



# Compliance and Inspection Updates

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# Outline

- 7 CFR 340 Regulations
- BRS Program Changes
- Inspection Data
- Compliance Outcomes
- Overview of Noncompliance





# Regulatory Reset: Changes to USDA Regulations



# Vacatur of the 2020 Biotechnology Rule

*Previously known  
as the SECURE rule*



All USDA Regulatory Status Review responses, Confirmation Request responses, and active permits issued before December 2, 2024, remain valid

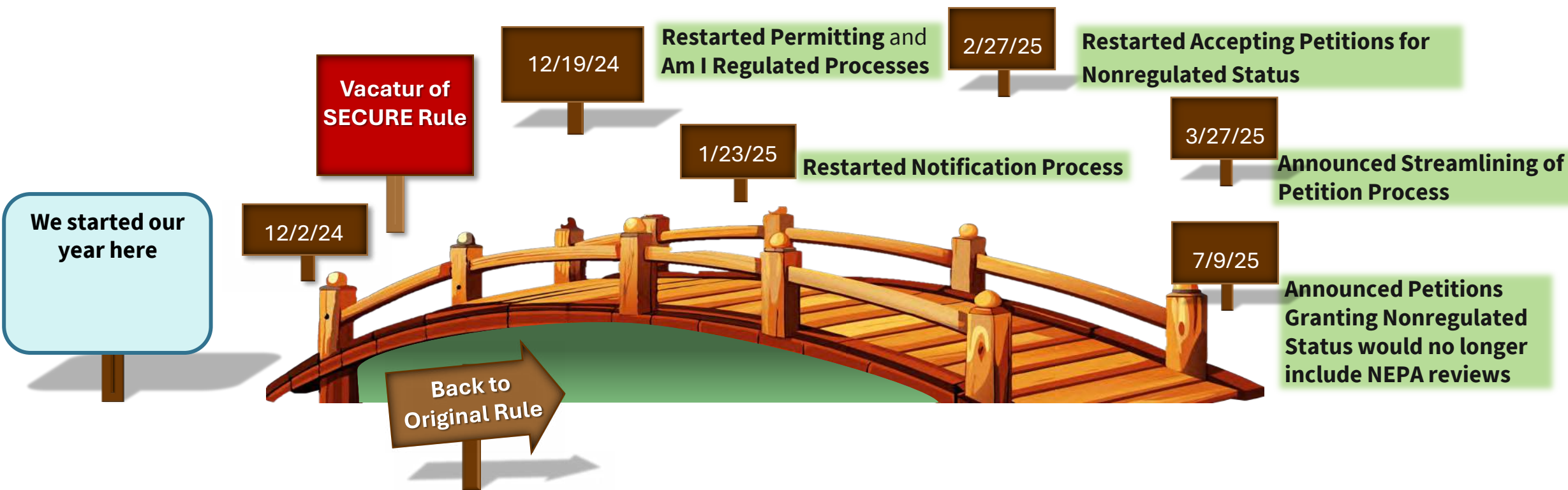


USDA worked to re-establish regulatory and nonregulatory processes under the regulations that were in place prior to the 2020 regulation, ensuring regulatory stability



With the lessons learned in the last 4 years, APHIS would increase efficiency of regulatory processes described in the 2019 regulation

**After four** years of use, and without notice, the Court **vacated the SECURE rule**, requiring BRS to revert to its original (2019) biotechnology regulations.



