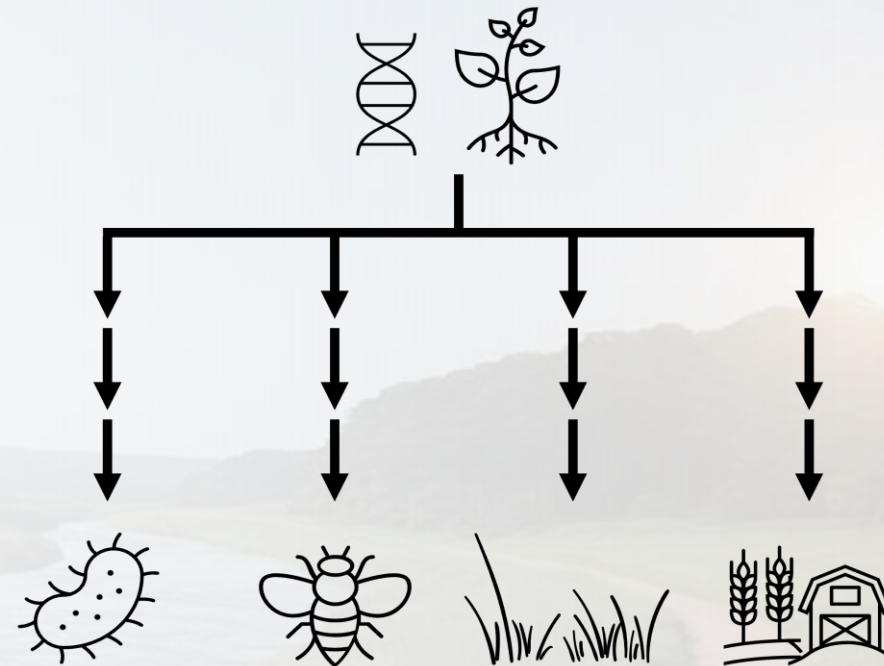
Existing literature or public reports



Logical reasoning or synthesis

# Problem Formulation

**Problem Formulation** helps determine what **information is needed to assess plausible plant pest risk for a particular plant + genetic modification (trait) combination**



Could the plausible ***phenotypic changes*** in ***this plant*** result in ***greater plant pest risk***?

# Petitioner Tips

- For plants without a prior petition, provide thorough information about the nonmodified plant
- Provide thorough explanation of mechanism of action (MOA)
- Provide thorough description of known and plausible phenotypic changes and if/how they affect plant pest risk



**\*\*We encourage pre-submission consultation\*\***

# Updated Petition Process

If technically incomplete, options are:

1) Respond within 7 days choosing one of the options;

- submit a revised petition addressing review comments, or
- pause the petition

- **No** NEPA analysis
- **Reduced** 3 FR Notices to 2
- **Reduced** regulatory timeline from 15 to 6 months for Determination



# FY 25 Petition Metrics

**FY 25 petitions and extensions received: 11**

**FY 25 petitions completed: 1**

**FY 25 petitions posted for public comment: 7**

**FY 25 petitions or extensions pending in various stages of review: 2**

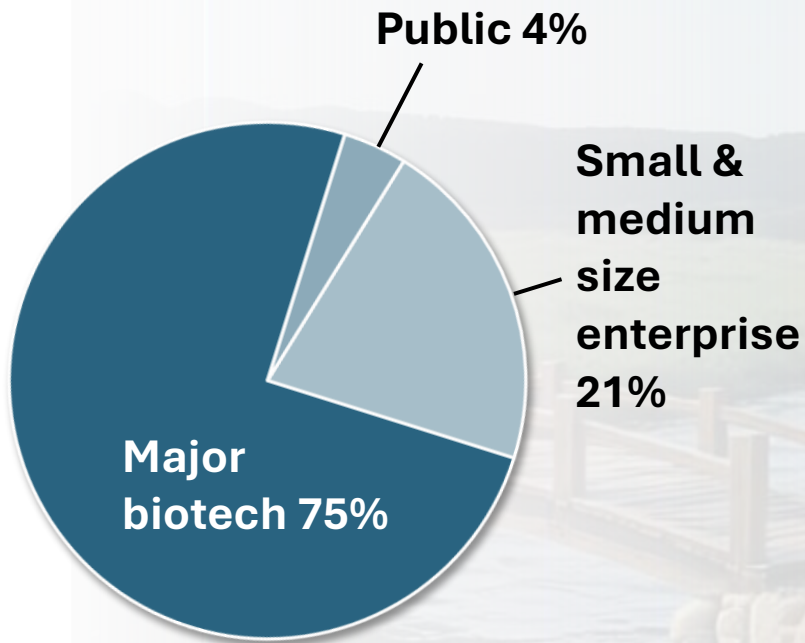
**FY 25 petitions withdrawn: 1**

# FY 25 Petition Submissions

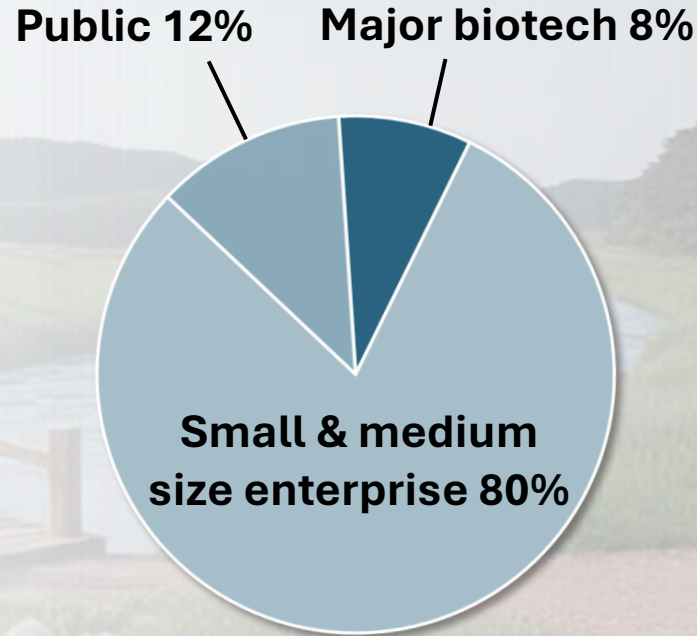
<b>Total</b>	<b>Total petitions and extensions received: 11</b>
<b>Species</b>	<b>Number of species received: 6</b>
<b>New Species</b>	<b>Number of new species received: 4</b>

