



United States Department of Agriculture

Biotechnology Regulatory Services Update

Alan Pearson
Assistant Deputy Administrator
Biotechnology Regulatory Services

National Plant Board
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Primary BRS Accomplishments & Activities Since Last NPB Presentation

- Issued 716 release authorizations for genetically engineered (GE) organisms
- Completed 5 deregulations
- Made 12 Am I Regulated determinations
- Responded to GE wheat incident

- Launched eFile pilot
- Published Proposed Rule revising biotechnology regulations

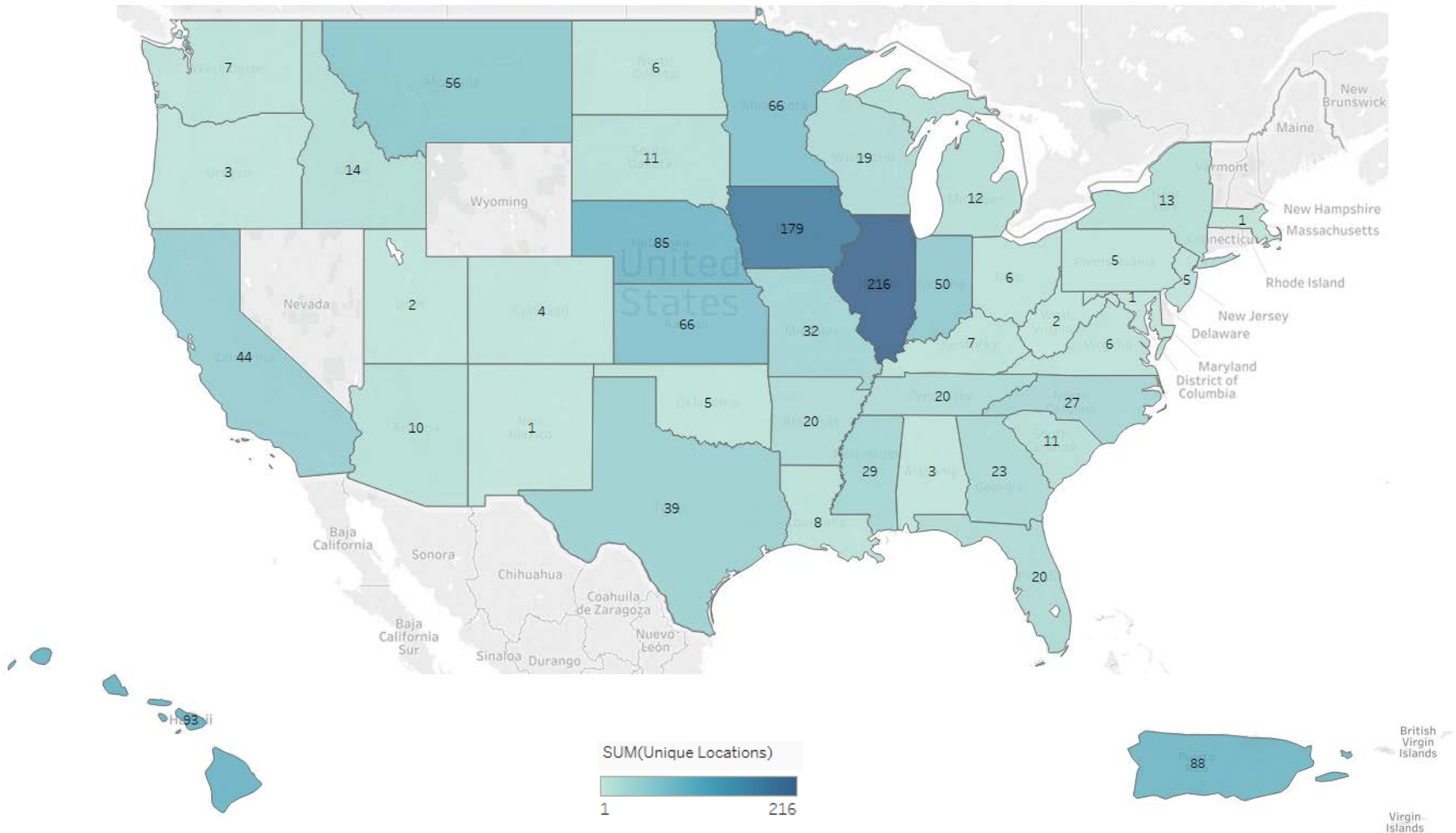


