Biotechnology Regulatory Services

Stakeholder Meeting

December 5, 2019

Welcome

Doug McKalip

Senior Advisor

Biotechnology Regulatory Services

Introduction

Greg Ibach
Under Secretary
USDA Marketing and Regulatory Programs

BRS Summary of FY19

A Look Ahead to FY20

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services

FY 19 Primary BRS

Accomplishments & Progress

- SECURE Rule
- ePermits → eFile Pilot
- Teamwork & ensuring excellent level of customer service

Authorized Activities with Regulated Articles, FY19

Number of Authorizations	Number of Sites	Number of Phenotypic Designations (crop-trait combination, all activities)
1,486	3,283	24,906

Petitions for Deregulation (FY19)

Three deregulation petitions completed (Path II)

- Texas A&M low gossypol Cotton
- BASF altered oil profile and herbicide resistant Canola
- Verdeca increased yield and glufosinate resistant Soybean

Petitions for Deregulation (FY20)

Currently:

10 Petitions in various stages

2 Extension requests

Am I Regulated?

"Does my GE organism meet the definition of a regulated article under *7 CFR part 340*?"

- FY 17: 14
- FY 18: 14
- FY 19: 12
- Inquiries under review: 17
  - 14 received after 3/31/19 (11 of these after 8/1/19)

Inspections

- With PPQ and States, conducted more than 600 safety inspections of authorized GE field trials
- Completed 53 virtual inspections of GE field trials

USDA / EPA / FDA

Biotechnology Unified Web Portal

- Outlined in Executive Order 13874
- Provides capability to query agencies
- Goal: User-friendly tool to navigate the regulatory system
- Detailed pages hosted by EPA, FDA and USDA
- Launch anticipated as early as next week

APHIS eFile

- Soft launch - July 23, 2019
- Transition ePermits → APHIS eFile
- Pilot Program
- Relationship between change in system and change in regulations

SECURE Rule (7 CFR part 340)

- June 2019 published new proposed rule – SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient)
- Comment period closed August 2019
- Received more than 6,100 comments

Looking Forward to 2020

- SECURE - Our No. 1 Strategic Initiative
- Ensuring appropriate staffing resources
- Maintaining excellent customer service
- Close working relations/communications

USDA

United States Department of Agriculture

Overview of Administration Biotechnology Activities

Fan-Li Chou
Biotechnology Coordinator
USDA Office of the Chief Economist

USDA

United States Department of Agriculture

Regulatory Operations Program (ROP) Update

Douglas Grant, Ph.D.
Chief, Western Compliance Assurance Branch
Biotechnology Regulatory Services (ROP)

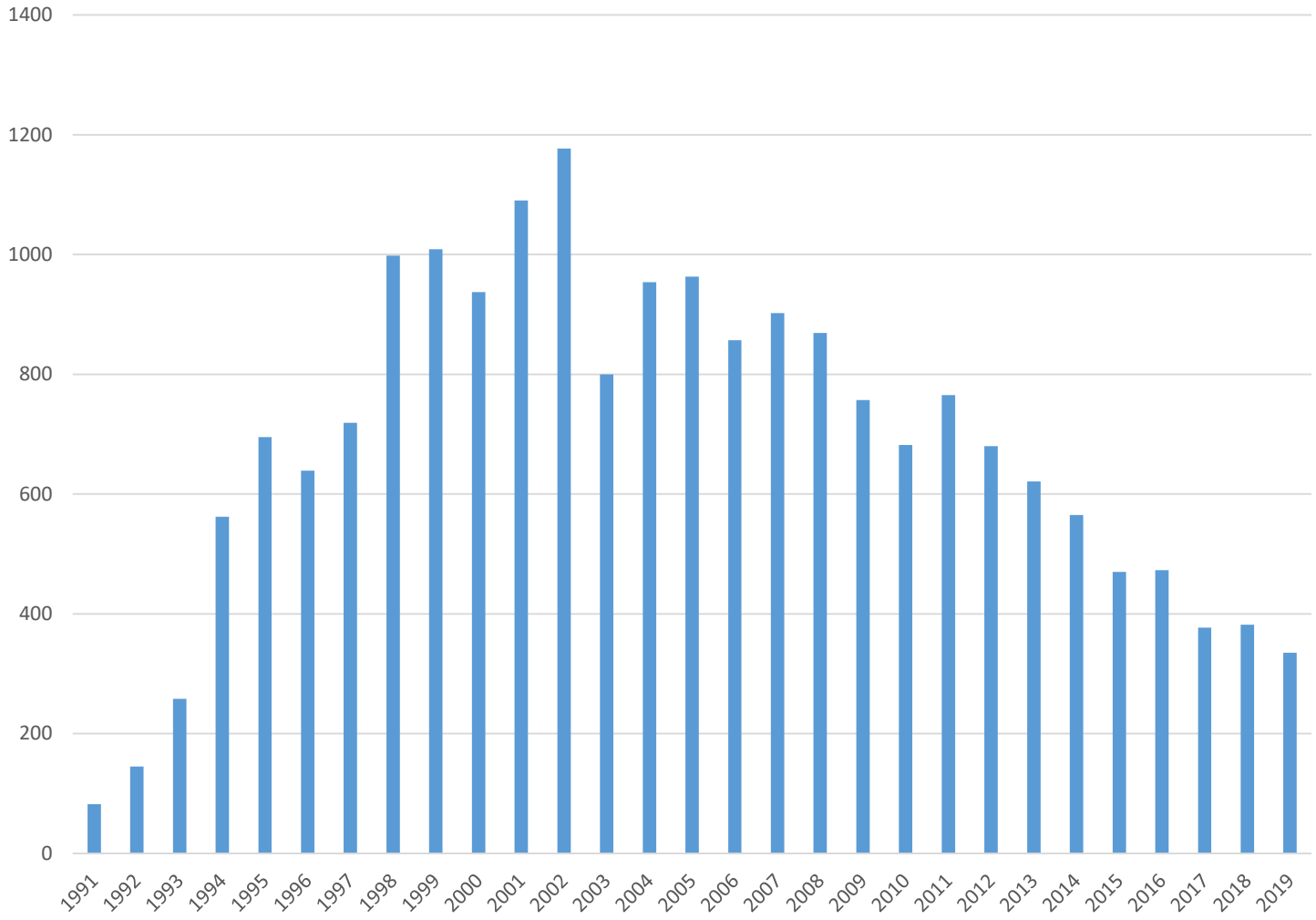
Release Authorizations Issued in FY18

Number of Release Authorizations	Number of Release Sites (authorized, not necessarily planted)	Number of Phenotypic Designations (crop-trait combos)
382	**4,481**	**32,628**