# Applicant Makeup

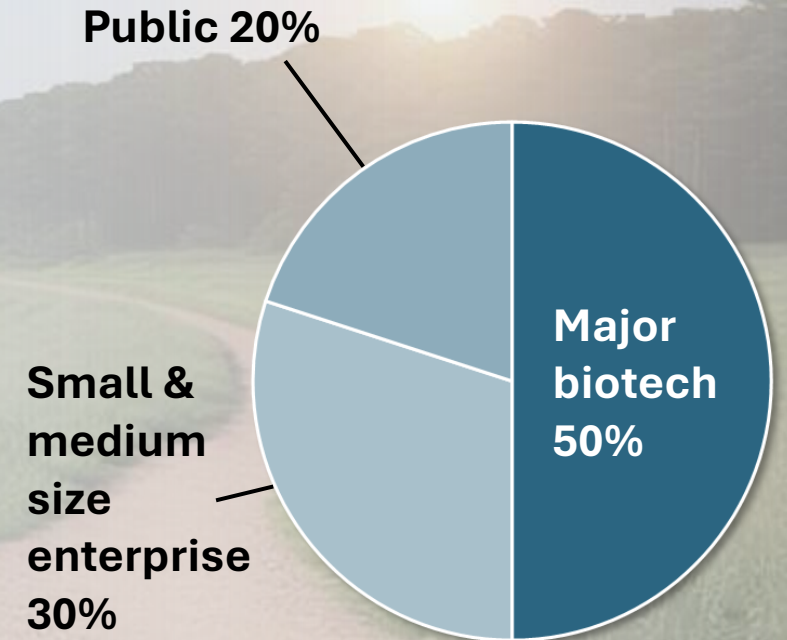
**Petitions  
1992 to 2020**



**RSRs under Secure  
2021 to 2024**



**FY 25 Petitions  
(out of 10)**



# Focus for FY 26

## Identify

Identify internal petition review steps where efficiency can be gained to consistently achieve regulatory timeline of 180 days.

## Clarify

Clarify information needed from petitioners based on crop-trait combinations.



# Resources

**Petitions Website:**



<https://www.aphis.usda.gov/petitions>

**Petitions Email Address:**



[BRS.Petitions@usda.gov](mailto:BRS.Petitions@usda.gov)



# Thank You!

Amanda Kenney, Ph.D.

Senior Biological Scientist

Subray Hegde, Ph.D.

Director

*Biotechnology Risk Analysis Programs (BRAP)*





# Q & A Panel

Donna Lalli,  
Michael Stulberg,  
Rebecca Fletcher,  
Amanda Kenney,  
and Subray Hegde

A scenic landscape featuring a river flowing through a valley. A wooden bridge crosses the river in the foreground. A dirt path leads from the bridge towards the right, where three wooden signs are posted. The sun is setting or rising in the background, creating a warm glow over the scene.

Organizational  
Updates

Petitions

Am I  
Regulated?



# BREAK

20 Minutes



# Permits and Notifications

Katharine Swoboda Bhattarai, Ph.D.

Biological Scientist

Janice Strachan, M.A.

Branch Chief

*Biotechnology Risk Analysis Programs (BRAP)*



# Permitting Business Process Improvement (BPI) Project

## OBJECTIVE

Re-establish a risk-based and familiarity-based approach for reviewing crop-trait-genotype combinations in permit applications

## GOAL

Restore track record of predictable and timely issuance of permits and confidence in BRS' permitting process

## MEASURABLE TARGETS

- Meet regulatory targets for average days to issue permits
- Issue 95% of BRS permits within the regulatory timeframe

# FY 24 BPI Process Improvements



Streamlined APHIS eFile permit review workflow



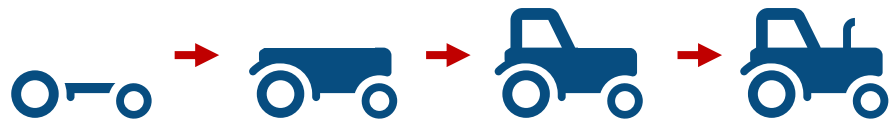
Implemented permitting flexibilities for import permits



Increased consistency of permit reviews and communication with applicants



Increased consistency of permit conditions



# FY 24 BPI Outcomes

**Exceeded BPI goal** of issuing 95% of permit applications within regulatory timeframes

## Permit Review Timeline

Reduced 3 hand-offs  
and eliminated 5.5 days

## Average Days to Issuance

Reduced by 9 days for  
movements and held  
steady for releases

## Permits Issued on Time

Increased by 9% for  
movements and  
1% for releases

# Challenge – Vacatur of Revised Regulations

Realign BRS permit and notification authorizations with original regulations

**1**

Walk back some BPI  
process improvements  
from FY 24

**2**

Resume accepting  
permit applications  
in APHIS eFile as  
soon as possible

**3**

Re-establish the  
notification process  
for crops and traits  
that BRS has extensive  
experience with

# Challenge Met – Permits



Realigned APHIS eFile permit workflow with original regulations



Realigned permit conditions with original regulations



Published revised permitting guidance documents on our website



Accepted permit applications in APHIS eFile starting on Dec 19, 2024

# Challenge Met – Notifications



Created temporary notification application pathway in APHIS eFile



Published revised notification guidance documents on our website



Accepted notification applications in APHIS eFile starting on Feb 7, 2025



Established notification review team & framework for documenting decisions

# Notifications Overview

Type	Notifications	Permits
Interstate Movement	10	60
Import	30	60
IMR/Release	30	120



Codified at 7 CFR § 340.3



Plants must meet 6 eligibility criteria and align with 6 performance standards



Reduced regulatory timeframes (days) compared to permits

# Notifications Overview

Notification application was established in APHIS eFile on June 13, 2025



Do you import, transport, or release into the environment genetically engineered organisms?

Check out our [Biotechnology Regulatory Services \(BRS\) Pre-Application Questionnaire](#).

## Notification Workflow

Authorization Progress

Application Review

State Review

Issue Acknowledgement

## Permit Workflow

Authorization Progress

Application Review

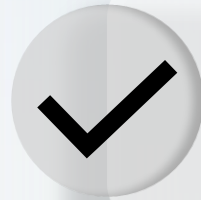
Conditions Collaboration

State Review

Permit Package

**BRS can convert notification applications that do not meet qualifications into permit applications**

# Additional BPI Accomplishments



Aligned authorization review processes with original regulations



Developed standardized permit conditions for cotton and tomato

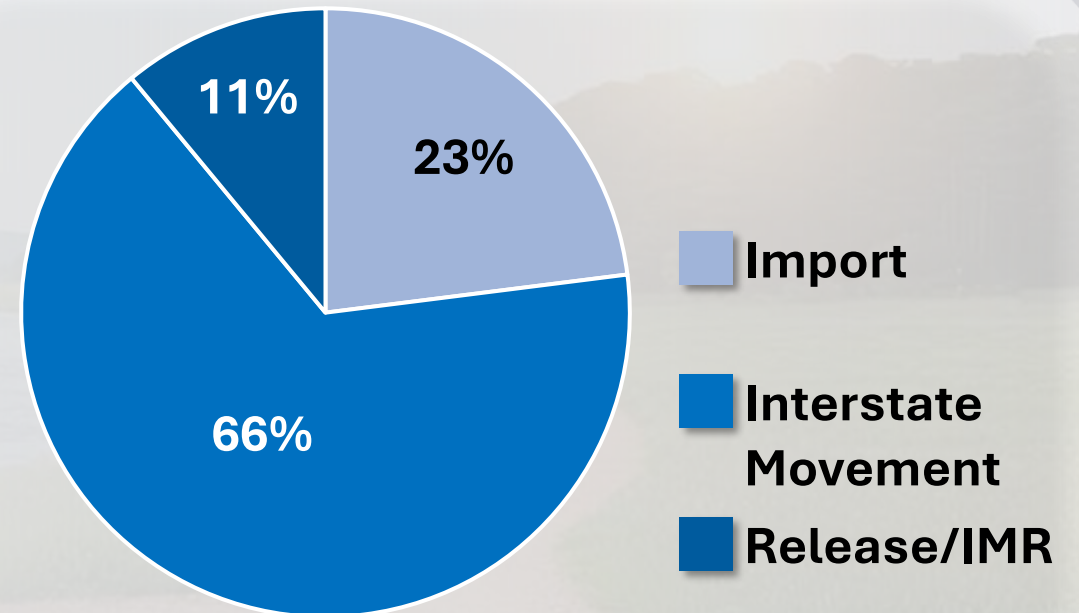


Examined PMPI and invertebrate permit review processes for potential efficiency gains