Release Authorizations Issued in FY18

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

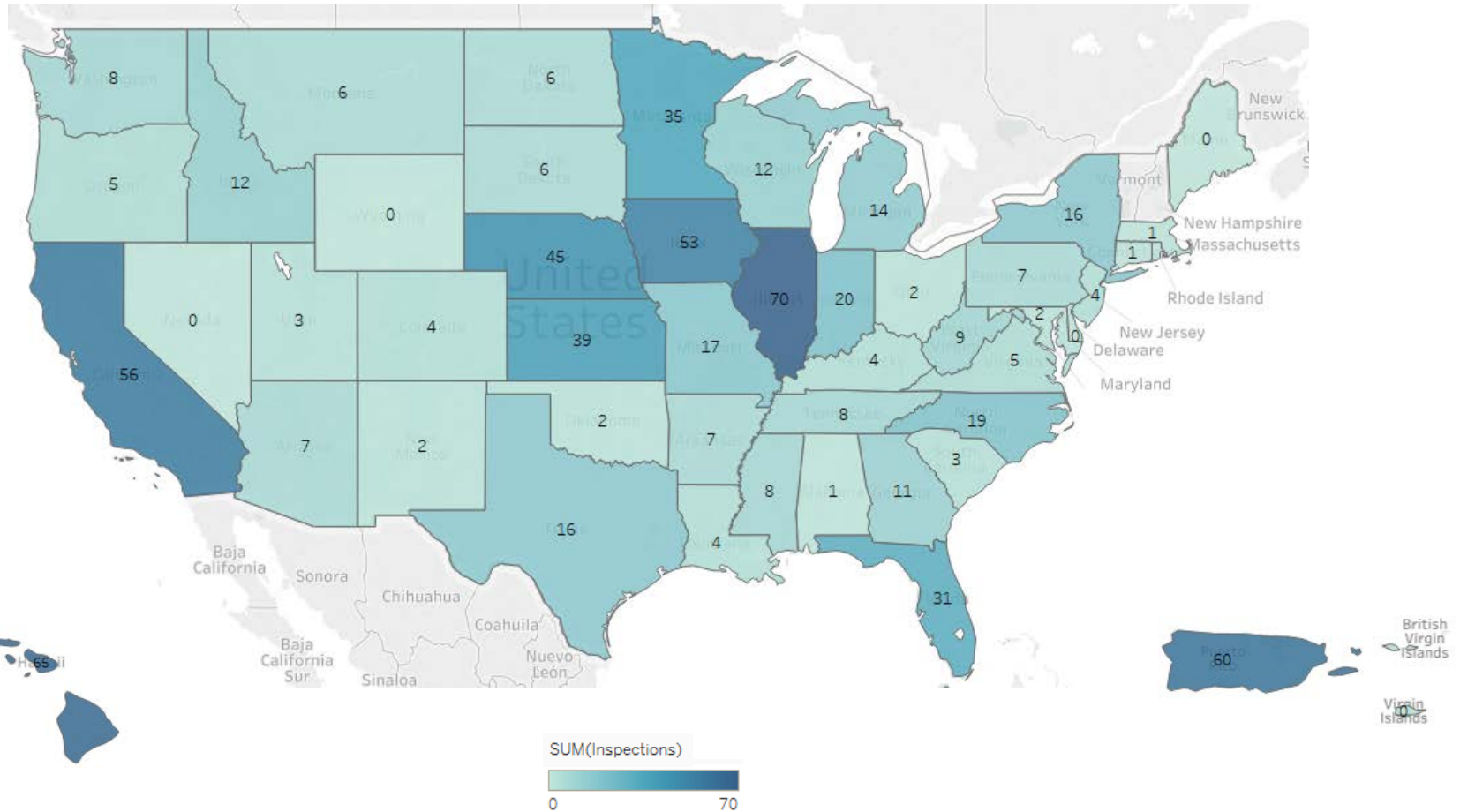
FY18 Unique Locations Planted

Total 1,315



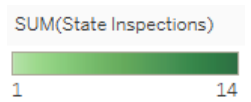
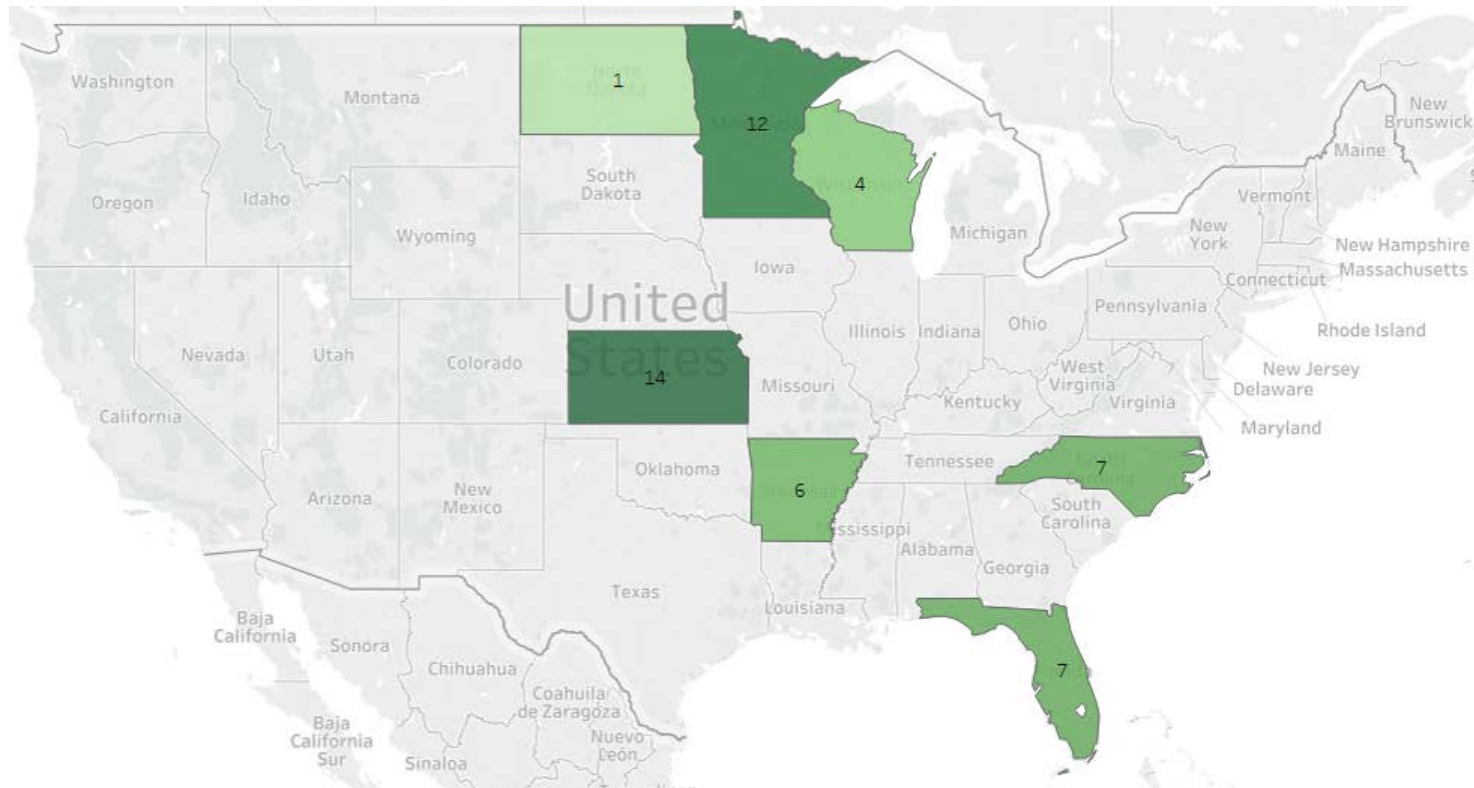
FY18 Conducted Inspections

