Biotechnology Regulatory Services

Stakeholder Meeting

December 9, 2020

Welcome

Doug McKalip
Senior Advisor
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
December 9, 2020

New BRS Staff

Ibrahim Shaqir
Associate Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
December 9, 2020


HELLO
MY NAME IS

BRS Organizational Structure

- Two Programs
  - Biotechnology Risk Analysis Programs (BRAP)
    - Plants Branch, Plant Pests
    - Protectants Branch
    - Plant Evaluation Branch
  - Regulatory Operations Programs (ROP)
    - Eastern Compliance Assurance Branch (ECAB)
    - Compliance Evaluation and Enforcement Branch (CEEB)
    - Western Compliance Assurance Branch (WCAB)
- Four Support Service Groups and Science Advisors in the Office of the Deputy Administrator
  - Communications
  - Intergovernmental Operations
  - Policy, Program, and International Collaboration (PPIC)
  - Resource Management Services (RMS)

BRAP

- Addresses potential plant pest risk and environmental impacts of organisms developed using genetic engineering on the human environment by conducting risk assessments and environmental assessments of these products.

- Reviews permit and notifications applications, petitions for deregulation, confirmation requests, potential noncompliance with permit conditions, and proposed regulatory changes.

BRAP

Suma Chakravarthy, ***Branch Chief***

Tyler Reid, ***1890 Scholar***

Senior Biological Scientist

Michael Stulberg

Martha Malapi-Wight

Biological Scientist

Srinivasa Chaluvadi

Rebecca Fletcher

Herbert Eichenseer

Natalie Howe

Ordom Huot

Colin Murphree

Sarah Prewitt

Katharine Swoboda-Bhattarai

ROP

- Ensures compliance with APHIS regulations (7 CFR part 340) through compliance inspections and evaluating and responding to noncompliance incidents

- Oversees reports submitted in connection with notifications and permits

Doug Grant, *ROP Director*

Heather Brown, *CEEB Senior Compliance Specialist*

Elizabeth Burns, *Regulatory Analyst*

Communications

- Develops and coordinates BRS communication strategies and outreach efforts
- Manages the BRS website content, supports strategic and operational planning
- Manages BRS response to Freedom of Information Act (FOIA) requests and provides associated guidance

Hannah Hamilton, *Branch Chief*

PPIC

- Conducts legal and policy analysis; guides policy development; manages a compliance assistance program; and assists program units to implement quality management principle and practices

- Point of contact for BRS international issues, training, and program activities and collaborates across the U.S. government to support plant health protection and trade missions

Kayla Knilans, *Biological Scientist*

Russell Duncan, *Agriculture Science Officer, International Services*

RMS

- Responsible for all administrative functions as they pertain to human, physical capital, and resource management; financial management; and data management

- Provides guidance and support on travel, training, and employee development

Djene Sylla, *Program Assistant*
Jason Chatman, *Management Analyst*

USDA

United States Department of Agriculture

Overview of FY20 Activities; Look Ahead to FY21 Priorities

Bernadette Juarez
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
December 9, 2020

SECURE Rule Implementation

- **BRS by the Numbers**
  https://www.aphis.usda.gov/brs/pdf/brs-numbers.pdf

- **About the SECURE Rule**
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision

- **Confirmation Request Process**
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmations/confirmation-process

- **Retired the "Am I Regulated?" Process**
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry

SECURE Rule Implementation

- **Plant-Trait-Mechanism of Action (MOA) Table**
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmations/plant-trait-moa

- **Guidance for Preparing Proposals for Plants with Additional Modifications that Qualify for Exemption**

- **Guidance for Requesting a Regulatory Status Review**

- **Guidance for Submitting Permit Applications**

SECURE Rule Implementation

International Outreach

- Publicized SECURE Rule through 98 offices of the Foreign Agricultural Service and APHIS' 28 international offices
- Multilateral, bilateral and regional meetings to share and encourage science-based approaches that are proportionate to the level of risk
  - Canada, Mexico, Brazil, Brazilian Regulators, Latin American and Caribbean Countries, Taipei, Taiwan, Korea, Dubai, and Japan
  - Upcoming interactions: Korea, EU Delegations; Spain, Portugal, and planned Latin American Regional outreach