# Microbe Permits

## Supplemental Permit Conditions

- Standardized conditions for import and interstate movement permits
  - All greenhouse use requests require an APHIS inspection → BRS inspection or PPQ inspection (within the last 3 years)
  - Inspection must apply to the organism
- Worked to standardize conditions for release permits



# Microbe Permits

## Kingdom-Level High-Throughput Permits

Authorize interstate movement only

Do not authorize greenhouse use

Require applicants to list each microorganism (genus and species)

Require applicants to list at least one construct

Have specific reporting requirements

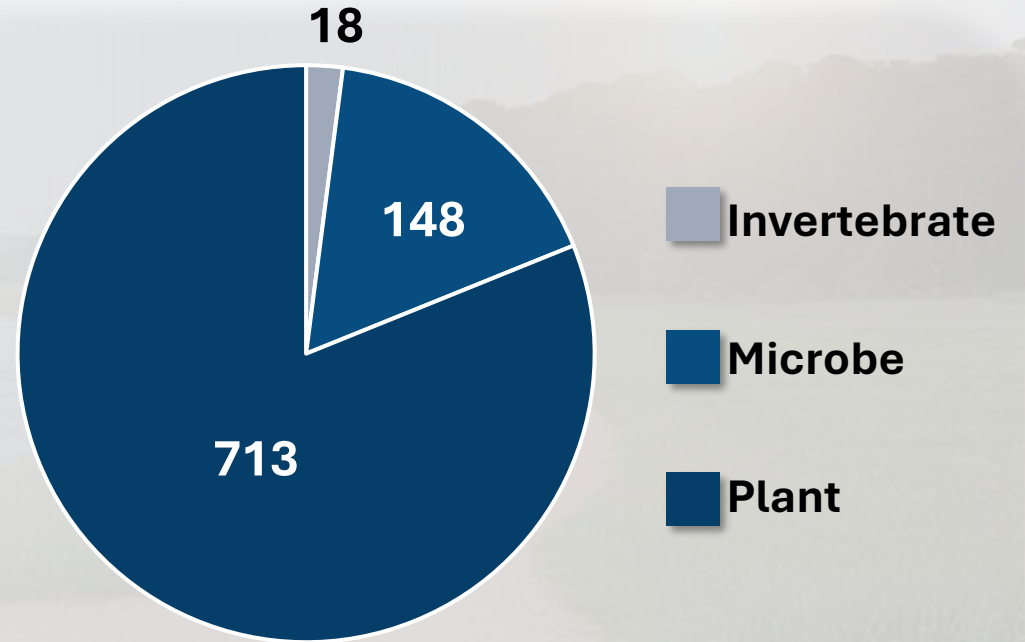
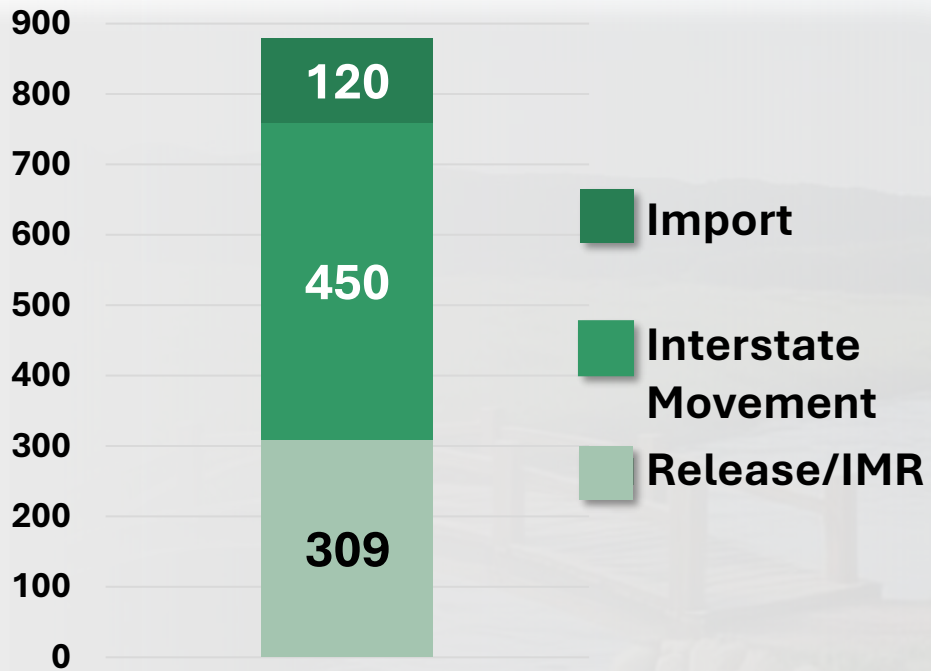
**Updated Permit  
User Guide:**