Total: 706



FY18 Conducted State Inspections

Total: 51



Citrus tristeza virus permit

- 2017 Permit application for statewide release of GE CTV in Florida to protect against citrus greening
- Prepared draft Pest Risk Assessment and draft Environmental Impact Statement
- Public comment period closed, now preparing final documents
- Worked with Florida State officials throughout process

Determinations of Nonregulated Status Since Last NPB Presentation

- Canola
 - Altered Oil Profile (2)
- Cotton
 - Low Gossypol
 - Glyphosate/Isoxaflutole resistance
- Soy
 - High yield/Glufosinate resistance
- Currently 8 pending petitions (all but 1 received after March 31)

Petition Procedure for Deregulation

- Deregulated status means that the GE organism and its progeny are no longer subject to regulation 7 CFR Part 340
- Deregulation does not affect any other obligations (e.g., food safety under FDA)
- Deregulation is not an approval to commercialize. Some GE plants have been deregulated but never commercialized

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>

Am I Regulated

- Not all GE organisms are subject to USDA APHIS' biotechnology regulations
- GE organisms are regulated if a plant pest is involved as donor, recipient, or vector agent
- APHIS receives questions about whether a GE organism is subject to this regulation (“Am I Regulated?”)

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated>

BiotechQuery@usda.gov

GE Wheat Incident

- APHIS BRS received a report of wheat that survived glyphosate treatment in a field in WA, May 24
- Monsanto events MON71800 and MON71300
 - previous incidents involved MON71700 and MON 71800, same gene for glyphosate resistance
- Mitigation plans and compliance agreements in place
- Good cooperation and assistance throughout the incident with the farmer, PPQ, and WA State authorities
- No evidence that any GE wheat has entered commerce, trade markets remain open



Personnel changes

- New Deputy Administrator Bernadette Juarez
- New Assistant Deputy Administrator Alan Pearson
- New Risk Assessment Programs Director Subray Hegde
- State Liaison TBD (interim Alan Pearson)



eFile

- Goals: More sustainable IT infrastructure
- Improved customer experience
- “Soft” pilot
 - Started July 23, 2019
 - Involves 23 applicants
 - Anticipate 21 or more States may receive at least one application for review during the pilot phase
 - ePermits will continue to handle most applications
- Projected launch: November 2019
 - ePermits will no longer be used for web applications

eFile.communications@usda.gov

Updating USDA APHIS Biotech Regulations

- June 6, 2019: USDA APHIS proposed revision to biotech regulations
- June 11, 2019: President signed Executive Order 13874 on Modernizing the Regulatory Framework for Agricultural Biotechnology Products



Executive Order (June 11, 2019)

- “It is the policy of the Federal Government to protect public health and the environment by adopting regulatory approaches for the products of agricultural biotechnology that are proportionate responses to the risks such products pose, and that avoid arbitrary or unjustifiable distinctions across like products developed through different technologies. Any regulatory regime for products of agricultural biotechnology should ensure public confidence in the oversight of such products and also promote future innovation and competitiveness.”