# Regulatory Landscape

Original Biotechnology Regulations - 33 years

Vacated Rule - 4 years



**R&D**  
29,543 authorizations

**Responses Confirming Nonregulated Status**  
168 in an average of 190 days

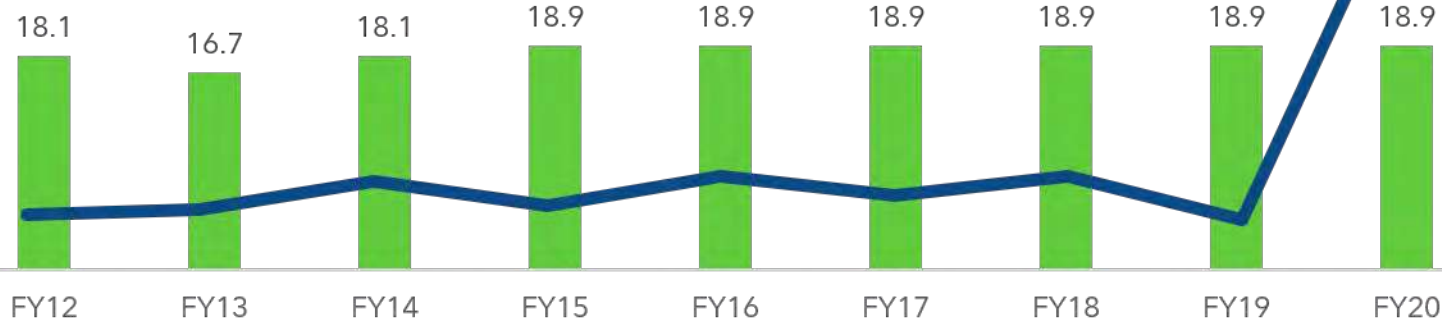
**Product Reviews**  
137 reviews involving 19 crop varieties completed in an average of 534 days



**R&D**  
2,591 authorizations

**Responses Confirming Exempt Status**  
99 in an average of 52 days




**Product Reviews**  
84 reviews involving 22 new crop varieties completed in an average of 236 days



— Product Approvals    ■ Appropriations (in millions)



# Key Regulatory Processes

Services	Products
<b>Am I Regulated</b> 	Developers may ask whether their product meets the regulatory definition of “regulated article”: voluntary and nonregulatory process
<b>Authorizations</b> 	Developers can seek authorization for contained and confined interstate movement, import and environmental release
<b>Petition</b> 	Developers of plants that meet the definition of “regulated article” may petition for nonregulated status by showing their product is unlikely to pose greater plant pest risk

# What is a Regulated Article?

APHIS authorizes the introduction (importation, interstate movement, environmental release) of regulated articles

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

**1**

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

**2**

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

# Not Subject to Regulation

The background of the slide features a close-up photograph of an orange tree. In the foreground, several bright white blossoms with yellow centers are in focus, surrounded by vibrant green leaves. In the background, out of focus, are several ripe, bright orange fruits hanging from the branches.

*USDA regulates organisms based on whether or not they contain plant pest sequences, not on technique used or the type of change made*

## Most Genome Edited Products

A genome edited organism (e.g., plant, microbe, insect) that is not a plant pest or likely to be a plant pest

## Some Transgenic Products

A transgenic organism that is not a plant pest and not likely to be a plant pest, and does not contain DNA sourced from a plant pest

# Am I Regulated?

Responding to “Am I Regulated?” inquires



Confirms if an organism meets the definition of a “regulated article”; is not a risk assessment