<https://www.aphis.usda.gov/sites/default/files/permit-guidance.pdf>

# FY 25 Results – Permits

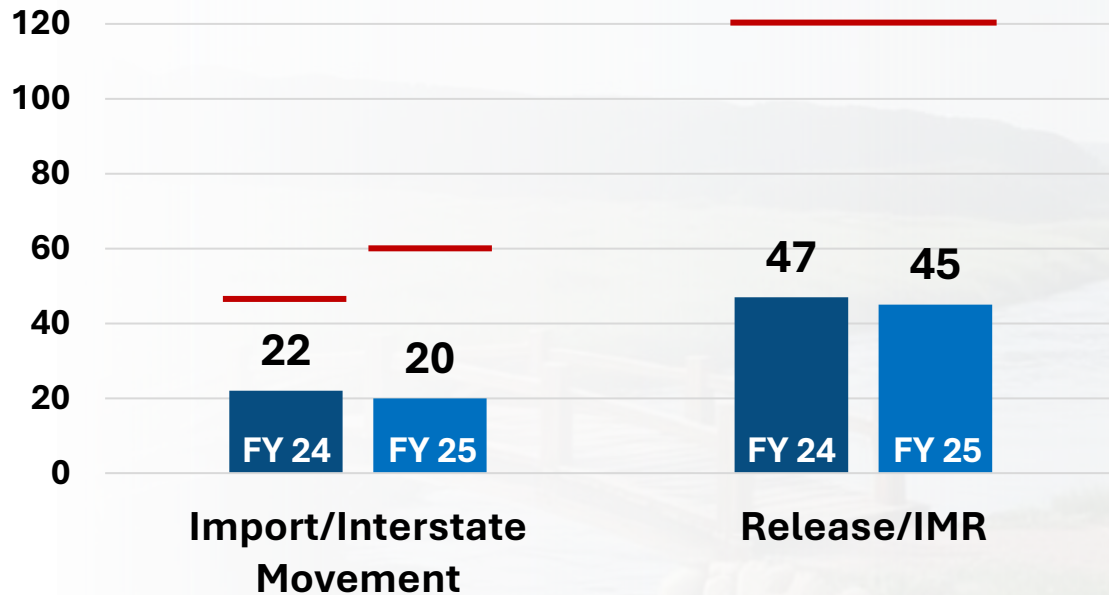
Issued 879 permits in FY 25



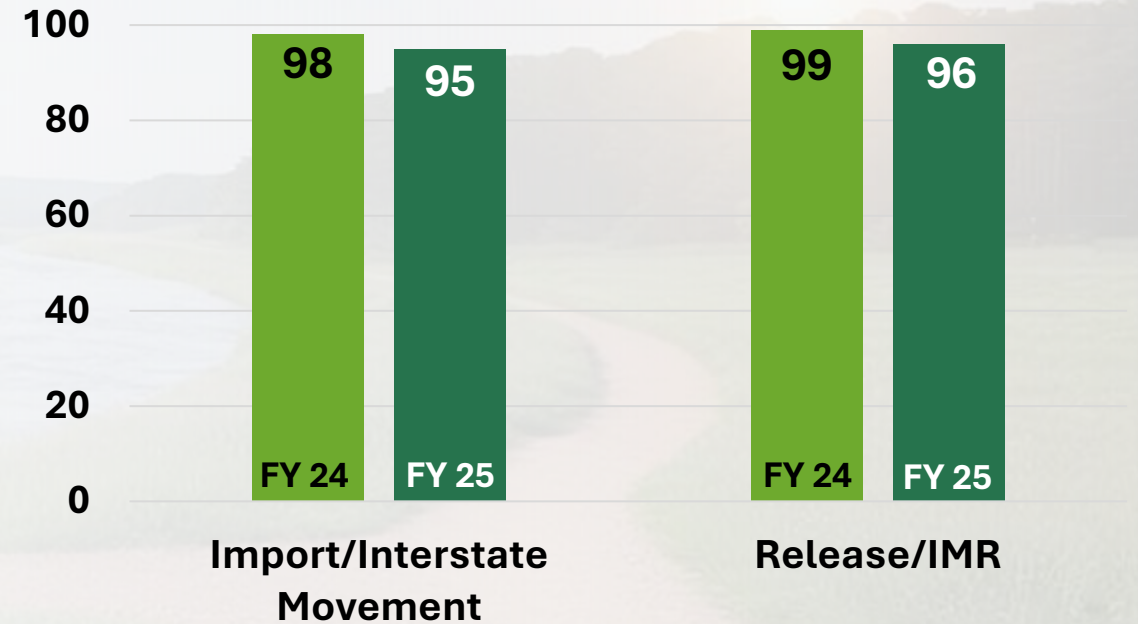
# FY 25 Results – Permits

**Exceeded BPI goal** of issuing 95% of permit applications within regulatory timeframes

### Average Number of Days to Process Permits Technical Completeness to Issuance

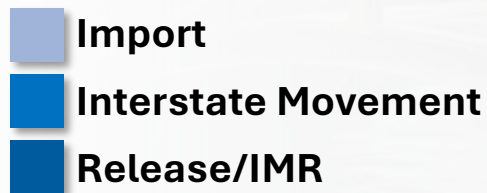
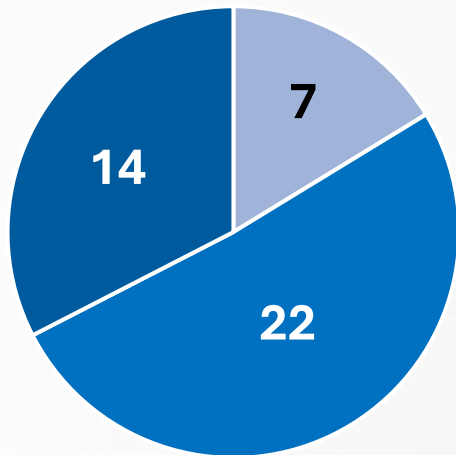


### Percentage of Permits Issued within Regulatory Timeframes

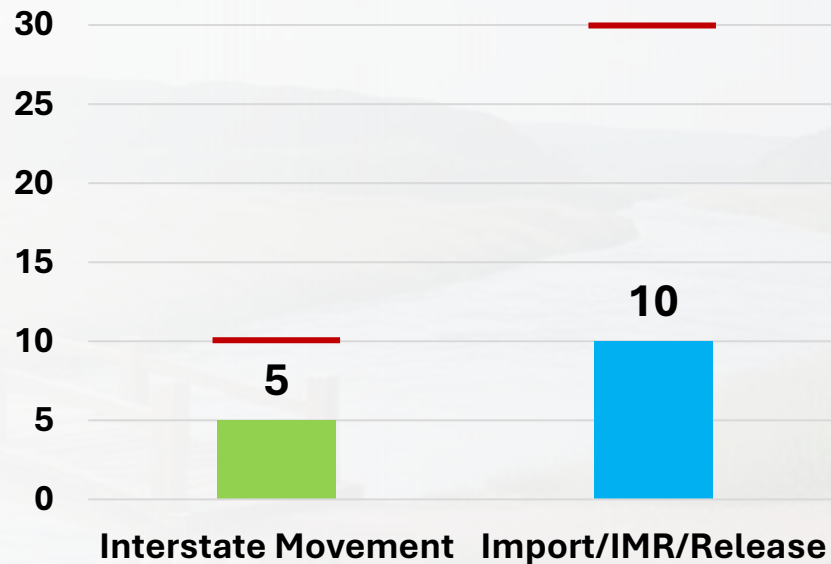


# FY 25 Results – Notifications

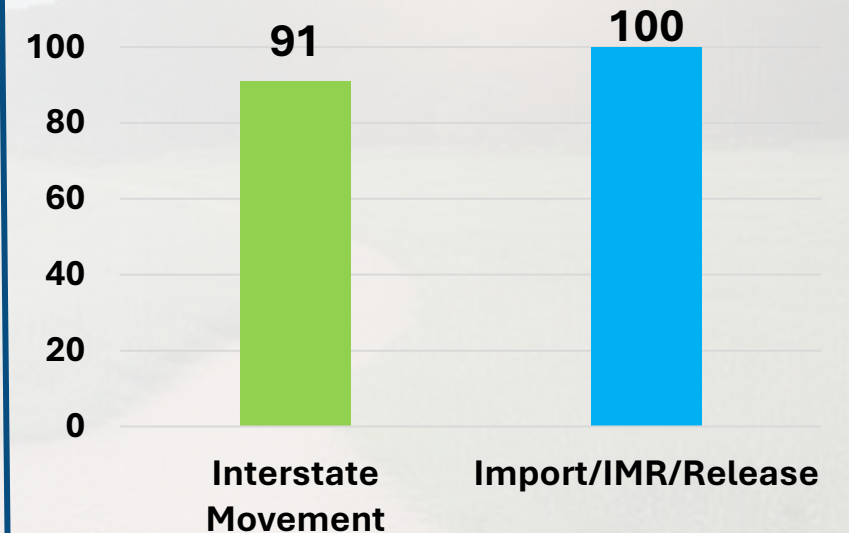
Acknowledged 43 notifications in FY 25



Average Number of Days to Process Notifications Technical Completeness to Issuance