Petition Pipeline

- **Determinations of nonregulated status to date: 133**
  - Determinations of Nonregulated status in FY2021: (0)
  - Determinations of Nonregulated status in FY2020: (1)
    - Simplot Z6 Potato (Extension) 08/28/2020
- **Draft PPRA + draft EA or extension + draft PPRSA**
  - Closed comment period (3): Monsanto Lygus cotton; Westhoff petunia; Pioneer enhanced yield maize
  - Open comment period (1): Pioneer SPTA maize
- **Petitions**
  - Closed comment period (4): Agrivida phytase maize; SUNY ESF blight tolerant chestnut; Bayer stacked herbicide resistant maize; BASF nematode protected soybean
  - Open comment period (1): Pioneer insect and herbicide resistant maize

Other Updates

- Advanced Notice of Proposed Rulemaking
- Regulation of the Movement of Animals Modified or Produced by Genetic Engineering
- Oversight of “amenable species” (cattle, sheep, goats, swine, horses, mules, or other equines, catfish, and poultry) developed using genetic engineering intended for agricultural purposes

Thank You

Bernadette Juarez
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Overview of SECURE Rule Guidance Documents

Alan Pearson
Assistant Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
December 9, 2020

Guidance for Preparing Proposals to Exempt Plants with Additional Modifications from Regulation

Required Information

- Requestor's name and contact information, including email
- Clear description of the additional genetic modification(s) that a plant or plants can contain and qualify for exemption, e.g.,
  - A specified number of changes achievable in cultivated plants
  - A specified number of changes achievable in a particular plant species
  - A type of modification other than those already listed in 7 CFR §§ 340.1(b)(1-3).
- A statement of the factual grounds demonstrating that plants containing the proposed genetic modification(s) could be achieved in conventional breeding
- Supportive scientific literature or publicly available information
- Any unfavorable information known to the requestor

Decision Standard

"Could be achieved through conventional breeding" means that the genetic modification is practically achievable through conventional breeding methods in the plant

For example, evidence that multiple desired traits or genetic modifications can be introduced in a plant on a practical basis would meet this standard

Process

- Submit proposals electronically via (b)(4)exemptionrequests@usda.gov
- If there is insufficient publicly available information supporting the proposal or APHIS disagrees that plants containing the modification(s) could be achieved through conventional breeding methods, APHIS will return the proposal and provide the reasons for the return in writing
- If APHIS determines that plants containing the modification(s) could be achieved through conventional breeding methods, it will publish the proposal and supporting information in the *Federal Register* for public comment. After review, APHIS will publish a subsequent notice in the *Federal Register* announcing its final determination
- APHIS will complete its review and make a final determination within 12 months of receiving all required information, except in circumstances that could not reasonably have been anticipated
- We recommend discussing your proposal with us prior to your first submission

Examples

The Guidance will include examples of proposals based on modifications already listed in 7 CFR §§ 340.1(b)(1-3)

Guidance for Requesting a Regulatory Status Review

Regulatory Status Review (RSR)

If a plant does not meet a regulatory exemption, the developer may seek a RSR for a plant developed using genetic engineering to determine whether it is regulated.

RSR evaluates the plant pest risk posed by the plant relative to that posed by its comparator plant based on:

- the biological properties of the plant;
- the trait (or new characteristic); and
- the mechanism of action (MOA, or how the modification caused the new trait to occur).

RSR - Definitions

Comparator plant. A plant used as a comparison or reference for a plant developed using genetic engineering to determine if the plant being evaluated poses an increased plant pest risk.

Trait. An observable (able to be seen or otherwise identified) characteristic of an organism. (§ 340.3)

Mechanism of Action (MOA). The biochemical process(es) through which genetic material determines a trait. (§ 340.3)

Plant pest risk. The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest. (§ 340.3)

RSR Process – Step 1

- Evaluates the characteristics of the plant relative to an appropriate comparator plant to identify whether a plausible pathway to increased plant pest risk exists.
- Is there a scientifically plausible hypothesis by which the trait and mechanism-of-action could change any of the following factors in a way that could lead to increased plant pest risk:
  - The distribution, density, or development of the plant and its sexually compatible relatives;
  - The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;
  - Harm to non-target organisms beneficial to agriculture; and/or
  - The weedy impacts of the plant and its sexually compatible relatives.

