



Biotechnology Regulatory Services Update

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Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

National Plant Board
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FY 15 Accomplishments

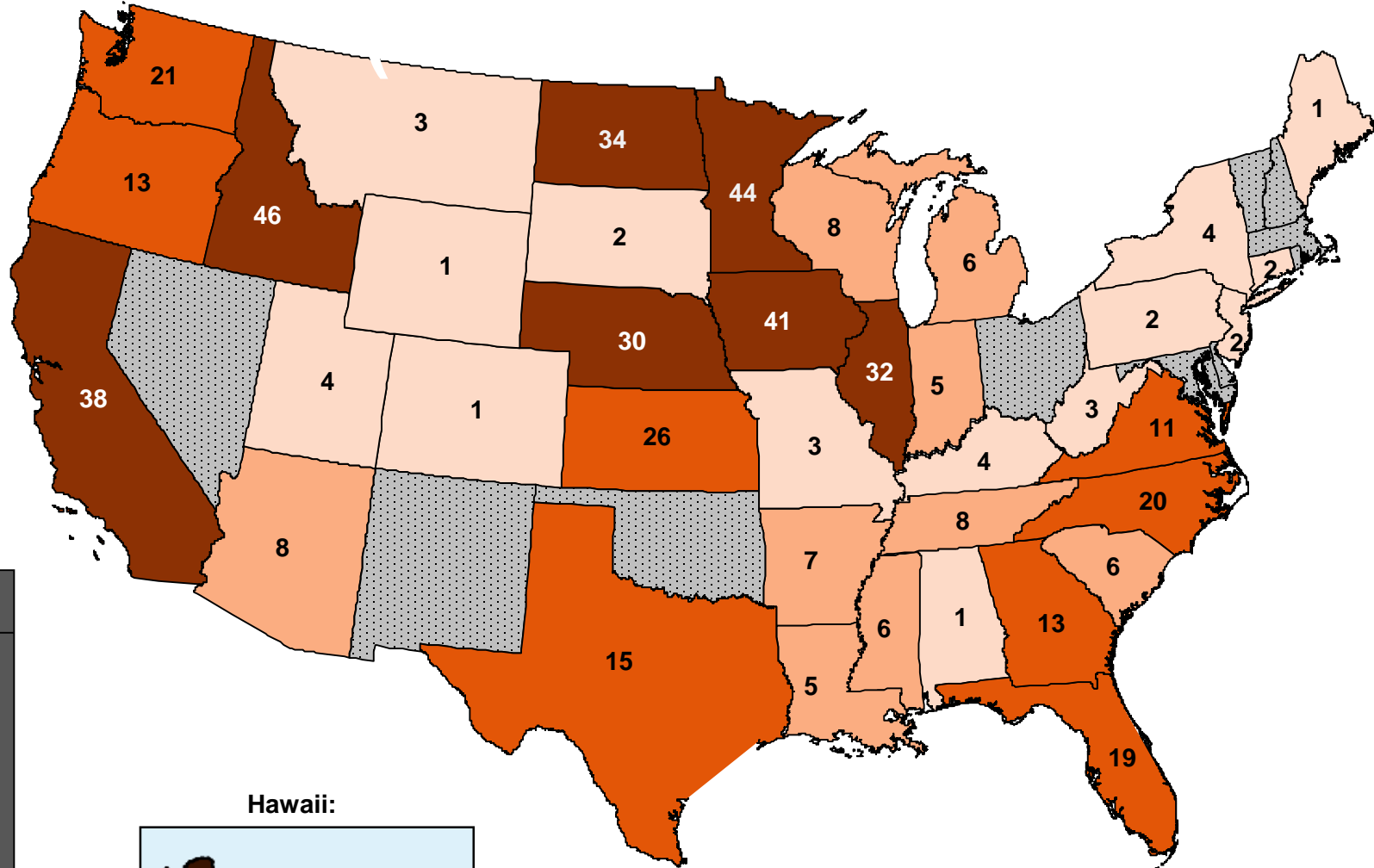
- **Extensions Project**
 - Leverage experience to increase efficiency
 - Expedited review of organisms similar to previously reviewed organisms
- **GE Wheat authorizations to permit**
- **Coordinated Framework 2.0**