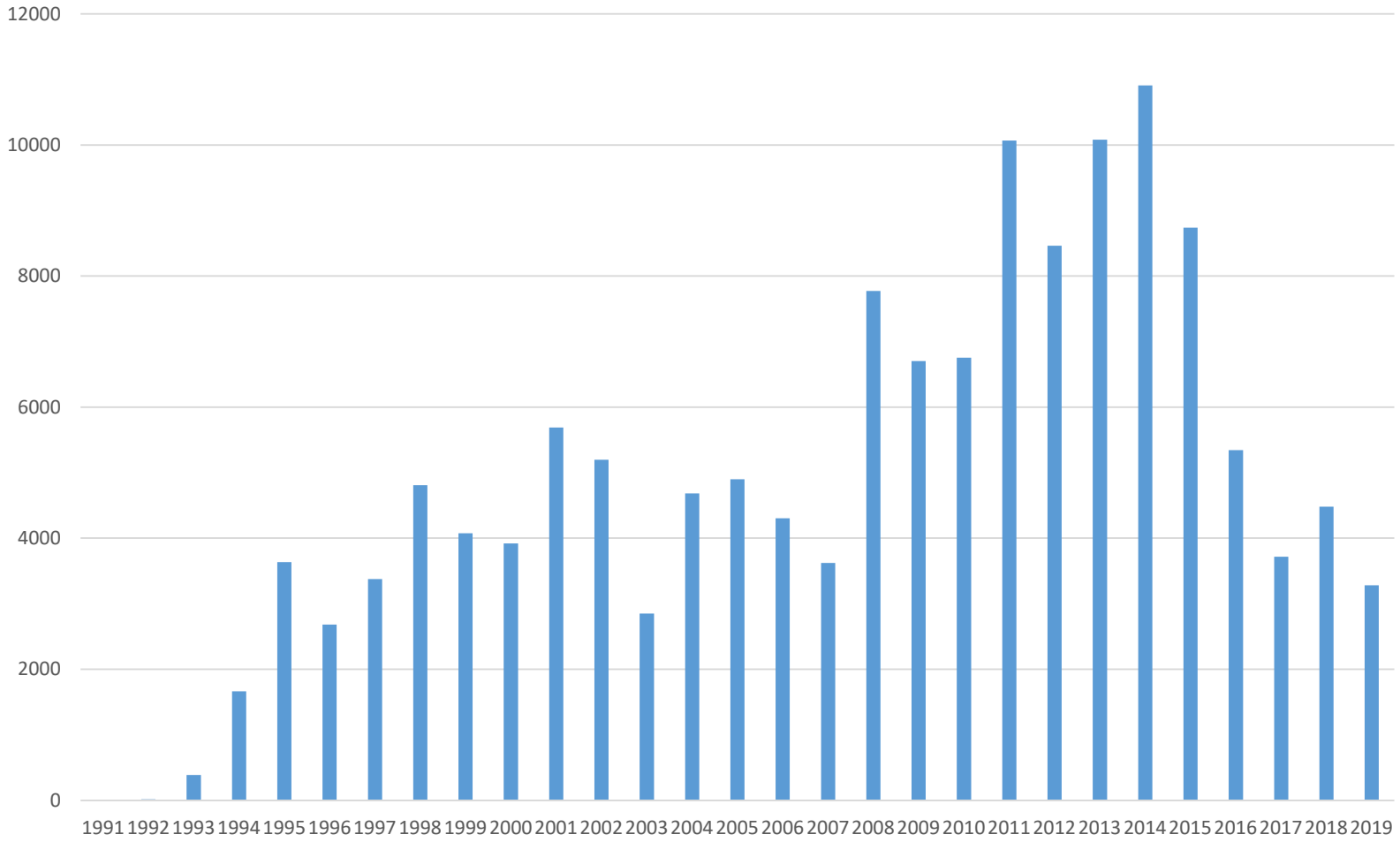
Release Authorizations Issued in FY19

Number of Release Authorizations	Number of Release Sites (authorized, not necessarily planted)	Number of Phenotypic Designations (crop-trait combos)
335	**3,283**	**19,320**

Release Authorizations



Authorized Field Release Sites



Inspection Selection and Execution

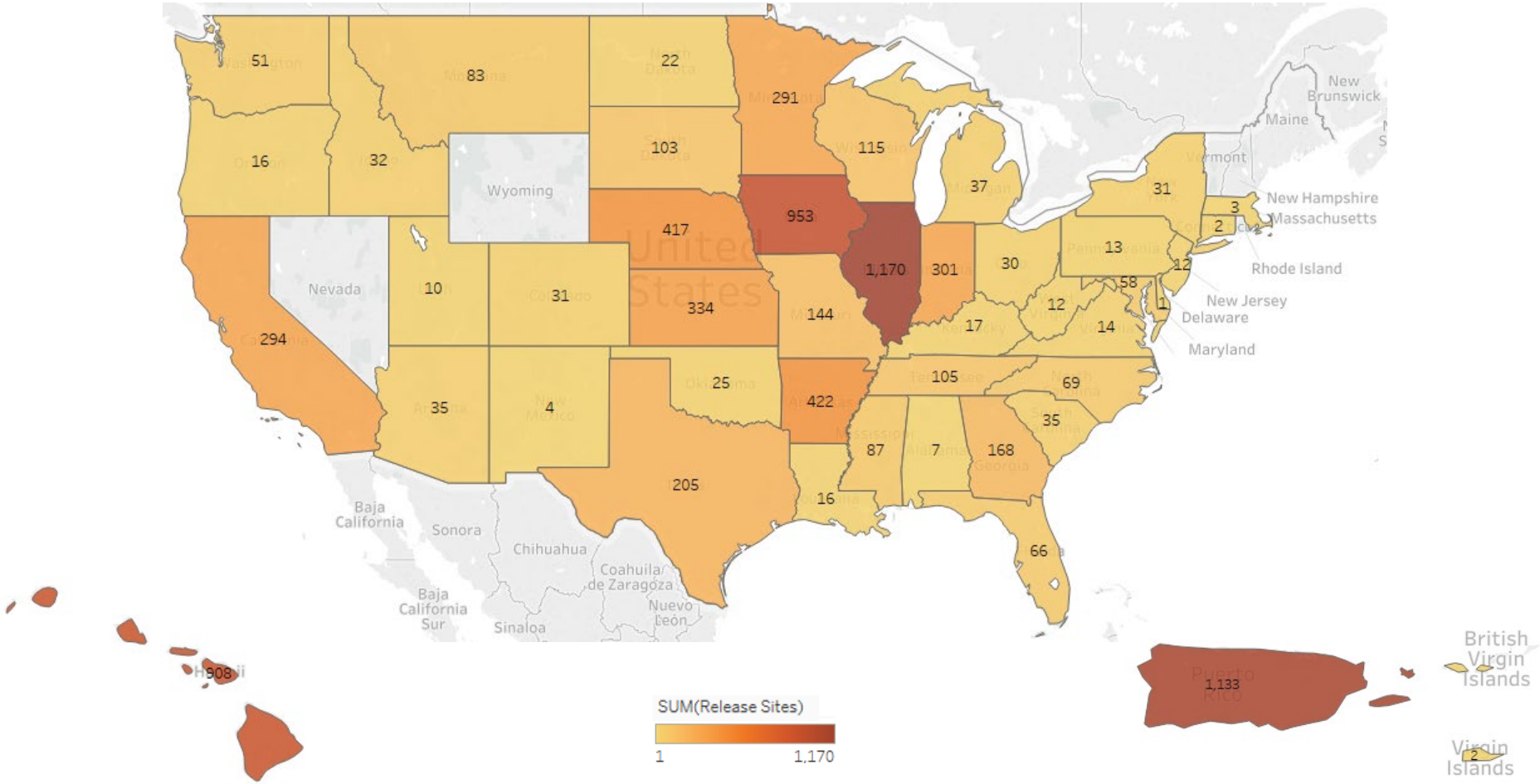
- Compile Post-Planting Report (PPR) data
  - Used to select planted sites (plantings) for inspection
  - Database and GIS
  - Consider compliance history
- Lower risk authorizations
  - Selected randomly
  - Geographically dispersed
- Higher risk authorizations
  - Inspected at least once in each state of release
  - Perennials inspected at least once per year
  - Pharmaceutical-industrial (PMPI) inspected multiple times per year