Voluntary and nonregulatory process



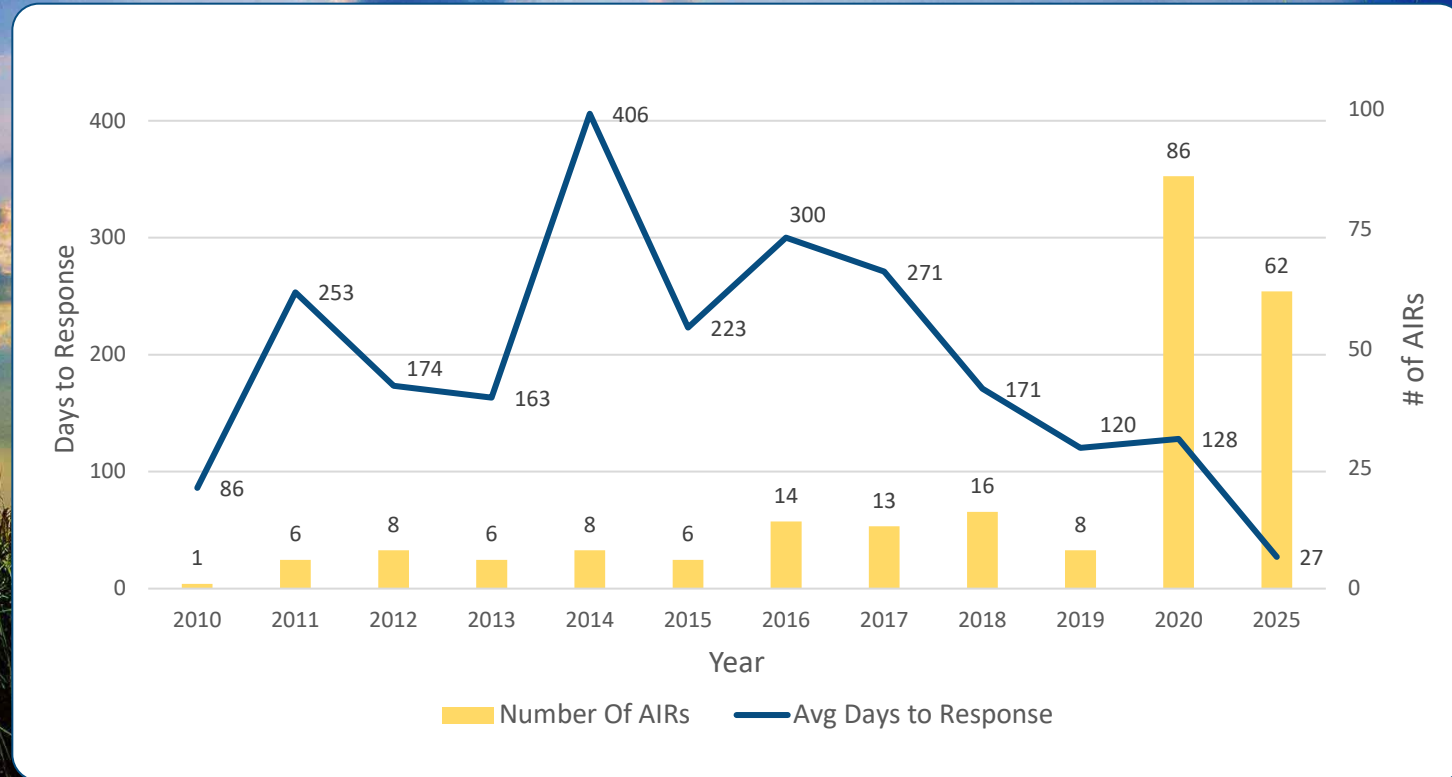
Inquiries may contain multiple products and hypothetical products



Since restarting this process, 50 out of 65 letters with genome edited products and 9 are microbes

# AIR Process Improvements

- Dedicated technical team; lead reviewer self-assigns based on interest and capacity
- Reduction in hand-offs
- Fewer review bottlenecks
- Single venue for policy discussions
- Internal timelines



# Authorizations

1. **Importation**
2. **Interstate movement**
3. **Environmental release**



[www.aphis.usda.gov/  
biotechnology/biotechnology-  
permits-notifications](http://www.aphis.usda.gov/biotechnology/biotechnology-permits-notifications)



## Permits

Certain modified microbes, insects, and modified plants require APHIS permits for their introduction



## Notifications

Administratively streamlined method for the introduction of a subset of modified plants that meet eligibility criteria and performance standards

# Petition for Nonregulated Status

Determination that a modified plant that meets the definition of a “regulated article” is unlikely to pose a greater plant pest risk than the nonmodified plant from which it was derived, and therefore is not regulated



[www.aphis.usda.gov/biotechnology/petitions](http://www.aphis.usda.gov/biotechnology/petitions)

**A description of the biology of the nonmodified plant**

**A detailed description of the differences in genotype between the modified and nonmodified plants**

**A detailed description of the phenotype of the modified plant, and of any known and potential phenotypic differences from the unmodified plant**