RSR Process – Step 1

- Generally completed within 180 days from receipt of a request that meets the information requirements

  - If APHIS does not identify a plausible pathway to increased plant pest risk, the plant is not subject to the regulations
    - APHIS will post the plant, trait, and MOA on its website

  - If APHIS does identify a plausible pathway to increased plant pest risk, it will provide feedback about the identified pathway(s) and the type(s) of additional information, if any, it would need to complete a plant pest risk assessment (PPRA). The requestor may:
    - elect to take no further action
    - obtain a permit to allow movement and/or confined release
    - submit a formal request that APHIS complete a PPRA
    - pause the RSR process

RSR Process – Step 2

- Plant Pest Risk Assessment (PPRA) evaluates the identified pathways and factors of concern to determine the likelihood and consequence of the plausible increased plant pest risk
  - Preliminary finding of unlikely to increase plant pest risk published in the *Federal Register*
  - Solicit and review comments from the public
  - If APHIS finds the plant is unlikely to pose an increased plant pest risk, the plant is not subject to the regulations
  - If APHIS does not make such a finding, the plant will remain regulated
- Generally completed within 15 months of receiving a complete initial request
  - Includes 30-day completeness review for any requested data
  - Excludes any pauses in the process
- Anyone can request a re-review based upon scientifically valid evidence relating to plant pest risk

Pausing the RSR Process

- APHIS will pause the RSR process after Step 1 until receiving a response from the requestor
- APHIS will pause the process while awaiting a response to completeness review in Step 2
- APHIS will otherwise not pause the RSR process after a complete request is submitted
- A requestor can request a pause in the RSR process at any time, e.g., if data from a laboratory or field study is needed to inform a PPRA, the RSR process can be paused until the data is provided to APHIS

RSR Request - Required Information

- Requestor's name, organization, and contact information, including email
- CBI Statement and, if there are CBI claims, CBI justification
- Scientific name of the comparator plant
- Genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant
- Detailed description of the new trait

Required Information: Genotype

If genetic material is inserted

- The DNA sequence of the inserted material
- Annotation of the inserted material, including for each construct component
  - Nucleotide position
  - Name (e.g., 35S promoter, catalase, nos terminator, noncoding spacer)
  - Donor organism(s) or source
  - Short description of the function, e.g.,
    - Enzyme involved in amylose synthesis
    - Confers glufosinate resistance
    - Native promoter
    - Nopaline synthase terminator

Required Information: Genotype

If genetic material is inserted

- Publicly available sequence identification, protein accession number, and enzyme commission number
- Identify promoters as constitutive, inducible, developmental, or tissue specific
  - If developmental/tissue specific, describe the stage(s)/tissue(s) in which the promotor is intended to be active
- Identify the nature and purpose (e.g., codon optimization, change in binding site of an enzyme) of any sequence alterations and alignment with the unmodified in the donor organism

Required Information: Genotype

If genetic material is not inserted

- Identify the gene(s) or genomic region(s) and the function(s) that are being modified
- Provide the DNA sequence of the entire modified region, including alignment with the unmodified sequence

Required Information: Description of the New Trait

- Purpose and intended phenotype of the new trait, including any expected differences from the phenotype of the comparator
- Available information on the MOA by which the intended trait is conferred, i.e., the biochemical process by which the genetic modification leads to the desired trait or phenotype
- Any expected changes in metabolism, physiology, and development due to the trait/genetic modification, to the extent known

Description of the New Trait: Examples

Trait: Herbicide resistance
Phenotype: Resistance to glyphosate
MOA: An insensitive form of EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) with a decreased binding affinity for glyphosate

Trait: Altered tuber amino acid profile
Phenotype: Reduced asparagine
MOA: Potato tuber-specific dsRNA-mediated degradation of Asn1 (asparagine synthetase-1) transcripts decreases Asn1 protein, resulting in reduced conversion of glutamine to asparagine in tubers.