Inspection Execution and Compliance

- Most field inspections are scheduled
  - Some are unannounced
  - Some are virtual
- Emphasis placed on species with heightened concern (such as perennials)
- Compliance Rates:
  - FY18 – 92%
  - FY19 – 97%

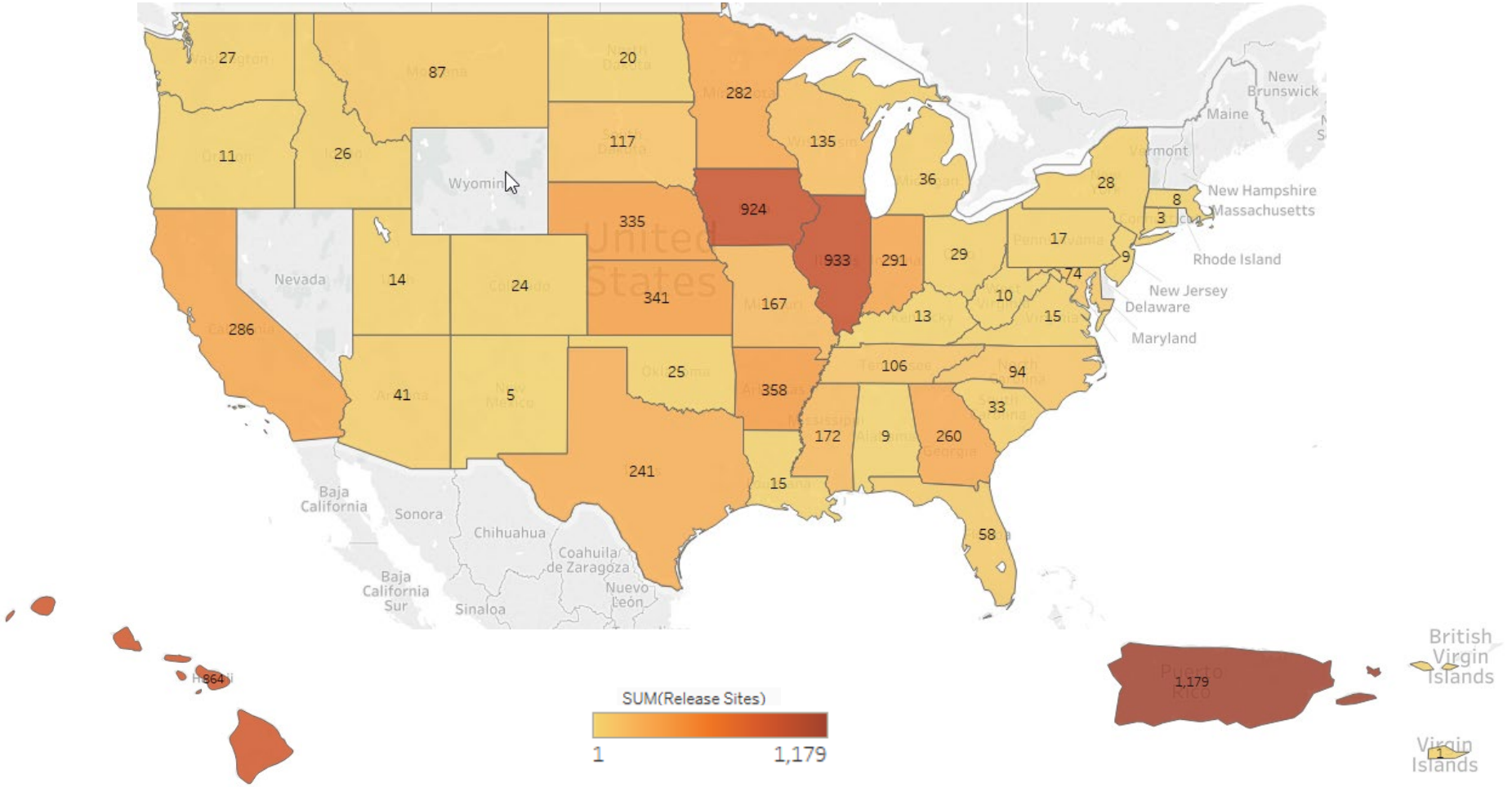
FY18 Valid Release Sites