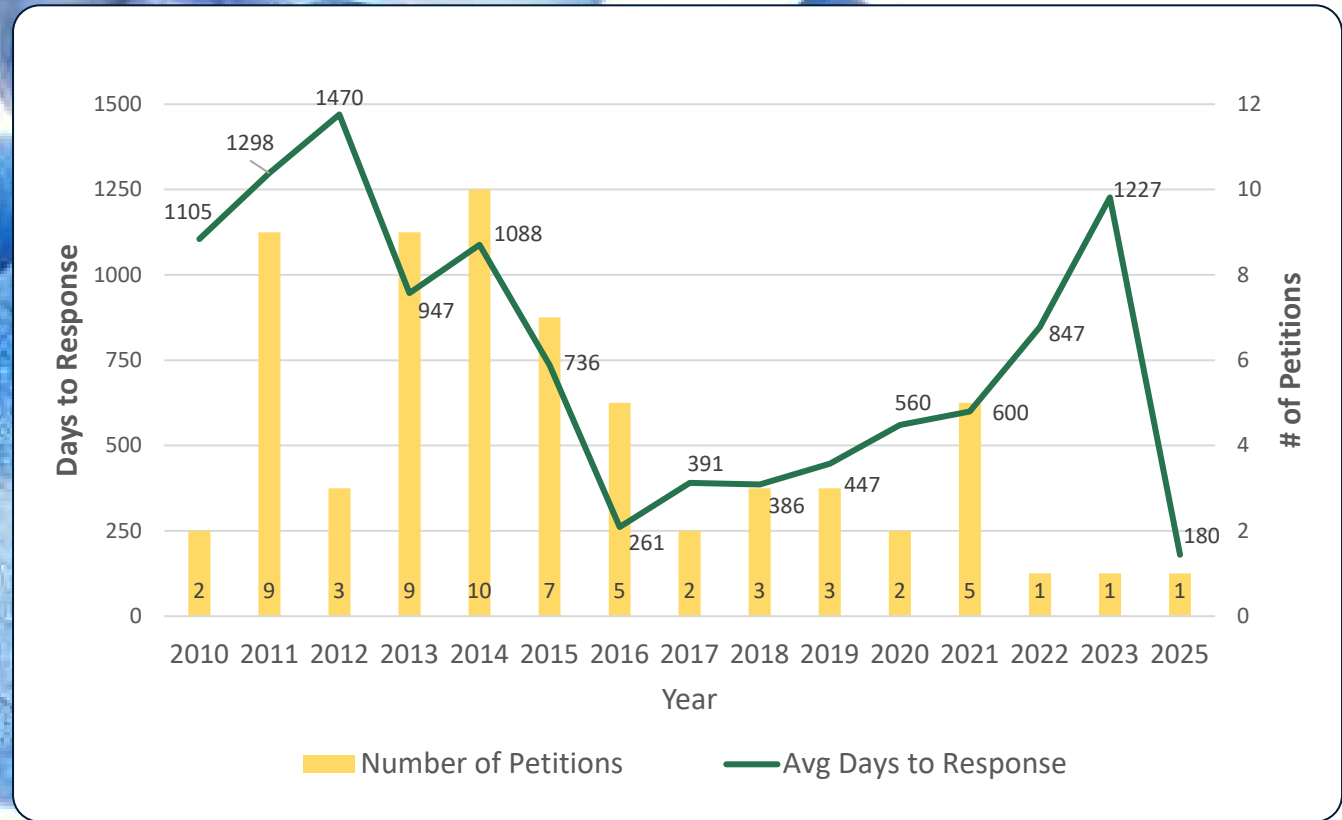
**Any relevant experimental data and publications**

**Field test reports for all trials conducted under authorization pursuant to 7 CFR part 340**

# Petition Process Improvements

Goal: Complete petition in 180 days

- Streamline document preparation
- Reduce clearance handoffs
- Use problem formulation to focus assessment
- Leverage EPA registration data for pesticidal traits

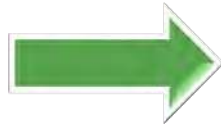


# Staffing Updates

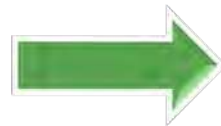
- Since October 2024:
  - Dr. Donna Lalli has joined BRS as the Deputy Administrator
  - Dr. Michael Stulberg is BRS' Associate Deputy Administrator
  - Dr. Phil Mason (WCAB) and Mr. Nate Yates (CEEB) have retired