Percentage of Notifications Acknowledged within Regulatory Timeframes

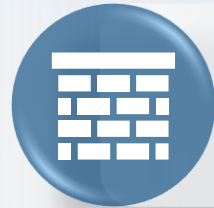


# Next Steps

*Use the BPI Project  
as a foundation for  
continued success*



Finish documenting BPI project process improvements and accomplishments



Build on efficiency gains going forward



Measure and monitor impacts of implemented initiatives and course correct as needed



Continue to implement process improvements that increase efficiency and consistency

# FY 26 Objectives

*Increase the consistency  
and timeliness of  
authorization reviews*



Ensure more interstate movement notification applications are acknowledged on time



Streamline review processes for PMPI and invertebrate authorizations



Update PMPI and invertebrate information in external guidance documents



Continue to improve communication with applicants and stakeholders



# For More Information

## BRS Website:



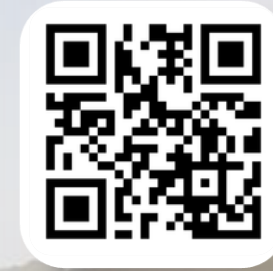
<https://www.aphis.usda.gov/biotechnology>

## APHIS eFile:



<https://efile.aphis.usda.gov/s/>

## Permits Email Address:



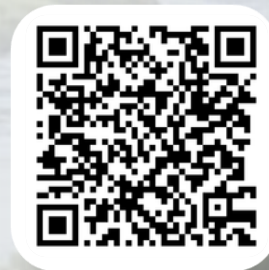
[BRSPermits@usda.gov](mailto:BRSPermits@usda.gov)

## Orig. Regulations (2025):



<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340>

## Permit User Guide:



<https://www.aphis.usda.gov/sites/default/files/permit-guidance.pdf>

## Notification User Guide:



<https://www.aphis.usda.gov/sites/default/files/notification-guidance.pdf>



# Thank You!

Katharine Swoboda Bhattarai, Ph.D.

Biological Scientist

Janice Strachan, M.A.

Branch Chief

*Biotechnology Risk Analysis Programs (BRAP)*





# Microbe Efforts

Alan Pearson, Ph.D.

BRS Assistant Deputy Administrator

John Sagle

PPQ PEIP Assistant Deputy Administrator

*Plant Exclusion & Import Programs (PEIP)*



John Sagle, PPQ

# New Microbial Biotechnologies

- **Drivers:** Genomics, genome editing, automation, AI – driven discovery and development; biotechnology as a national priority.
- **Uses:** Plant health and nutrition (pesticides, fertilizers, biostimulants), food, fuels, chemicals, materials, etc.
- **Impact:** Increase in APHIS permit applications

# BRS Permitted Microorganisms

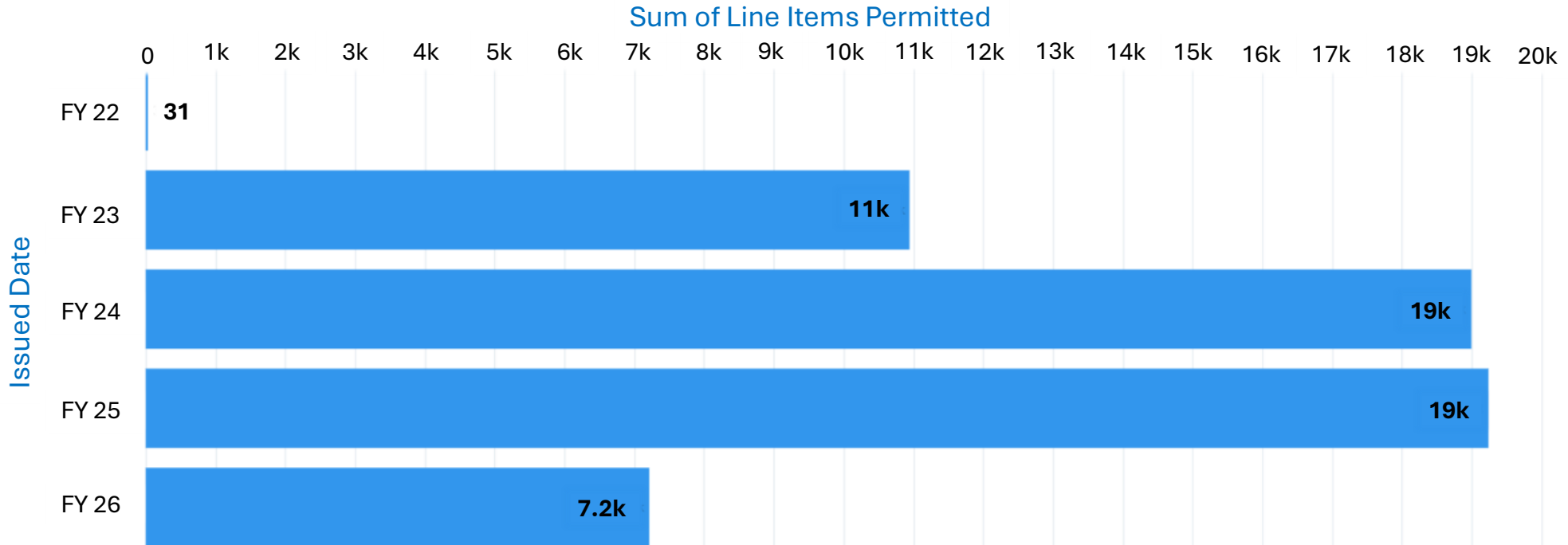
Over 4,600 unique modified microorganisms permitted

	FY 21	FY 22	FY 23	FY 24	FY 25
Movement	65	446	1551	2654	2151
Release		14	38	67	283
Total	65	460	1589	2721	2434

# PPQ Permitted Microorganisms

Over 7,300 unique microorganisms evaluated and permitted

Number of Permitted Microorganisms (Line Items/Articles)



# Concerns We've Heard

BRS and PPQ lack a harmonized approach to microbe regulation for plant health

There are no clear, predictable pathways for *commercialization* of modified microbes regulated by BRS

BRS permit conditions for field releases of modified microbes are not risk-based and fit-for-purpose

# Developing a Harmonized APHIS Framework for Microbe Regulation

Established the core principle for the framework.



Established the foundation of APHIS's harmonized framework.



Jointly defined scientific criteria to assess microbes under a harmonized framework.



# Core Principle

For an organism to be regulated as a plant pest, there must be demonstrated evidence or a plausible hypothesis that the organism can cause direct or indirect harm to plants.