Total 7,884



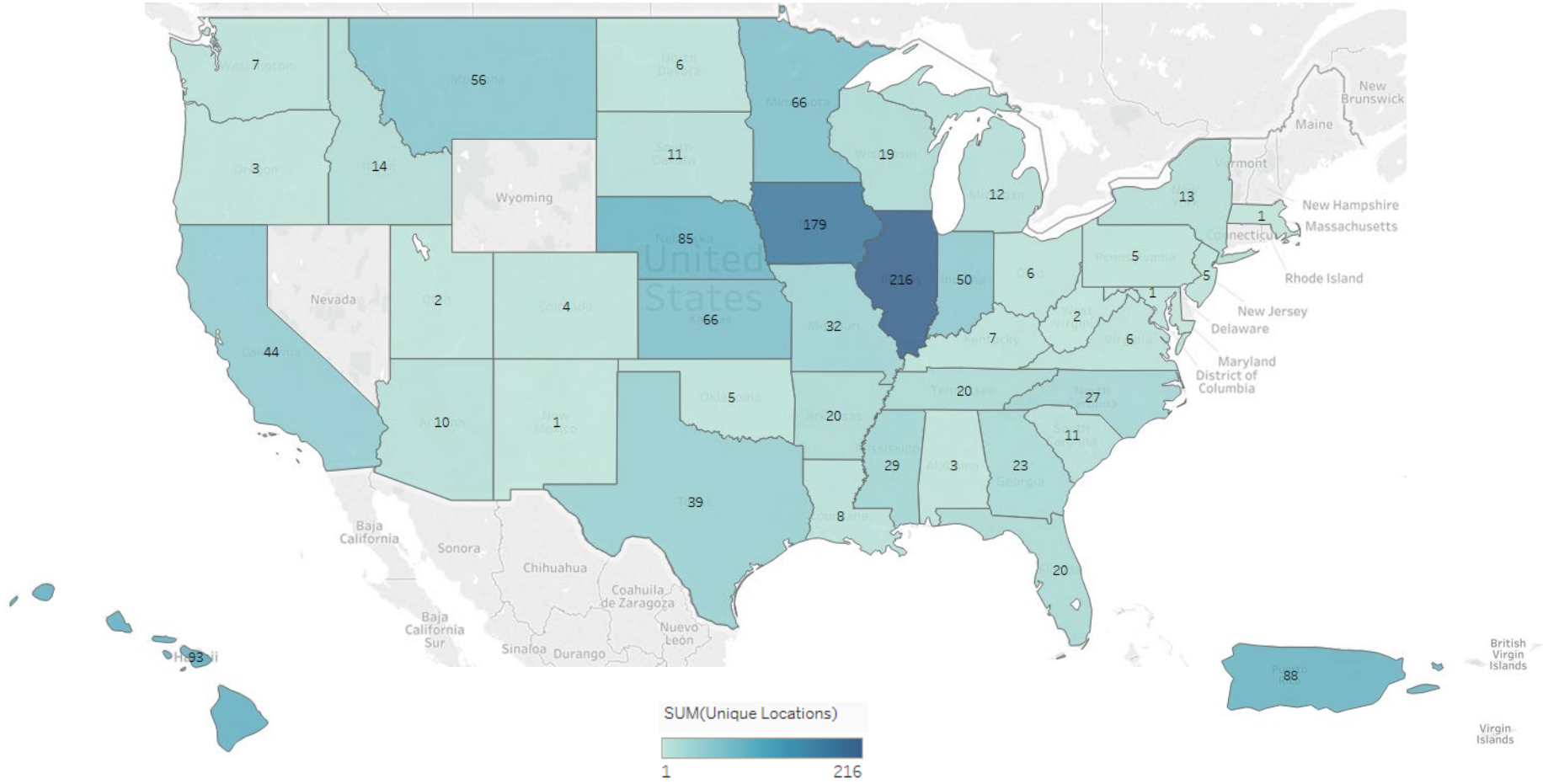
FY19 Valid Release Sites

Total 7,723



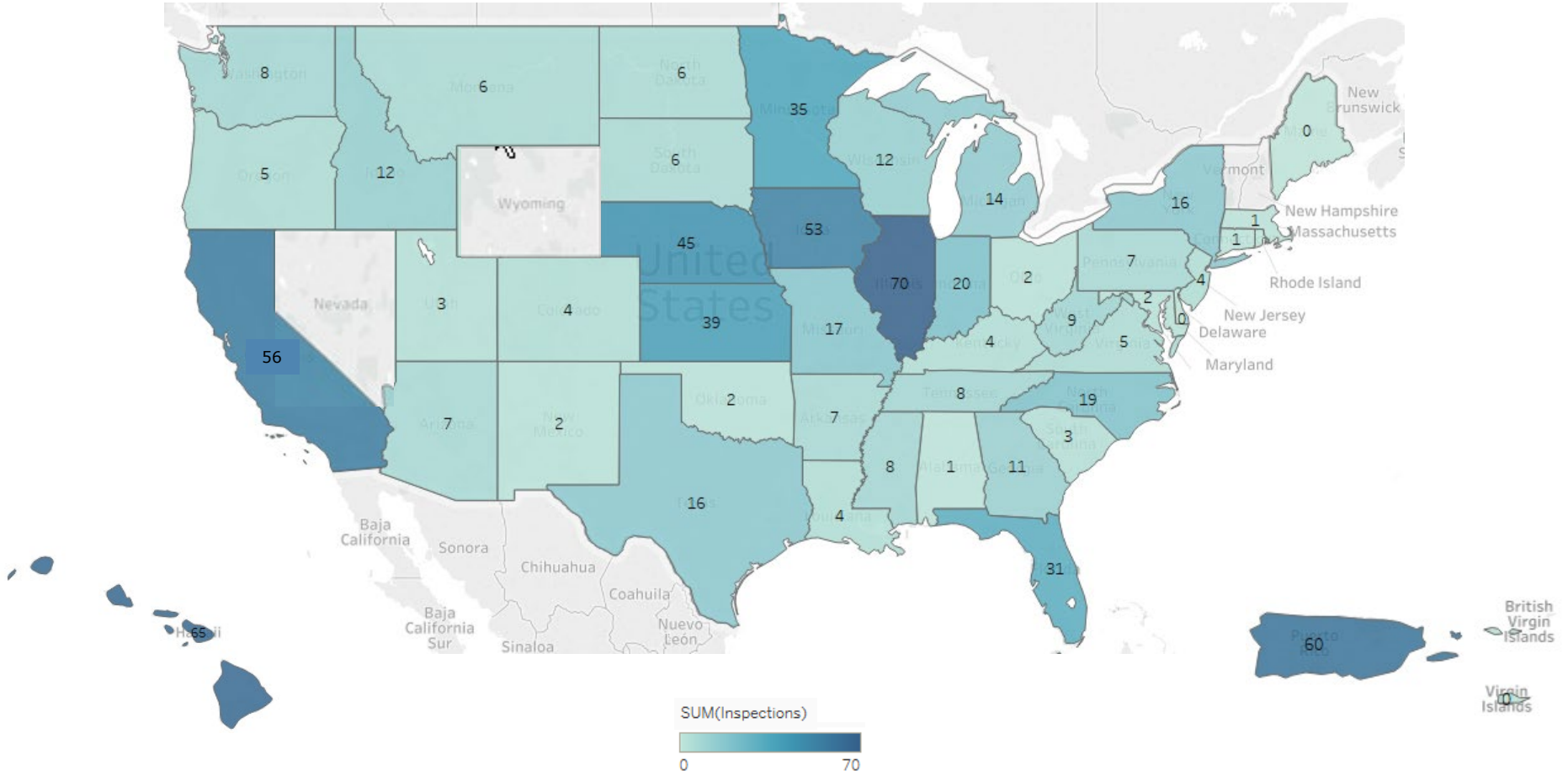
FY18 Unique Locations Planted

Total 1,315



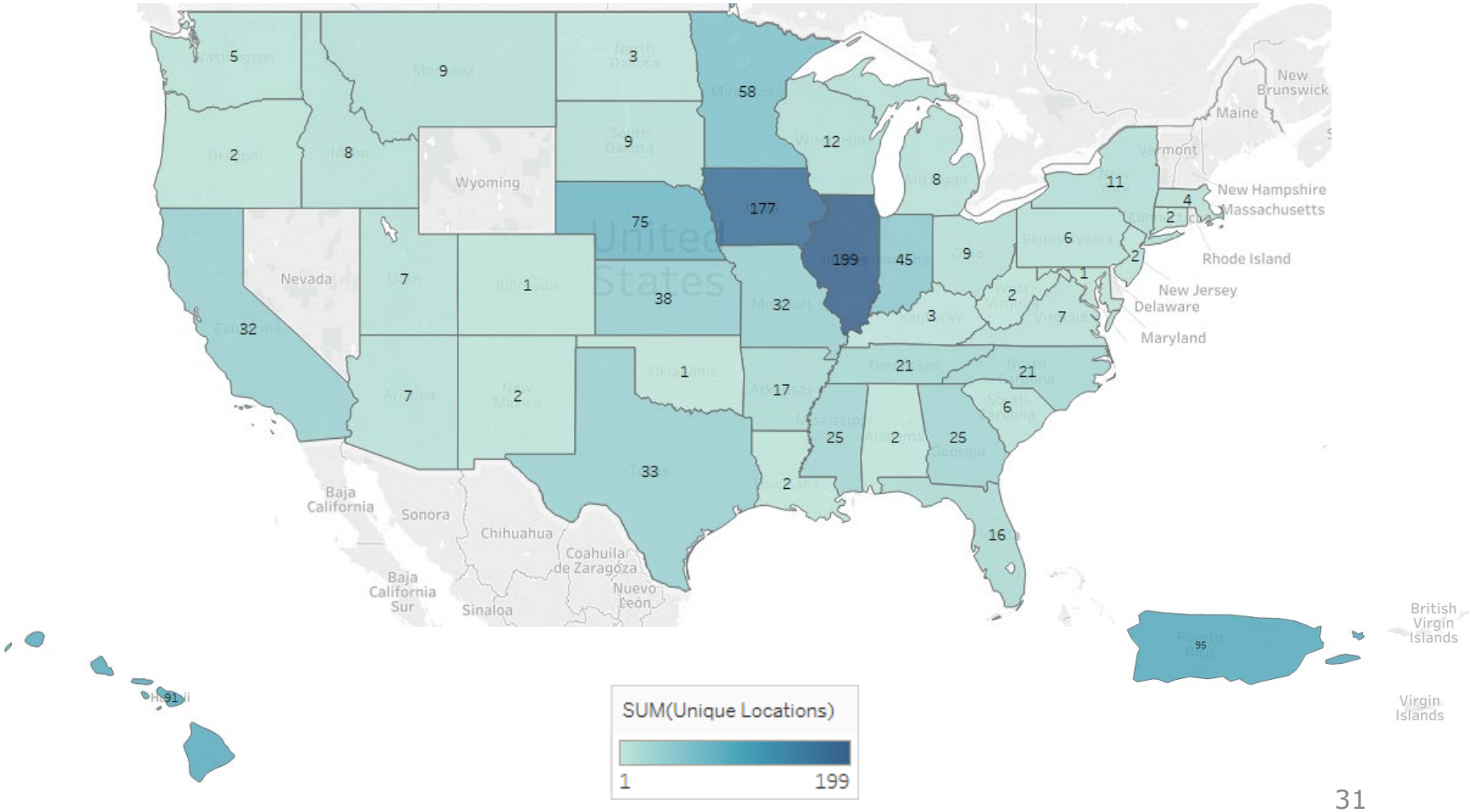
FY18 Conducted Inspections

Total 706



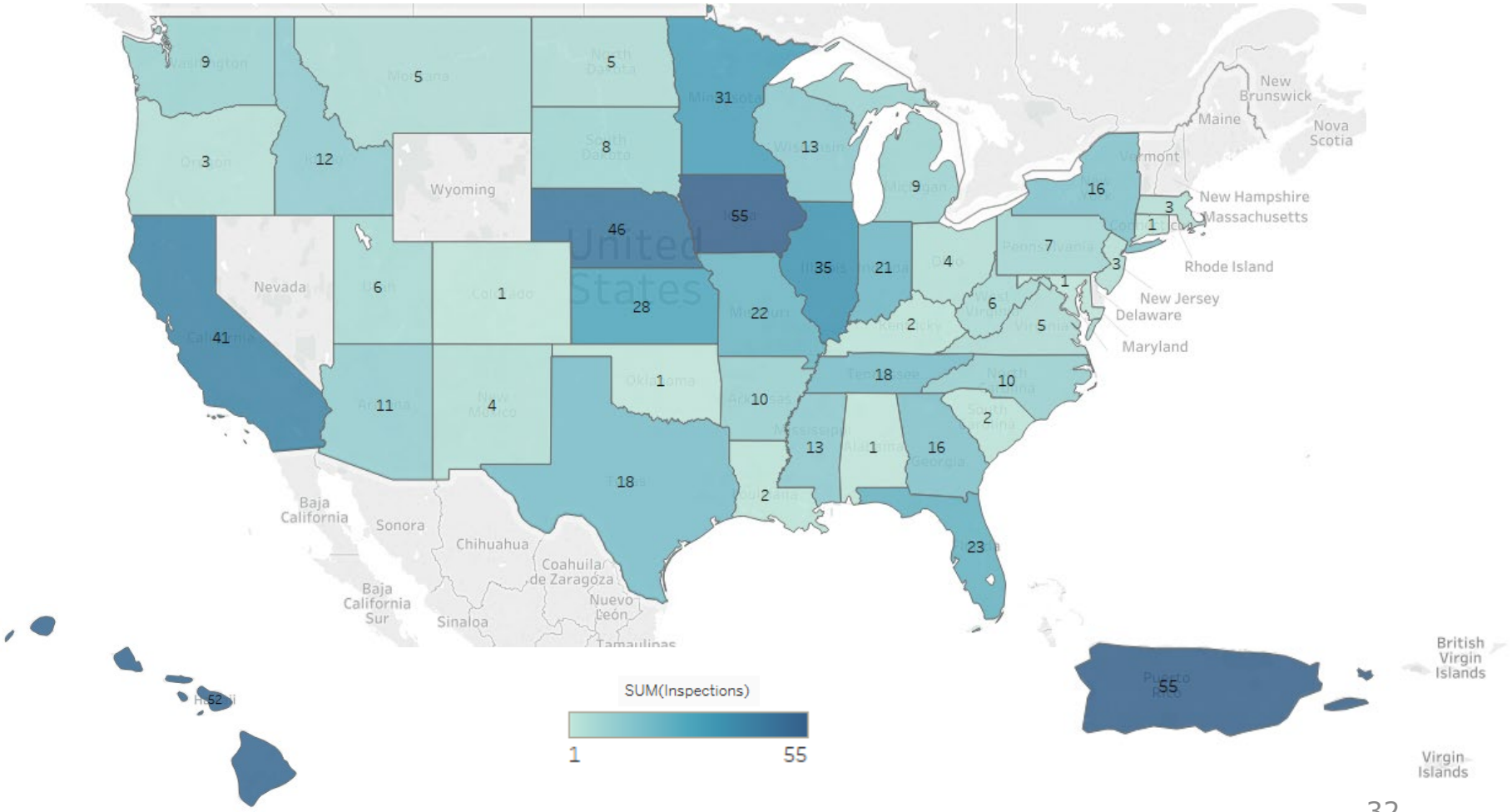
FY19 Unique Locations Planted

Total 1,131



FY19 Conducted Inspections

Total 636



Percentage of Inspections Conducted in FY14-19

	BRS	PPQ	State
FY14	6.6%	85.4%	8%
FY15	43%	50.7%	6.3%
FY16	56.2%	36.8%	7%
FY17	65%	28%	7%
FY18	**69.1%**	**23.7%**	**7.2%**
FY19	**68.8%**	**25.1%**	**6.1%**