Optional Information

Additional information may be submitted, but should be limited to that which informs an initial evaluation

Examples

- Whether the MOA is identical or similar to a previously reviewed MOA (provide explanation of similarity)
- Additional information on how the genetic material or its product participates in or interacts with metabolic, physiological, or developmental processes in the plant or in other organisms

PPRA: Additional Information

Additional information pertaining to the PPRA will not be reviewed unless a plausible pathway to plant pest risk is identified, and should not be submitted until the requestor directs BRS to conduct a PPRA

Thereafter, a requestor can submit additional supporting data anytime before APHIS makes its determination

Data submissions should address the plausible pathways to increased plant pest risk identified in the initial review

APHIS will use publicly available information and any additional information that the requestor chooses to submit when conducting a PPRA

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FY 2020 Compliance Activities and APHIS eFile Updates

Douglas Grant
Director, Regulatory Operations Programs
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
December 9, 2020

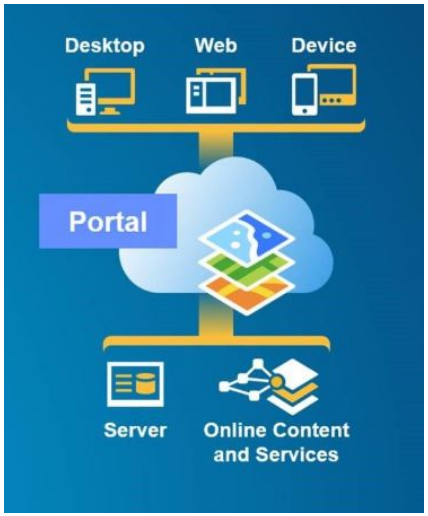
Inspection Selection and Execution

- Compile Post-Planting Report (PPR) data
  - Used to select planted sites (plantings) for inspection
  - Database and GIS
  - Consider compliance history
  - Lower risk trials selected at lower frequency

- Shift to virtual inspections during pandemic
  - Piloted virtual inspections in FY18 (as Monitoring and Evaluation Interviews (MEIs))
  - 100% virtual inspections beginning in March 2020
  - Pre-review records and photos
  - Video conferencing technology for remote visualization
  - Remote sensing for trial sites review

APHIS GIS Portal and Use of Remote Sensing

- Analyze geospatial data gathered from applicants and inspections
  - Map GPS coordinates
- APHIS-wide mapping capabilities within a **data-secure** cloud space
  - FedRAMP authorized



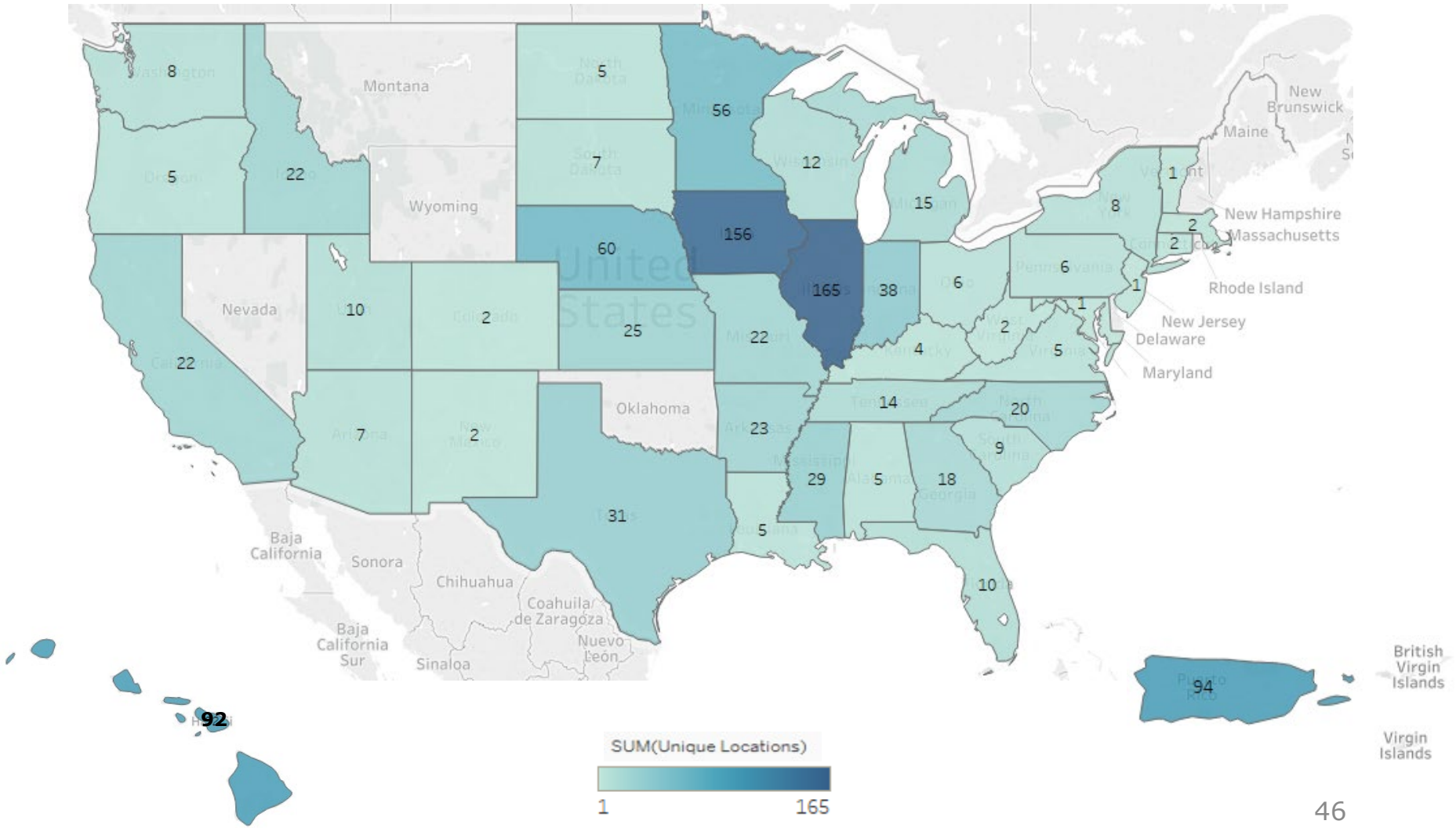
- Remote Sensing
  - Satellite imagery to find best image dates to support compliance inspections
  - Support or refute observations from virtual inspections