# Examples of Microbes Regulated by APHIS

The foundation of  
the harmonized  
framework and  
some of the key  
scientific criteria

## Plant Pathogens

- A microbe is regulated if there is evidence demonstrating the microbe's ability to infect and cause disease in a plant; even a single credible report indicating pathogenic potential could meet the threshold.



## Insecticidal Microbes

- A microbe is regulated if there is evidence that it harms or could plausibly harm a beneficial insect and could lead to plant harm.

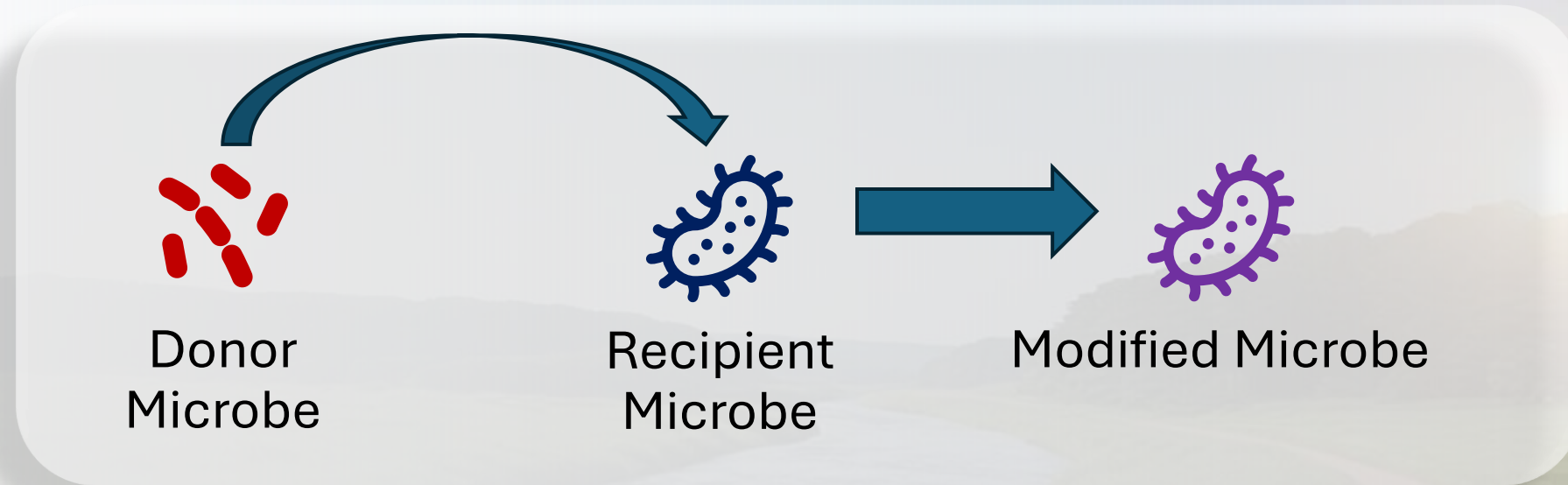


## Anti-microbial Microbes

- A microbe is regulated when evidence indicates its antimicrobial properties could plausibly lead to indirect plant harm; the mere production of antimicrobial compounds does not meet that threshold.



# How Will This Framework Apply to Modified Microbes?



If either the donor microbe or the recipient microbe are known to or could plausibly harm plants, then the modified microbe would be subject to regulation.

# Advancing the Microbial Harmonization Framework: Future Directions and Implementation



Finalize scientific criteria



Implement harmonized framework



Stakeholder engagement and guidance

# Regulated Microbes: Plant Pest Risk Spectrum

Low

High



Plant Pest Risk

BRS is currently discussing different criteria for categorizing microbes based on levels of plant pest risk

# Pathways to Commercialization

Plant Pest Risk or Uncertainty

Lab Trials

For highest risk or greatest uncertainty: contained studies only. Gather data to inform outdoor trials.

Permitted Field Trials

Small Scale. Gather data to inform off-ramps.

Commercial permits

Large scale. Interim off-ramp, or where conditions are required for final release.

?

Deregulation  
LONPR  
Exemption

Submission and APHIS review.

# Risk and Performance Based Permitting Conditions for Microbe Releases

- FY 26 priority: Establish a set of standardized but customizable performance-based conditions for environmental releases
- More stringent → less stringent based on data and experience
- Examples:
  - Eliminate isolation zone and/or reduce perimeter zone when appropriate
  - Change approach to post-trial monitoring
  - Change approach to devitalization

# Permitting Next Steps

- Update microbe permit authorization workflows
- Update pre-authorization facility inspection worksheets
- Train additional inspectors
- Update the Permit User Guide
- Develop approach and conditions for commercial permits



# Thank You!

Alan Pearson, Ph.D.

BRS Assistant Deputy Administrator

John Sagle

PPQ PEIP Assistant Deputy Administrator

*Plant Exclusion & Import Programs (PEIP)*





# Regulatory Operations Update

Doug Grant, Ph.D.

Director

*Regulatory Operations Programs (ROP)*





# Outline

- Staffing Changes
- Inspection Data
- Compliance Outcomes
- Overview of Noncompliance

# ROP Staffing Updates

FY 25 and FY 26 changes:

- Dr. Phillip Mason (WCAB BC) retired in April
- Mr. Nathaniel Yates (CEEB BC) retired in January
- Ms. Heather Brown acting WCB BC (as of Feb. 2, 2026)

# Regulatory Operations Programs (ROP) FY 25 Restructuring

FY 24 - three  
branches



Now we have  
two branches



&



# Compliance Inspection Goals

## Compliance Oversight

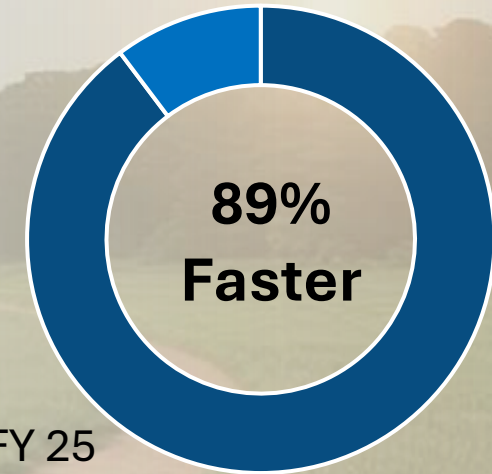
Target: **Complete 500 compliance inspections and issue 90% of noncompliance notices within 14 days** of completing an inspection.

## Target Exceeded

- Completed 505 inspections. Above target by 5 inspections of the 500.
- **Issued 93%** of noncompliance notices within 14 days of inspection.