Inspection Numbers

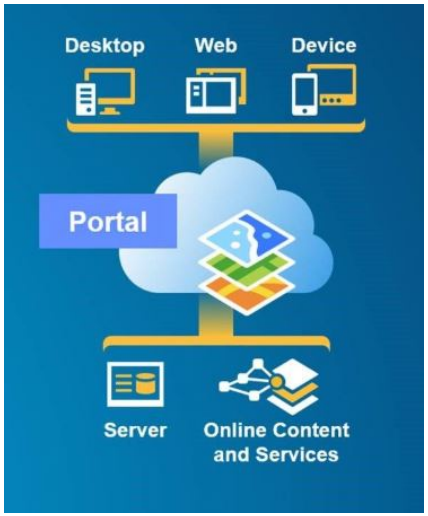
	Total Inspections	Virtual	Unannounced
FY18	706	27	43
FY19	636	53	43

Records and Reports

ROP FY19 Projects

APHIS GIS Portal – Mapping in the Cloud

- Portal allows BRS to analyze geospatial data provided by applicants and obtained from inspections
  - Map GPS coordinates
- Part of an APHIS-wide effort to advance mapping capabilities within a **data-secure** cloud space
  - FedRAMP authorized



- **Mobile Data Collection – **testing****
  - App for data collection, during inspections
  - Geospatial data synced directly to Portal

Incident Notification

- Incident may be discovered
  - During inspection
  - Third-party report
  - Self report
- Compliance inbox: BRSCompliance@usda.gov
- Compliance hotline: (301) 851-3935
- Standard Permit Conditions - 7 CFR 340.4(f):

(10) APHIS shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours **in the event of any accidental or unauthorized release** of the regulated article;

2019 GE Wheat Incident Summary

- APHIS BRS received a report of wheat that survived glyphosate treatment in a fallow field in WA
  - Incident response late May through early July
- Good cooperation and communication throughout the incident with the grower, developer, and WA State authorities
- Mitigation plans and compliance agreement
- No evidence that any GE wheat entered commerce, trade markets remained open
- Recently BRS collaborated with WSU to develop Best Management Practices (BMPs) guidance

USDA

United States Department of Agriculture

APHIS eFile Update

Ibrahim Shaqir

BRS Stakeholder Meeting
December 5, 2019

Applicant involvement during the pilot has led to **tangible improvements** to APHIS eFile that otherwise would have been impossible

76 Pieces of **applicant feedback received**

31 System **enhancements** completed

The APHIS eFile Pilot will continue to be the avenue where BRS and its stakeholders collaborate to develop **the best online experience**

An update on the full release timeline will be shared in early Summer 2020

Collaboration Case Study for Success:
BRS & Applicant "Previously Submitted Construct Tiger Team"

A **group of BRS employees** and **pilot applicants** met to tackle a challenge identified during the pilot:

…the Previously Submitted Construct feature **would not work for applicants**

Through their collaboration and close communication, a solution was identified and **will go live in the coming days!**

Join the Expanded eFile Pilot!

Pilot applicants…

- ✓ Can apply for **multi-year permits**
- ✓ **Provide input** to enhance the system
- ✓ Use the new **Organizational Access** feature

Email us to get involved! efile.communications@usda.gov

Pilot applicants may continue to use ePermits for all Permit and Notification Applications

APHIS eFile Highlights

Organizational Access

- **Exclusive** to APHIS eFile
- Allows companies to **organize and manage their employees' access** within the system

XML Compliance Reporting

THANK YOU!

BRS Pilot Applicants
For an incredible job navigating a new system and providing helpful feedback!

BRS Stakeholders
For patience and participation on this journey!

Questions? Reach out to us at
eFile.Communications@usda.gov

Procedures & Formatting for Submitting Petitions

Under 7 CFR 340.6

Maxine Ball
Management Analyst
BRS Communications

What We Will Cover Today

- Number of Copies
- Structure and Formatting
- Certification Statement and Signatures
- Completeness of Package
- Marking for CBI
- Guidelines - CBI, CBI-Deleted and No-CBI Deleted Petition Versions

Number of Copies to Send

Send (2) two copies of a petition to:

Ms. Cynthia A. Eck
Document Control Officer
Animal and Plant Health Inspection Service,
Biotechnology Regulatory Services
4700 River Road, Unit 146,
Riverdale, Maryland 20737-1237

Structure & Formatting Fall Under Our Regulations

Structure as follows:

Each petition submission shall be dated.

On the cover page provide the following statement AND a signature:

The undersigned submits this petition under 7 CFR 340.6 to request that the Administrator, make a determination that the article should not be regulated under 7 CFR part 340.

(Signature)

Provide a Statement of Grounds:

A person must present a full statement explaining the factual grounds why the organism should not be regulated under 7 CFR part 340.

Certification Statement & Signature Required

Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner which are unfavorable to the petition.

(Signature)

(Name of Petitioner)

(Mailing Address)

(Telephone Number)

Administratively Complete?

Is the Petition package complete?

The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination.

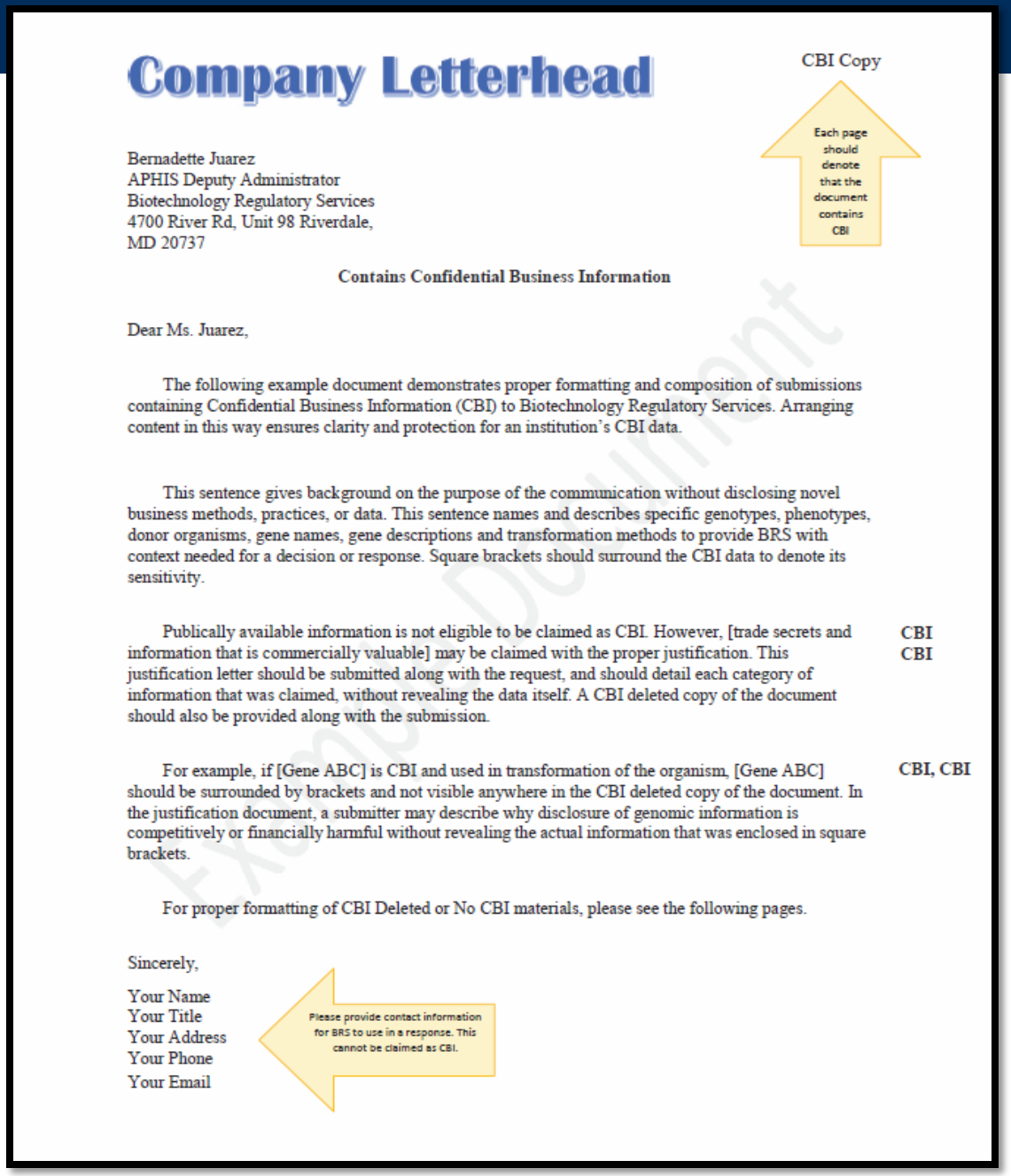
A complete list of all items required to submit a petition, can be found in paragraph (c) of 7 CFR 340.6.