Executive Order (June 11, 2019)

- Regulatory streamlining to implement policy
 - Make decisions on risk associated with the product and its intended use, basing decisions on the best available scientific evidence
 - Provide timely and efficient review
 - Provide transparent, predictable, and consistent regulation
 - Exempt low-risk products from undue regulation
 - Remove undue barriers that impede small developers from bringing safe genome-edited specialty crop plant to the marketplace



Executive Order (June 11, 2019)

- Unified Biotechnology Web-based Platform
 - Provide links to USG regulatory information
 - Allow developers to submit inquiries about the regulatory process for their products and receive single, coordinated response from the regulatory agencies
- Domestic engagement and international outreach
 - Increase public confidence in the safe use of agricultural biotechnology
 - Increase international acceptance of products of agricultural biotechnology

USDA APHIS Proposed Revision to Biotech Regulation (7 CFR part 340)

- On June 6, 2019, APHIS published a proposed revision to the biotech regulations at 7 CFR part 340.
 - In response to advances in genetic engineering and our understanding of the plant pest risk they pose.
 - Changes the definition of which GE organisms would be regulated
 - Incorporates Secretary Perdue's March 2018 statement on plant breeding innovations, including gene editing
 - Any changes to USDA APHIS biotech regulation would not affect obligations under FDA or EPA laws or regulations

USDA APHIS Proposed Revision to Biotech Regulation (7 CFR part 340)

- New definition for genetic engineering
 - “techniques that use recombinant or synthetic nucleic acids to modify or create a genome”

- Exempt certain GE plants from the regulation
 - GE plants that could be produced through traditional breeding (including certain products of gene editing)
 - GE plants with plant-trait-mechanism of action combinations that have been already been evaluated by APHIS using a Regulatory Status Review process and found to be unlikely to pose a plant pest risk

USDA APHIS Proposed Revision to Biotech Regulation (7 CFR part 340)

- Regulatory Status Review process that will consider the plant-trait-mechanism of action combination and whether the GE plant poses a plant pest risk
- Permit would be required for movement of “GE organisms” that are found to pose a plant pest risk
- Movement = importation, interstate movement, or environmental release

USDA APHIS Proposed Revision to Biotech Regulation (7 CFR part 340)

- Under the proposed rule, researchers or developers using GE plants can:
 - Self-determine if their GE plant is exempted from this regulation
 - Request a regulatory status review by USDA APHIS to ascertain if the GE plant requires a permit
 - Request a permit when the researcher wants to import, move interstate, or release into the environment

USDA APHIS Proposed Revision to Biotech Regulation (7 CFR part 340)

- Public comment period: June 6-August 5, 2019
- Proposed rule and supporting documents are online
- Comments from governments, organizations, individuals help to improve the proposed rule
- 6150 Comments received