## Improved Service Delivery

Notices of Noncompliance



FY 25  
Average:  
11 Days

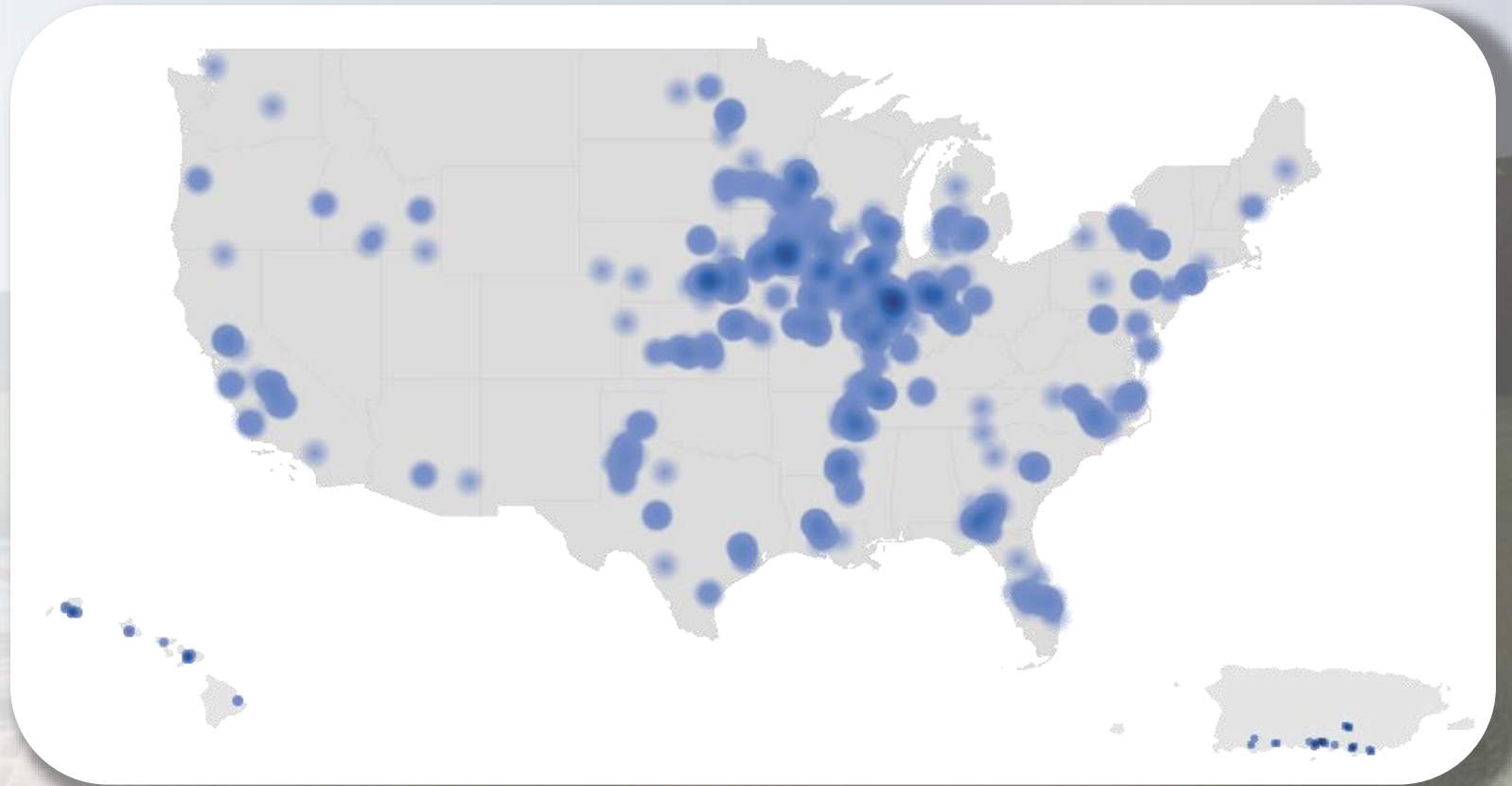
# Permitting Statistics

- Number of permits and release sites authorized FY 21 – FY 25
- 4,319 Release Sites Authorized in FY 25

<b>Fiscal Year</b>	<b># of Permits Issued</b>	<b># of Release Sites Authorized</b>
<b>FY 25 (permits + notifications)</b>	922	4,319
<b>FY 24</b>	874	5,058
<b>FY 23</b>	783	4,357
<b>FY 22</b>	757	4,431
<b>FY 21 (permits + notifications)</b>	723	2,726

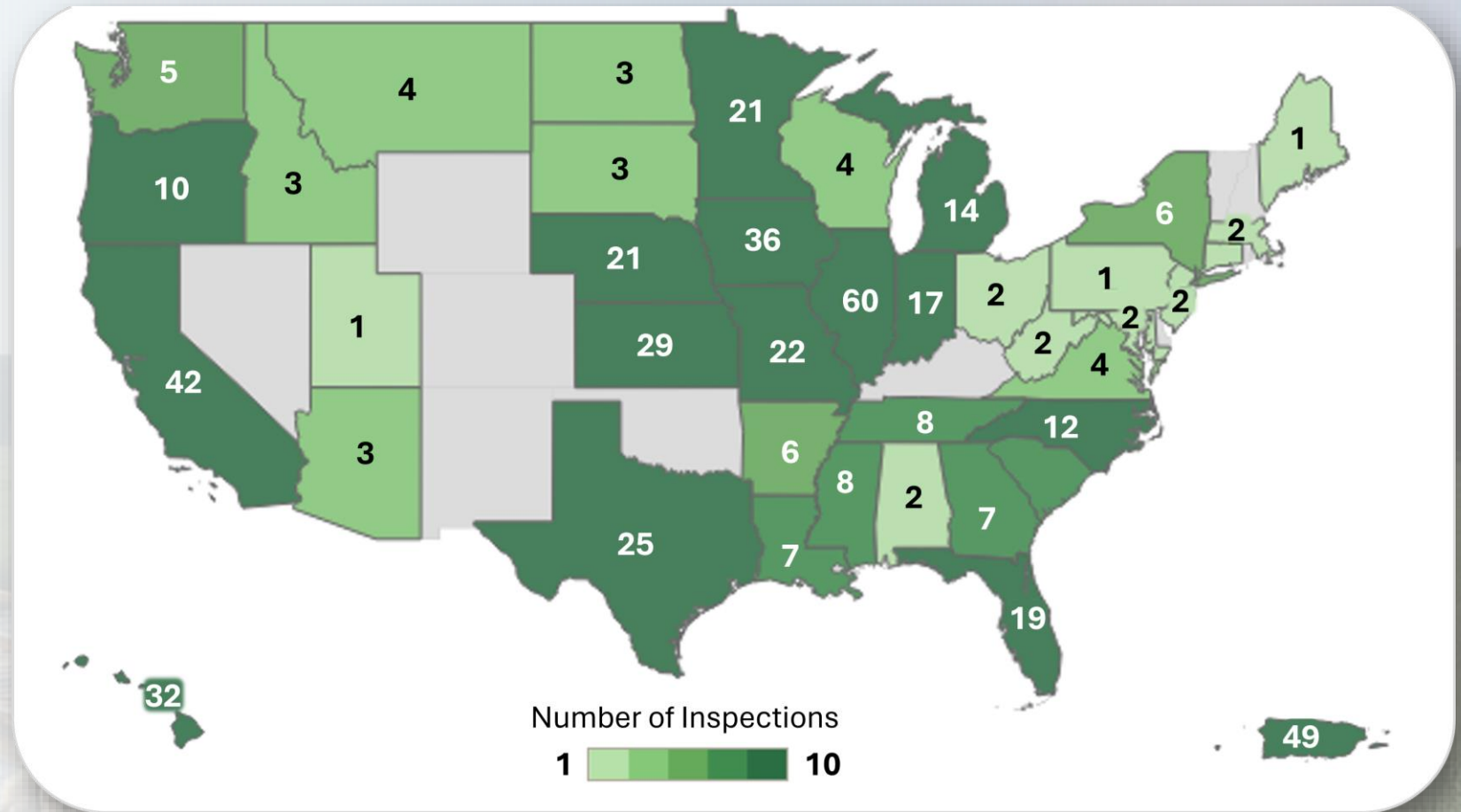
# FY 25 Density Map of Unique Locations Planted