Marking for CBI

Justifying and Marking a Petition for Confidential Business Information:

- If portions of the petition contain trade secret or confidential business information (CBI):
  - Each page of the petition should be marked "CBI Copy."
  - Each page of the petition where CBI information was deleted should be marked "CBI Deleted" AND marked on each page where the CBI was deleted: "CBI Deleted."
  - If a petition does not contain CBI, the first page of both copies shall be marked: "No CBI."

Use the following *Guidelines* to prepare CBI versions of the Petition:



Company Letterhead

CBI Copy

Each page should denote that the document contains CBI

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98 Riverdale,
MD 20737

Contains Confidential Business Information

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of submissions containing Confidential Business Information (CBI) to Biotechnology Regulatory Services. Arranging content in this way ensures clarity and protection for an institution's CBI data.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes specific genotypes, phenotypes, donor organisms, gene names, gene descriptions and transformation methods to provide BRS with context needed for a decision or response. Square brackets should surround the CBI data to denote its sensitivity.

Publically available information is not eligible to be claimed as CBI. However, [trade secrets and information that is commercially valuable] may be claimed with the proper justification. This justification letter should be submitted along with the request, and should detail each category of information that was claimed, without revealing the data itself. A CBI deleted copy of the document should also be provided along with the submission. **CBI CBI**

For example, if [Gene ABC] is CBI and used in transformation of the organism, [Gene ABC] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter may describe why disclosure of genomic information is competitively or financially harmful without revealing the actual information that was enclosed in square brackets. **CBI, CBI**

For proper formatting of CBI Deleted or No CBI materials, please see the following pages.

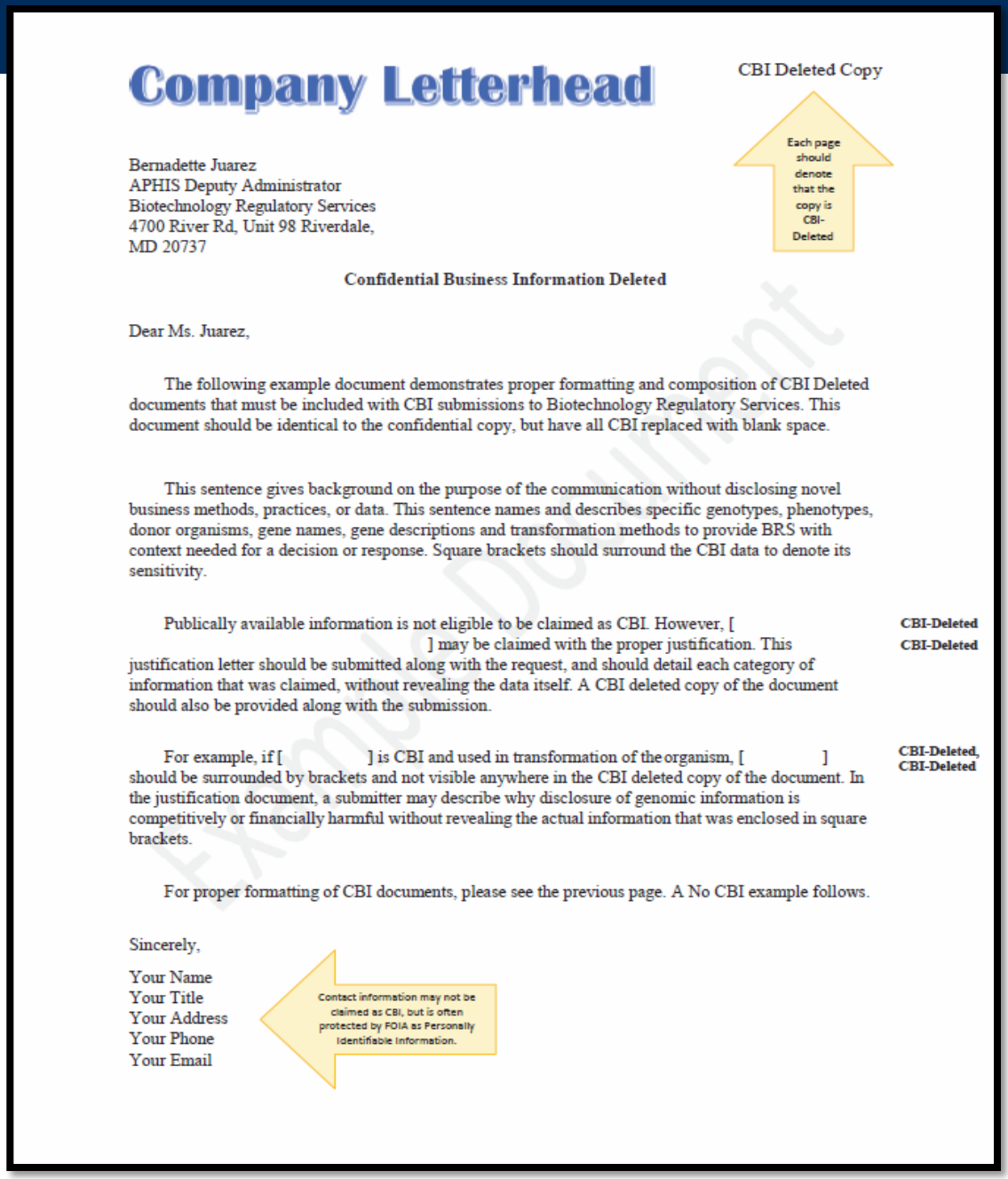
Sincerely,

Your Name
Your Title
Your Address
Your Phone
Your Email

Please provide contact information for BRS to use in a response. This cannot be claimed as CBI.