Inspection Execution and Compliance

- Compliance Rates:
  - FY 19 – 97%
  - FY 20 – 95%
- Notices sent in FY 20:
  - Compliant Inspections: 80%
  - Non-compliant Inspections: 5%
  - Other Inspections: 15%
- Common Compliance Challenges in FY 20:
  - Release in areas or quantities not authorized: 12
  - Failure to comply with Supplemental Permit Conditions: 19
  - Late or missing Post-Planting Report (PPR): 28
  - Late or missing Field Test Report (FTR): 21
  - Often associated with pandemic related challenges

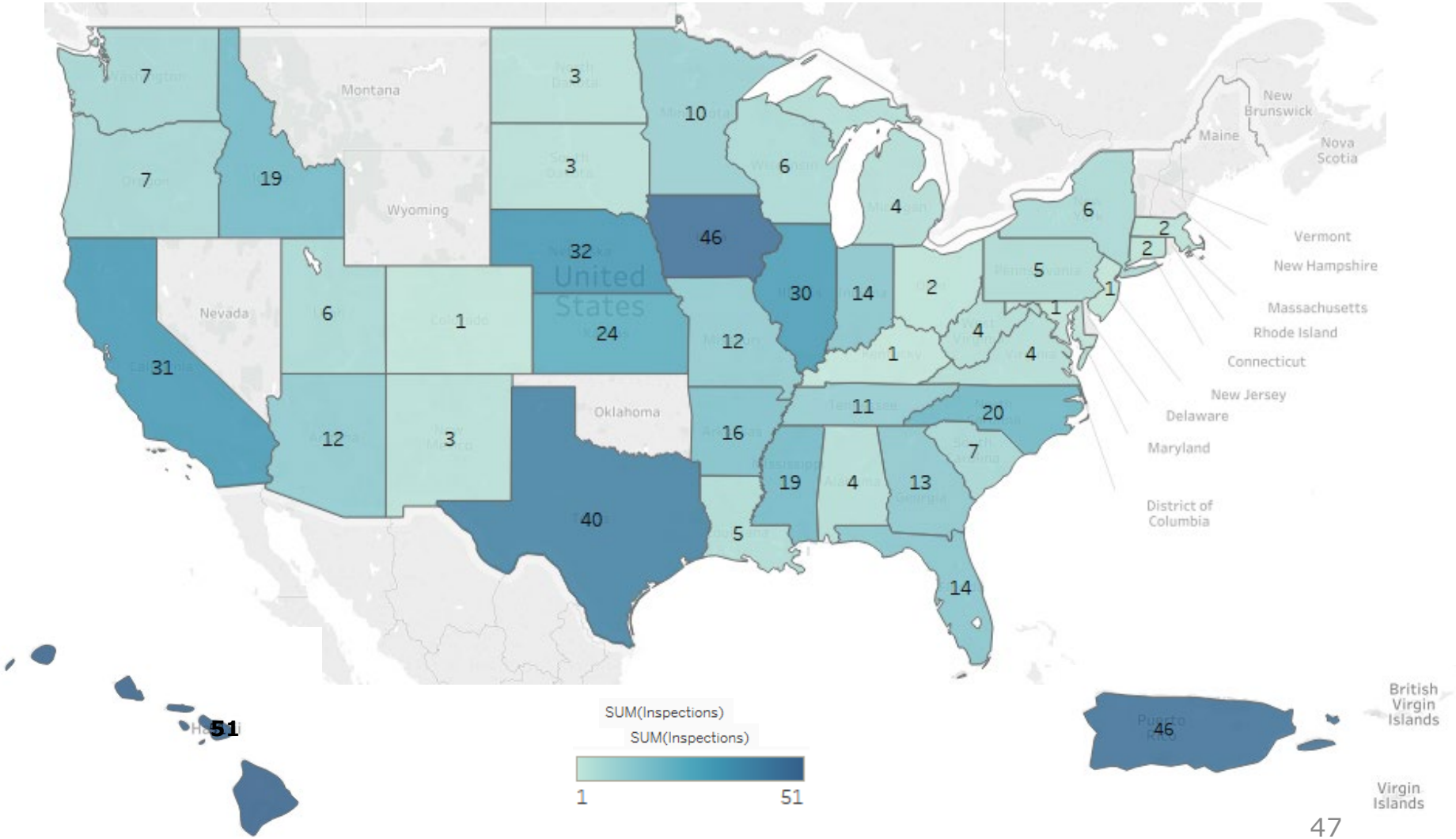
FY 20 Unique Locations Planted

Total 1,027



FY 20 Conducted Inspections

Total 544



% of Inspections Conducted By Organization

FY 14-20 (Even Years)

FY	BRS	PPQ	State
14	6.6%	85.4%	8.0%
16	56.2%	36.8%	7.0%
18	69.1%	23.7%	7.2%
20	95.6%	3.9%	0.5%

FY 20 BRS Inspections by Quarter

Quarter	New	Cumulative
1	69	69
2	89	158
3	69	227
4	317	544

APHIS eFile Update and ePermits Transition

APHIS eFile Progress

48 Pilot Applicants

82 Authorizations Submitted

59 Authorizations Processed

Improved User Registration and continued development throughout BRS' Pilot Program!

Transition to APHIS eFile

APRIL 1, 2021

- Last day to submit notifications in APHIS eFile

APRIL 4, 2021

- Last day to submit any permit and notifications applications in ePermits (includes XML applications)

APRIL 5, 2021

- Applicants must use APHIS eFile to submit permit applications