<https://www.regulations.gov/docket?D=APHIS-2018-0034>

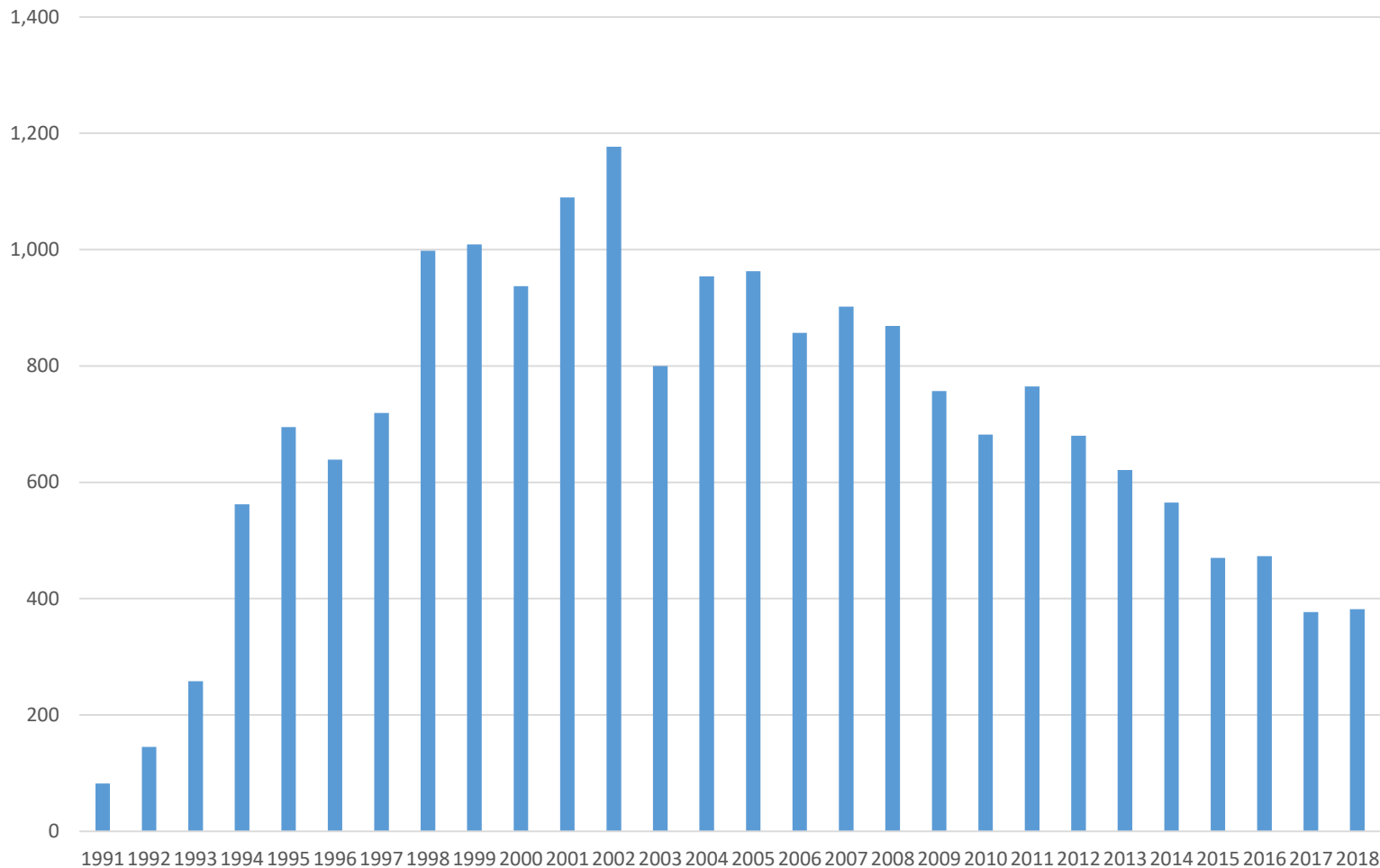
Contacts

- For issues related to inspections
 - Catherine.D.Cook@usda.gov (Eastern Region)
 - Sarah.T.Allely@usda.gov (Western Region)
- For other issues
 - Alan.Pearson@usda.gov