**Total Unique  
Planting Locations = 848**



# FY 25 Inspections by State/Territory

**Total Inspections  
Conducted = 505**



# FY 25 BRS Inspections by Quarter

Quarter	New	Cumulative
<b>1</b>	<b>71</b>	<b>71</b>
<b>2</b>	<b>89</b>	<b>160</b>
<b>3</b>	<b>149</b>	<b>309</b>
<b>4</b>	<b>196</b>	<b>505</b>



# FY 25 Compliance Statistics

Performed **244** compliance evaluations from all sources (inspections, self-reports, records reviews)

**128** Notices of Noncompliance sent

**45** Resulting from Inspections

# In-Person Inspections

In FY 25, 92% of inspections were in-person (467 of 505)



# FY 25 Compliance

- 91% of inspections were found to be compliant
- NONCs resulting from inspection avg days to issue = 11
- 93% issued within 14 days (85% in FY 24)



## Compliance Agreements

BRS initiated 18  
Compliance Agreements



## Proactive Compliance Assessments

BRS completed 13  
Proactive Compliance Assessments

# FY 25 Most Common Noncompliance Issues

- **70** late or missing reports (**28** late planting/environmental release reports)
- **25** incomplete records (**9** equipment cleaning, **8** in-season monitoring, **7** volunteer monitoring)
- **24** unauthorized movement and release (**11** unauthorized releases/areas not authorized, **6** unauthorized movements)
- **22** missing records or reports (**7** missing equipment cleaning records)



# Resources

ROP updated the *Guide for Submitting Data for Reports and Notices in APHIS eFile* to include information requirements for Notifications and reflect regulation changes to 7 CFR 340 (2019) for Permits post-vacatur.

The final updated Guide was published March 21, 2025



<https://www.aphis.usda.gov/sites/default/files/report-and-notices-guide.pdf>



# Thank You!

Doug Grant, Ph.D.

Director

*Regulatory Operations Programs (ROP)*

A wooden signpost with a sign that reads "Regulatory Operations". The sign is mounted on a wooden post and is positioned on a dirt path that curves through a green field. In the background, there are rolling hills and a sun setting or rising over a line of trees.

Regulatory  
Operations



# International Engagement

Suma Chakravarthy, Ph.D.

Science Advisor

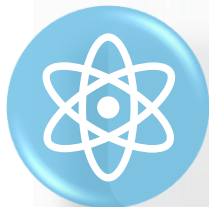
*Office of the Deputy Administrator*



# Presentations on APHIS Regulations



Continue to build and maintain international coalitions and relations



Highlight the importance of science and risk-based regulations, efficiency, transparency, and stakeholder engagements



Provide messaging on the flexibility of USDA regulations and continued approvals post-vacatur in December 2024



Improve global understanding of the USDA position on products of genome editing

# Presentations on APHIS Regulations

## US-Korea August 2025



## US-Japan August 2025



Work with interagency partners such as EPA, FDA, State, USDA-FAS and USDA-APHIS-IS to coordinate these engagements

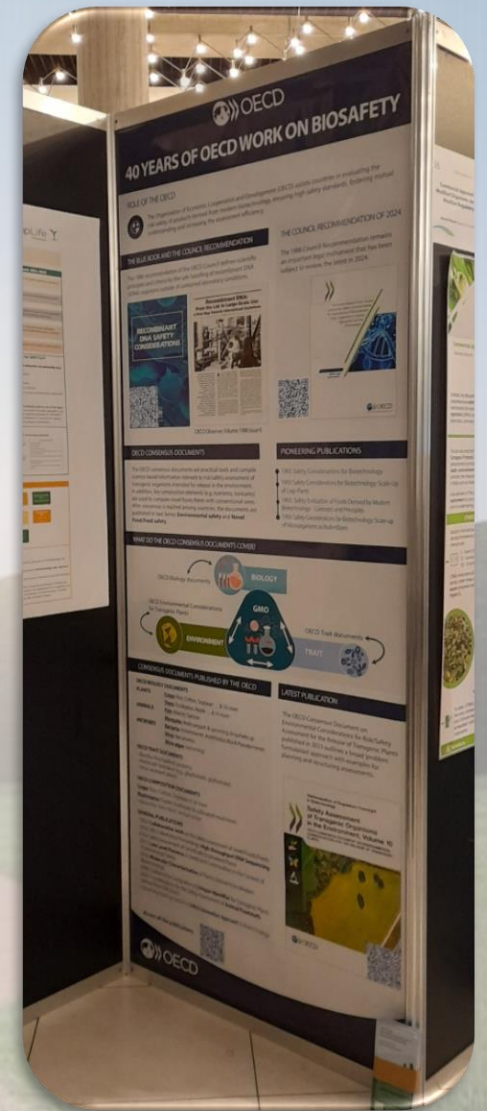
# Multilateral Fora and Organizations

## Organization for Economic Cooperation and Development (OECD) Working Party for the Harmonization of Regulatory Oversight in Biotechnology (WP-HROB) Meeting

- Produce technical documents to support the assessment of agricultural biotechnology products; 38 member countries
- Lead the USG delegation and participated in 7 ongoing OECD projects

## International Society for Biosafety Research (ISBR) 17<sup>th</sup> Symposium

- Served on the scientific planning committee



OECD poster at ISBR

# Multilateral Fora and Organizations

**High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) at the Asia-Pacific Economic Cooperation (APEC) Meeting**  
(Korea, attended by 16 APEC economies and 3 non-APEC economies)

**Cartagena Protocol COP-MOP Meeting** (Colombia)



HLPDAB at APEC August 2025

# Technical Expertise on Trade Agreements

Supported United States Trade Representative and APHIS-International Services efforts in:

- Establishing trade agreements with 12 countries
- Reviewing WTO accession documents for 3 countries



# Thank You!

Suma Chakravarthy, Ph.D.

Science Advisor

*Office of the Deputy Administrator*





# Q & A Panel

Katharine Swoboda Bhattarai,  
Janice Strachan, Alan Pearson,  
John Sagle, Doug Grant,  
and Suma Chakravarthy

The background of the slide is a scenic landscape featuring a dirt path that curves through a grassy field. In the distance, there are rolling hills and a body of water. The sky is a clear, light blue. Overlaid on this scene are several wooden signs on posts. The signs are arranged in a way that suggests a path or a series of choices. The signs are: 'Regulatory Operations' (top left), 'Microbe Efforts' (middle left), 'International Engagement' (top right), and 'Permits/ Notifications' (bottom right).

Regulatory  
Operations

Microbe  
Efforts

International  
Engagement

Permits/  
Notifications

# Thank you for attending!