Example Document

Use the following *Guidelines* to prepare the CBI-Deleted versions of the Petition:



Company Letterhead

CBI Deleted Copy

Each page should denote that the copy is CBI-Deleted

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98 Riverdale,
MD 20737

Confidential Business Information Deleted

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of CBI Deleted documents that must be included with CBI submissions to Biotechnology Regulatory Services. This document should be identical to the confidential copy, but have all CBI replaced with blank space.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes specific genotypes, phenotypes, donor organisms, gene names, gene descriptions and transformation methods to provide BRS with context needed for a decision or response. Square brackets should surround the CBI data to denote its sensitivity.

Publically available information is not eligible to be claimed as CBI. However, [ ] may be claimed with the proper justification. This justification letter should be submitted along with the request, and should detail each category of information that was claimed, without revealing the data itself. A CBI deleted copy of the document should also be provided along with the submission. **CBI-Deleted** **CBI-Deleted**

For example, if [ ] is CBI and used in transformation of the organism, [ ] should be surrounded by brackets and not visible anywhere in the CBI deleted copy of the document. In the justification document, a submitter may describe why disclosure of genomic information is competitively or financially harmful without revealing the actual information that was enclosed in square brackets. **CBI-Deleted, CBI-Deleted**

For proper formatting of CBI documents, please see the previous page. A No CBI example follows.

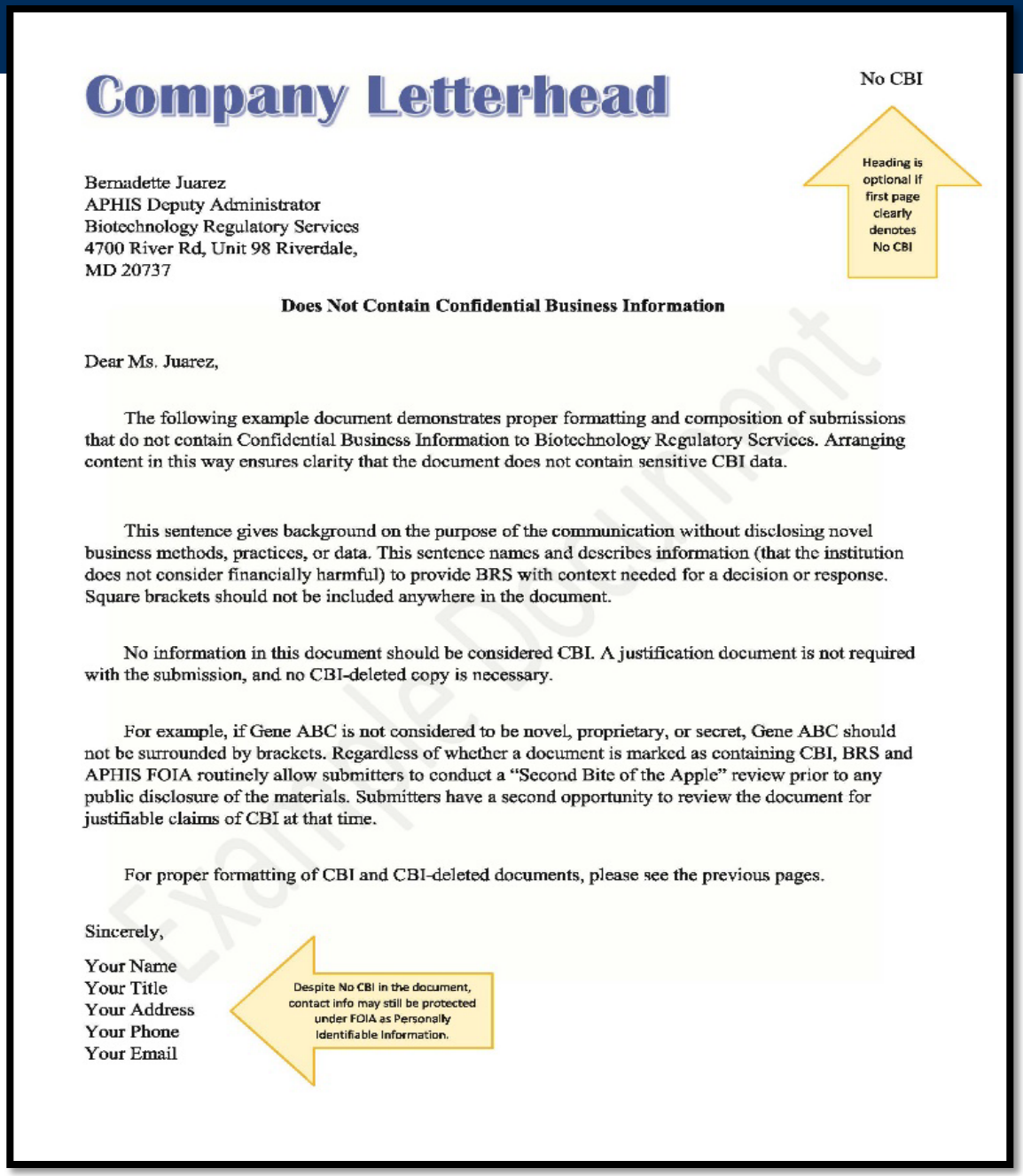
Sincerely,

Your Name
Your Title
Your Address
Your Phone
Your Email

Contact information may not be claimed as CBI, but is often protected by FOIA as Personally Identifiable Information.

Example Document

Use the following *Guidelines* to prepare No-CBI versions of the Petition:



Company Letterhead

No CBI

Heading is optional if first page clearly denotes No CBI

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98 Riverdale,
MD 20737

Does Not Contain Confidential Business Information

Dear Ms. Juarez,

The following example document demonstrates proper formatting and composition of submissions that do not contain Confidential Business Information to Biotechnology Regulatory Services. Arranging content in this way ensures clarity that the document does not contain sensitive CBI data.

This sentence gives background on the purpose of the communication without disclosing novel business methods, practices, or data. This sentence names and describes information (that the institution does not consider financially harmful) to provide BRS with context needed for a decision or response. Square brackets should not be included anywhere in the document.

No information in this document should be considered CBI. A justification document is not required with the submission, and no CBI-deleted copy is necessary.

For example, if Gene ABC is not considered to be novel, proprietary, or secret, Gene ABC should not be surrounded by brackets. Regardless of whether a document is marked as containing CBI, BRS and APHIS FOIA routinely allow submitters to conduct a "Second Bite of the Apple" review prior to any public disclosure of the materials. Submitters have a second opportunity to review the document for justifiable claims of CBI at that time.

For proper formatting of CBI and CBI-deleted documents, please see the previous pages.

Sincerely,

Your Name
Your Title
Your Address
Your Phone
Your Email

Despite No CBI in the document, contact info may still be protected under FOIA as Personally Identifiable Information.

Follow Up Questions

BRS Document Control Officer:

Cindy Eck

Cynthia.A.Eck@usda.gov (301) 851-3892

BRS Document Management Analysts:

Maxine Ball Maxine.Ball@usda.gov

Helana Johnson Helana.D.Johnson@usda.gov

USDA

United States Department of Agriculture