# Regulatory Operations Programs (ROP) FY25 Restructuring

FY 24 - three  
branches



Now we have  
two branches



&





# Compliance and Inspection Data



# 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 2025 Average:  
11 Days





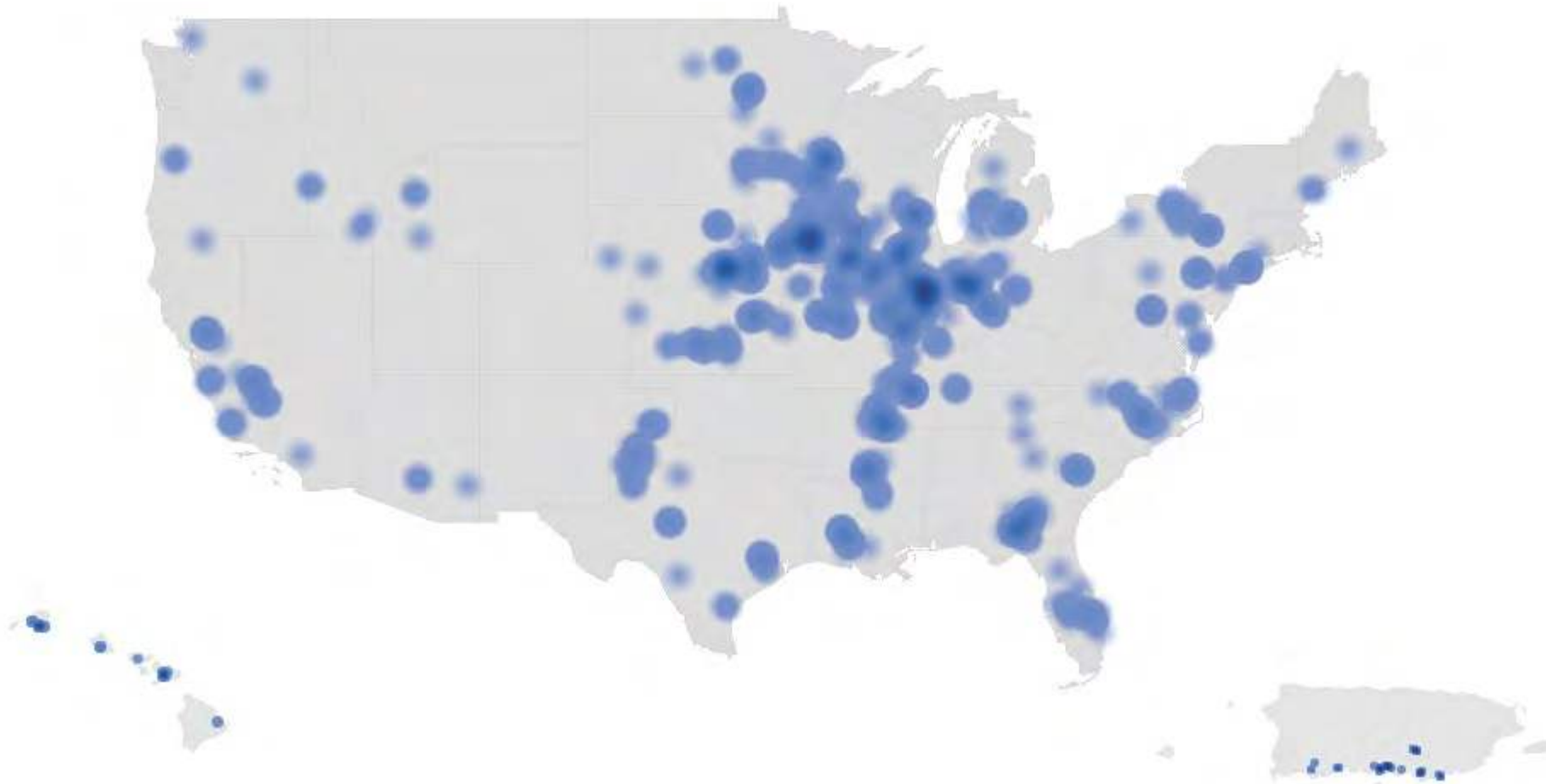
# Permitting Statistics

- Number of permits, release sites and constructs authorized FY 21 – FY 25.
- 4,165 Release Sites Authorized in FY 25.

<b>Fiscal Year</b>	<b># of Permits Issued</b>	<b># of Release Sites Authorized</b>	<b># of Constructs Authorized</b>
<b>FY 25 (permits + notifications)</b>	765	4,165	26,543
<b>FY 24</b>	875	5,059	31,718
<b>FY 23</b>	766	4,356	22,051
<b>FY 22</b>	758	4,446	21,670
<b>FY 21 (permits + notifications)</b>	723	2,726	16,036