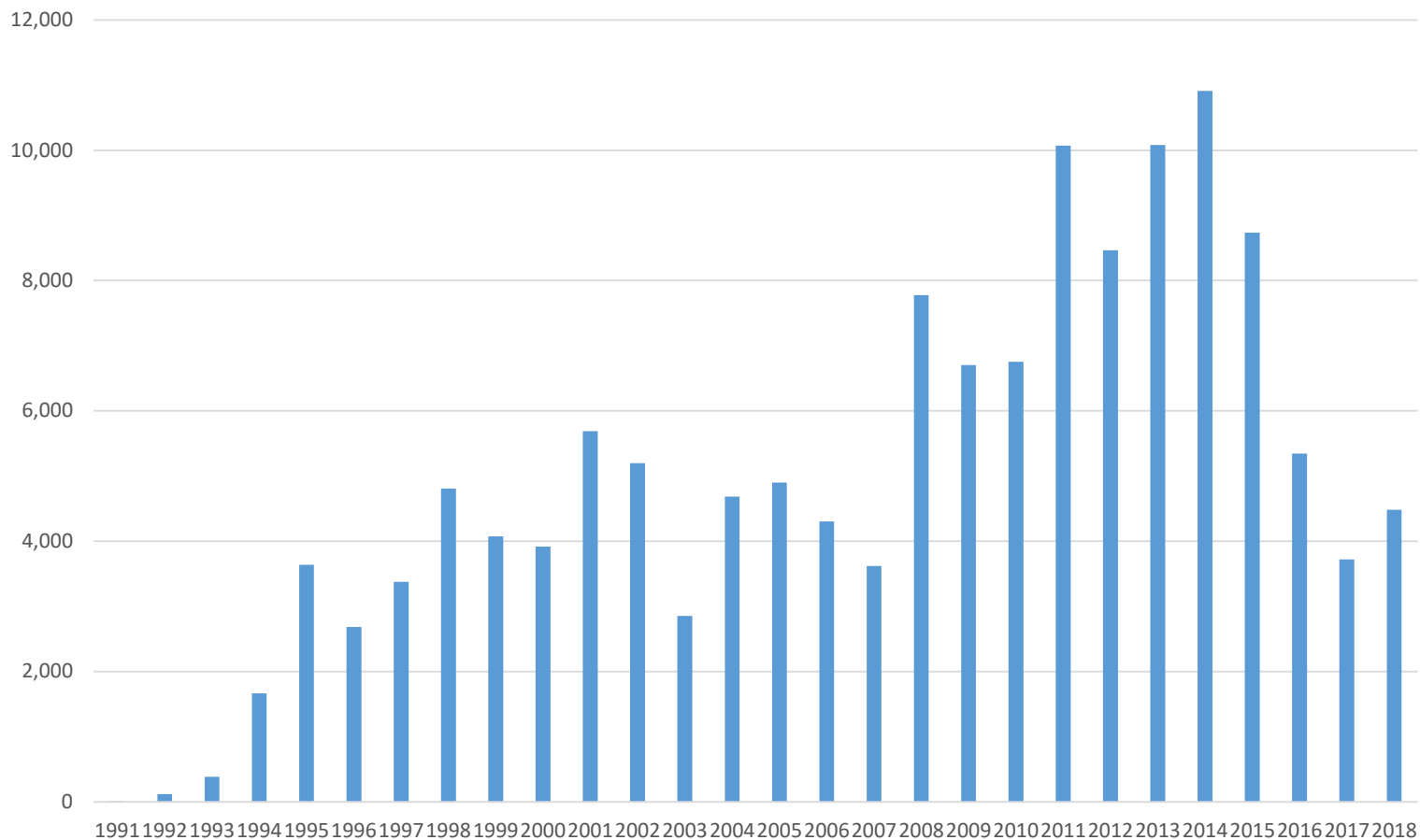


Questions ?