- Applicants can use APHIS eFile to request confirmation of exemption from regulation

Transition to APHIS eFile

- Supportive user guides
- Instructor-led and recorded training for applicants:
  - Navigating the Applicant Portal
  - Using BRS' updated Permitting Assistant
  - Preparing and managing Permit Applications
  - Submitting requests for confirmation of exemption from regulation
- Update on BRS website
  - Sign up for stakeholder registry at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology

ePermits Future Availability

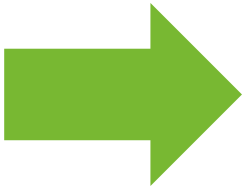
- Applications submitted in ePermits will complete their life cycle in ePermits
- Compliance reports for ePermits authorizations should be submitted in ePermits
- For the foreseeable future:
  - No restrictions to ePermits read access
  - No data migration from ePermits to APHIS eFile

APHIS eFile Early Adoption

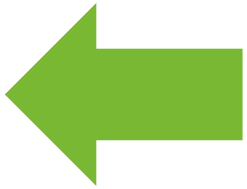
- Get acquainted with the user interface
- Submit multiyear permit applications
- Take advantage of “Previously Submitted Constructs”
- Set up sharing accounts for their teams
- Visit https://efile.aphis.usda.gov/
  - Register with your eAuthentication Account
  - Submit your first application!

Contact APHIS-BRS eFile Team

Questions?
Comments?
Need help?
Want to transition early?



efile.communications@usda.gov



Thank you!

Closing

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