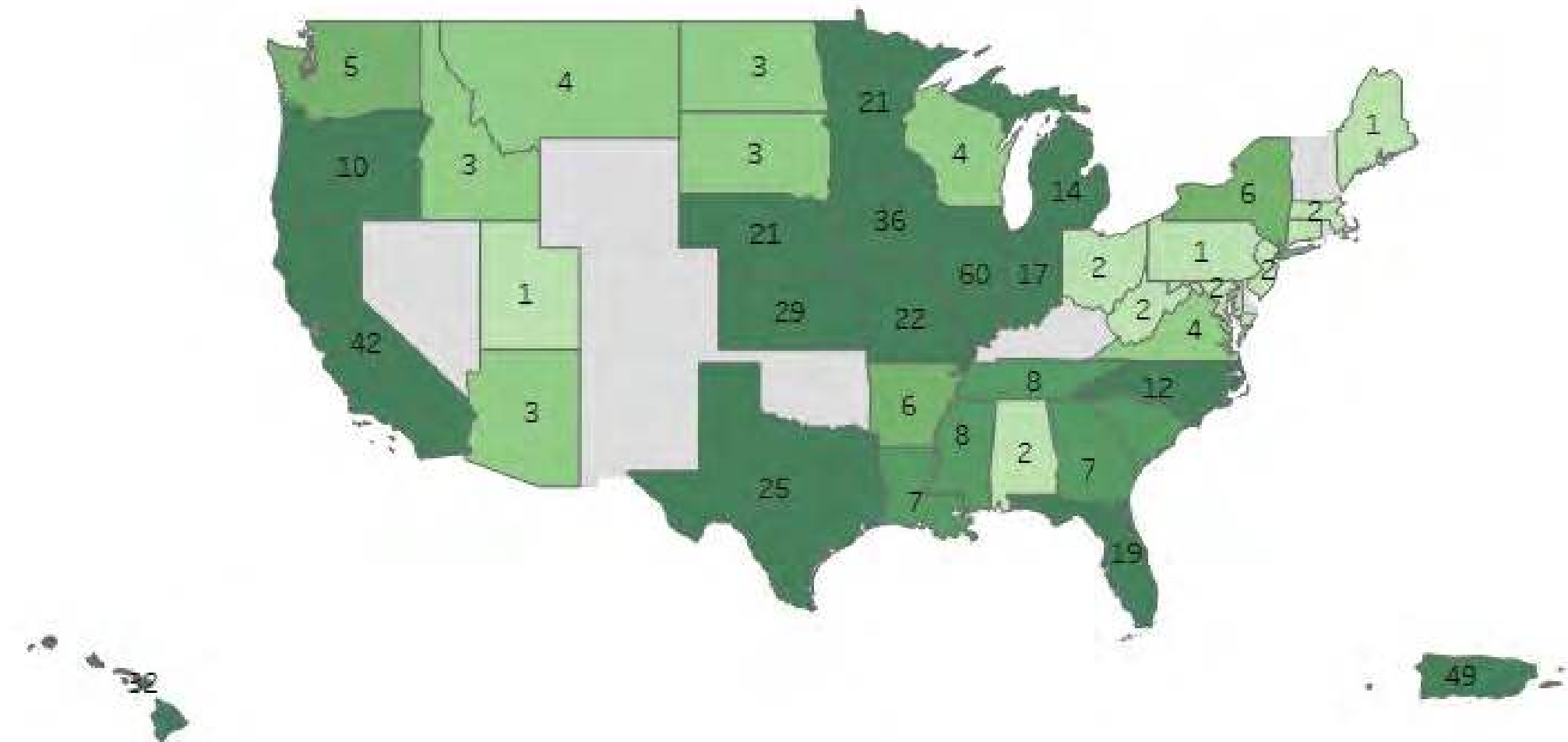
# FY 2025 Density Map of Unique Locations Planted

## Total Unique Planting Locations = 848



# FY 2025 Inspections by State/Territory

## Total Inspections Conducted = 505



# **FY 2025 BRS Inspections by Quarter**

<b>Quarter</b>	<b>New</b>	<b>Cumulative</b>
<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>

# In-Person Inspections

**In FY 2025, 92% of inspections were in-person (467 of 505)**



# 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
- BRS ROP 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

- The AIR table can be found at:

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

- BRS Petition Table:

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

- If you are applying to obtain a Permit or Notification:

<https://www.aphis.usda.gov/biotechnology/biotechnology-permits-notifications>

- BRS *Guide for Submitting Data for Reports and Notices in APHIS eFile:*

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



Thank You!