Petitions

- FY15-8 approved
- FY16-6 approved
- 2 Remain-(EIS in both cases)
 - FT Eucalyptus
 - HT Creeping Bentgrass



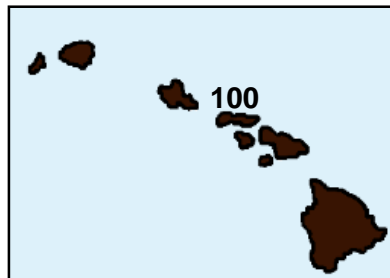
Inspections



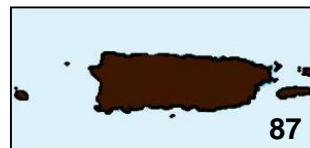
Inspections



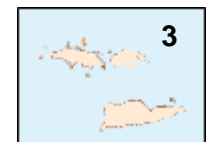
Hawaii:



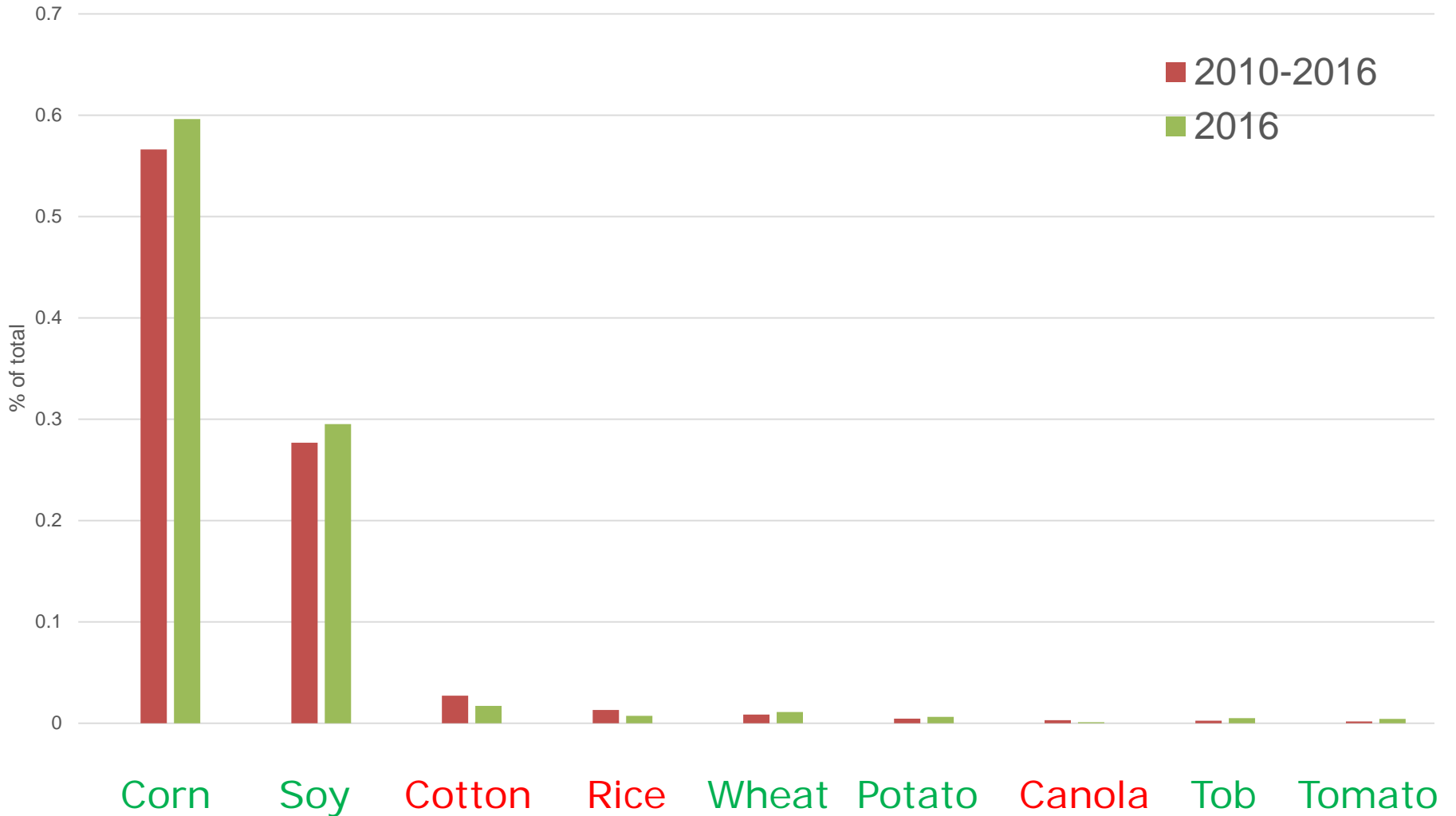
Puerto Rico:



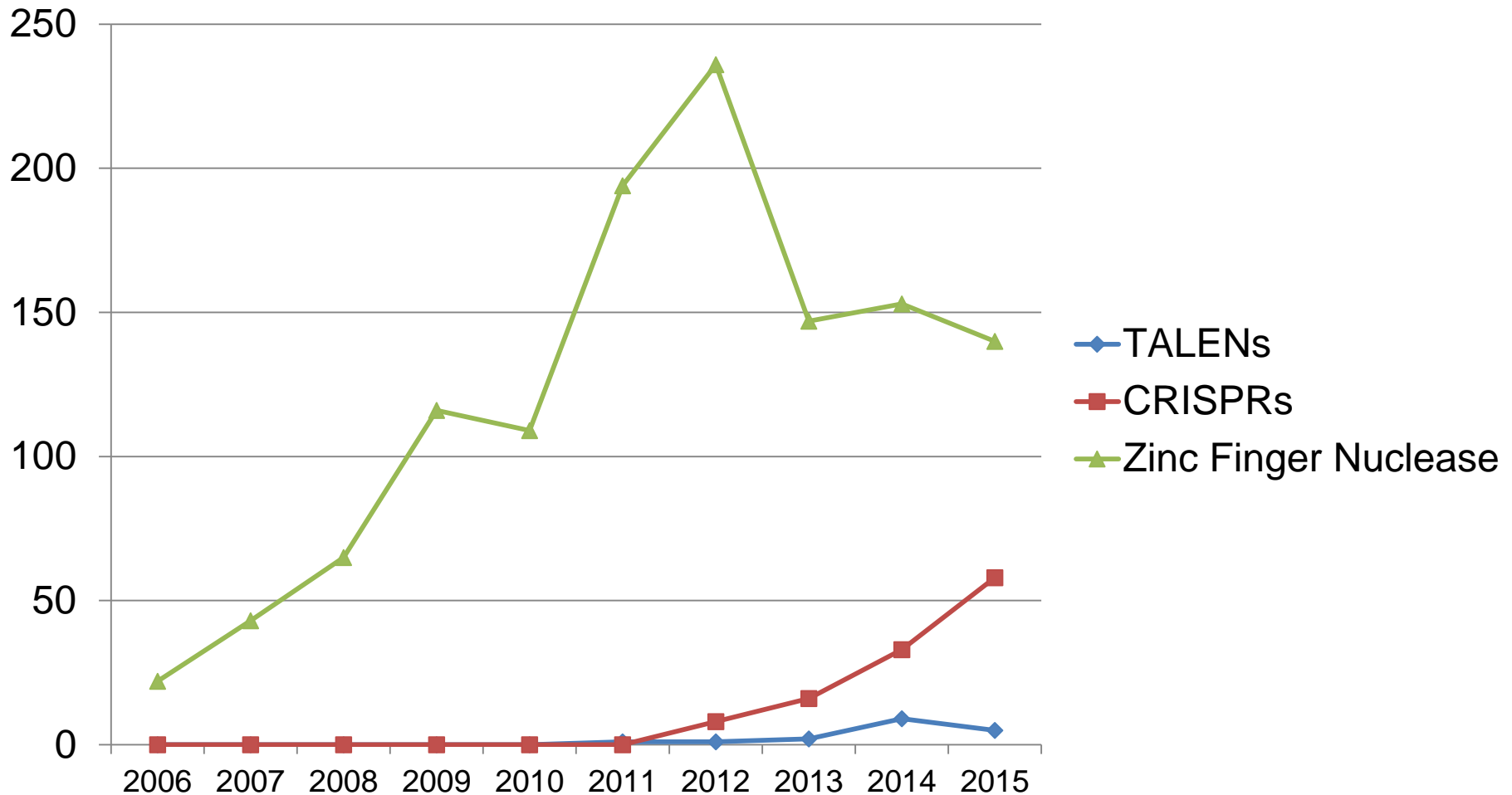
US Virgin Islands:



Trends in Authorizations



Number of Authorizations for Organisms Produced with Gene Editing Technologies



7 CFR part 340

Revised Regulations

USDA's "Topline Messaging" (1 of 2)

- USDA's biotech regulations have protected public health, welfare, safety, and our environment while protecting economic growth, innovation, competitiveness
- Science is changing rapidly
- Regulations are from 1987 (a few tweaks in 29 years)

7 CFR part 340

Revised Regulations

USDA's "Topline Messaging"(2 of 2)

- Plant Protection Act of 2000
- Focus on risk
- Move from "Regulate first/analyze later" to...
- Regulatory Relief

Need for Change

- Regulatory Experience
- Plant Protection Act of 2000
- 2005 and 2015 OIG audits
- 2008 Farm Bill
- Focus on GE organisms that pose a risk to Plant Health
- Analyze First, Regulate as Appropriate

NOI (Notice of Intent) to Conduct an EIS (Environmental Impact Statement):

CURRENT PLAN: Three Alternatives

- No Action
- Current Thinking
- Regulate all GE organisms

New Regulations

This is our CURRENT THINKING

- From “Regulate First/analyze later” to “Analyze first/regulate when risk can be documented ”
- Broader Range must come in for review
 - Technically regulation, but...
- Require further oversight ONLY w/documented risk
- Regulation will be Risk-based

Key Changes

- New Scope
 - Modify Plant Pest trigger → Review trigger
 - Drop vector as trigger
 - Add Noxious weed review trigger
 - Provide exemptions from regulation
- Add Regulatory status evaluations

Key Changes

- New definition of Genetic engineering (broader)
- Eliminate notifications, courtesy permits, and current version of petitions

Revising the Coordinated Framework (CF)

- White House Memo – July 2, 2015
 - to heads of FDA, EPA and USDA.
 - Biotechnology Working Group was established.
- Two components of the one-year mission:
 - Update the CF to clarify current roles and responsibilities (Neil Hoffman).
 - Develop a long term to ensure that the Federal regulatory system is equipped to assess the risks associated with future products (Sid Abel).

Revising the Coordinated Framework (CF)

- Requirement for Independent Assessment
 - A horizon scanning study will be conducted by the National Research Council.
- Public Meetings
 - Oct 30, 2015 – hosted by FDA in White Oak, MD
 - Mar 9, 2016 – hosted by EPA in Dallas, TX
 - Mar 30, 2016 – hosted by USDA in Davis, CA.

For More Information

USDA-APHIS-BRS:

http://www.aphis.usda.gov/biotechnology/brs_main.shtml

QUESTIONS ?