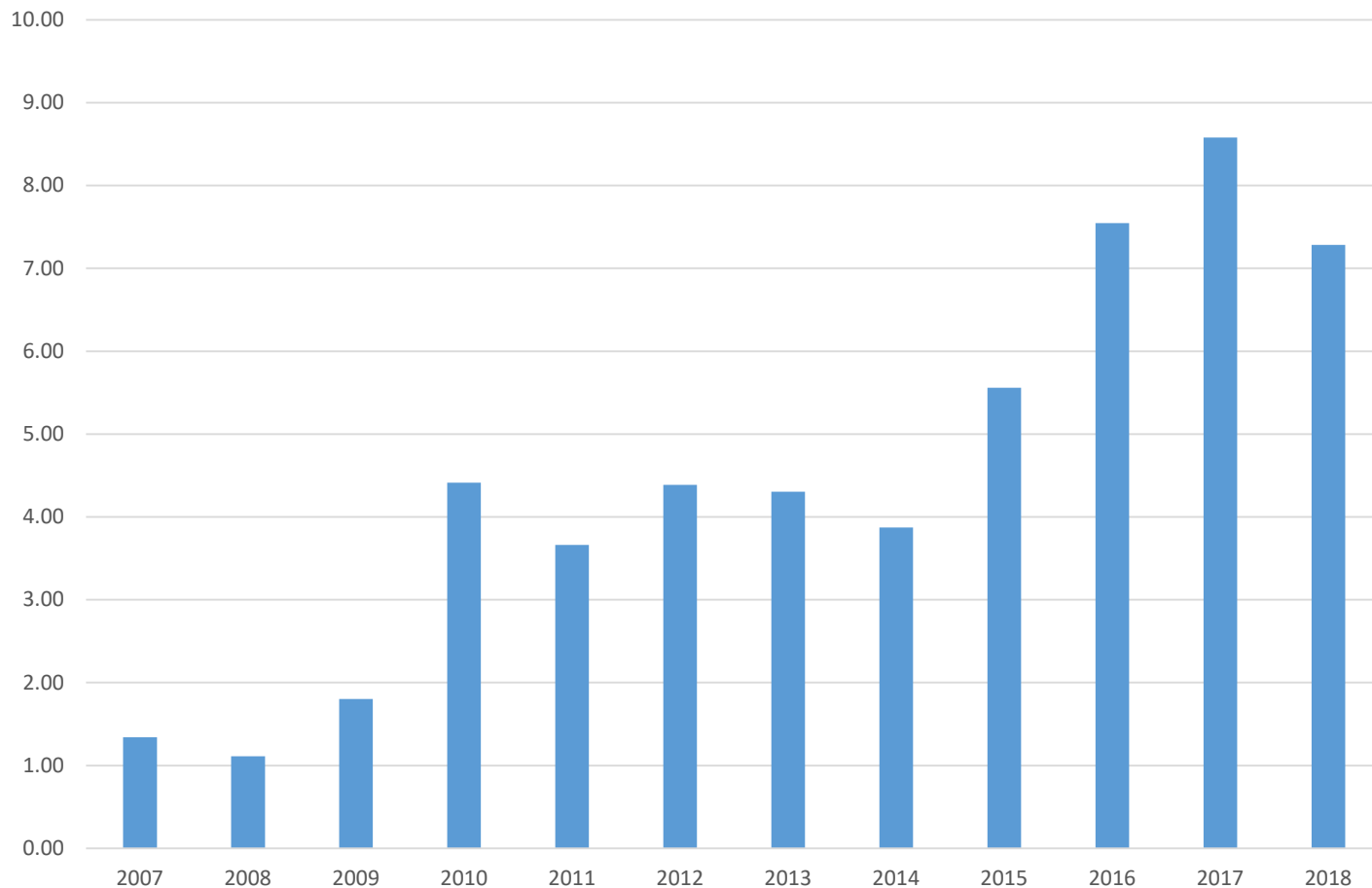
Release Authorizations



Authorized Field Release Sites



Phenotypic Designations/Release Site



Percentage of Inspections Conducted in FY2018

	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%

GE Plants with Nonregulated Status

- Alfalfa (2) – HT, PQ
- Apple (2) – PQ
- Canola (11) – HT, AP, PQ
- Corn (38) – HT, IR, AP, PQ
- Cotton (18) – HT, IR
- Papaya (2) – VR
- Potato (9) – IR, VR, PQ, FR
- Soybean (20) – HT, IR, AP, PQ
- Sugar Beet (3) – HT
- Rose (1) – PQ
- Squash (2) – VR
- Tobacco (1) – PQ

Not in commercial production

Chicory (1) – AP

Creeping Bentgrass (1) – HT

Flax (1) – HT

Plum (1) – VR

Rice (2) – HT

Tomato (11) – IR, PQ

HT – Herbicide Tolerant
 IR – Insect Resistant
 VR – Virus Resistant
 AP – Agronomic Properties
 PQ – Product Quality

Challenges

- Changing technology and products
- Gene/genome editing
- GE biocontrol organisms (intended to persist)
- Gene drives (intended to spread and persist)
- GE plant viruses (e.g., CTV)
- More complex products (e.g. GE viruses to be delivered in the field by insects, themselves possibly GE)