



USDA-APHIS

Our Role in the Regulation of Products of Biotechnology

John Turner, Ph. D.

September 19, 2016

Experience Regulating Genetically Engineered Plants

- 1987 – APHIS regulations for genetically engineered organisms
- USDA APHIS has been regulating GE plants to ensure safety to plant health for nearly 30 years
- Over 100,000 field sites authorized
- Nonregulated status granted to 120 petitions



Our Regulatory Framework for Protecting Plant Health: Overview

Law: Plant Protection Act

Protection Goal: To protect plants and plant products from plant pests.

Regulation: 7 CFR 340

<https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology>

- Organisms are subject to our regulations if:
 - The organism has been altered or produced through genetic engineering (recombinant DNA techniques),

and

 - The organism is produced using plant pests (i.e. donor, recipient, or vector is a plant pest) *or*
 - There is otherwise a reason to believe that the organism is a plant pest.

- Not all organisms produced using modern biotechnology techniques are regulated.

Regulated Activities

- If a GE organism is regulated, a Permit or Notification is required for the following activities:

- Importation
- Interstate movement
- Field test (confined release)



Confined Field Trials

- Field testing focuses primarily on confinement; a full data package on the GE trait is not needed.
- Risk assessment relies on familiarity with the plant, the trait, and the environment.
- Characteristics of the plant are often key:
 - Is it outcrossing or self-pollinating?
 - Is it weedy or invasive?
 - Are there wild relatives?
 - Can the plant or offspring persist after the test is over?
 - Would the trait be expected to change the plants weediness, invasiveness, or reproductive biology?



Petition Process for nonregulated Status

- After safety has been established through field testing and other research activities, a developer may petition APHIS to grant “nonregulated status”
 - No longer a regulated article
 - Free to be moved and planted without permits or further APHIS oversight.

Petition Process for nonregulated Status

APHIS BRS conducts two evaluations:

- Plant Pest Risk Assessment to determine if the GE organism poses a risk as a plant pest (Plant Protection Act)
- Environmental Assessment or Environmental Impact Statement to broader evaluate environmental impacts of APHIS-BRS decision (National Environmental Policy Act; NEPA)

Petition Evaluation

- Comprehensive scientific review – Team of scientists
- Crop biology and taxonomy
- Any genotypic differences
- Any phenotypic differences
- Field test reports for all releases conducted in the U.S.
- Relevant experimental data, publications and other data upon which to base a determination

Petition Process for nonregulated Status

- **Components of a Plant Pest Risk Assessment:**
 - Create pest or disease problems for agriculture.
 - Become a weed.
 - Increase the weediness of sexually compatible plants.
 - Harm non-target organisms (beneficial, endangered).
 - Affect agricultural practices in a way which could create disease and pest problems.
 - Transmit the genes to organisms with which it does not normally interbreed.

GE plants with Nonregulated Status

- APHIS-BRS has made determinations of nonregulated status in response to 120 petitions, representing 17 plant species
- The determination of nonregulated status extends to the GE plant and its offspring
- Actual commercialization of GE plants with nonregulated status is determined by market demand, not the APHIS decision.

GE Plants with ¹Nonregulated Status under 7 CFR part 340

Alfalfa – HT, PQ

Canola – HT, AP, PQ

Corn – HT, IR, AP, PQ

Cotton – HT, IR

Papaya – VR

Soybean – HT, IR, AP, PQ

Sugar Beet – HT

Rose – PQ

Squash – VR

Tobacco – PQ

Apple – PQ

Chicory – AP

Flax – AP

Plum – VR

Potato – IR, VR, PQ, FR

Rice – HT

Tomato – PQ



HT – Herbicide Tolerant

IR – Insect Resistant

VR – Virus Resistant

AP – Agronomic Properties

PQ – Product Quality

FR – Fungal Resistant

¹Nonregulated status does not necessarily mean that the plant is in commercial production

Extensions of Non-regulated Status

- APHIS-BRS has a process allowing for a reduced data package and an expedited review for the deregulation of GE plants which are similar to other GE plants already de-regulated.
- We call these requests process “extensions” because we are extending non-regulated status from the previously de-regulated organism (called the antecedent) to the new organism.
- Extensions allow us to leverage previous work and experience without compromising safety.
- Recent extensions have been completed in 5-7 months.

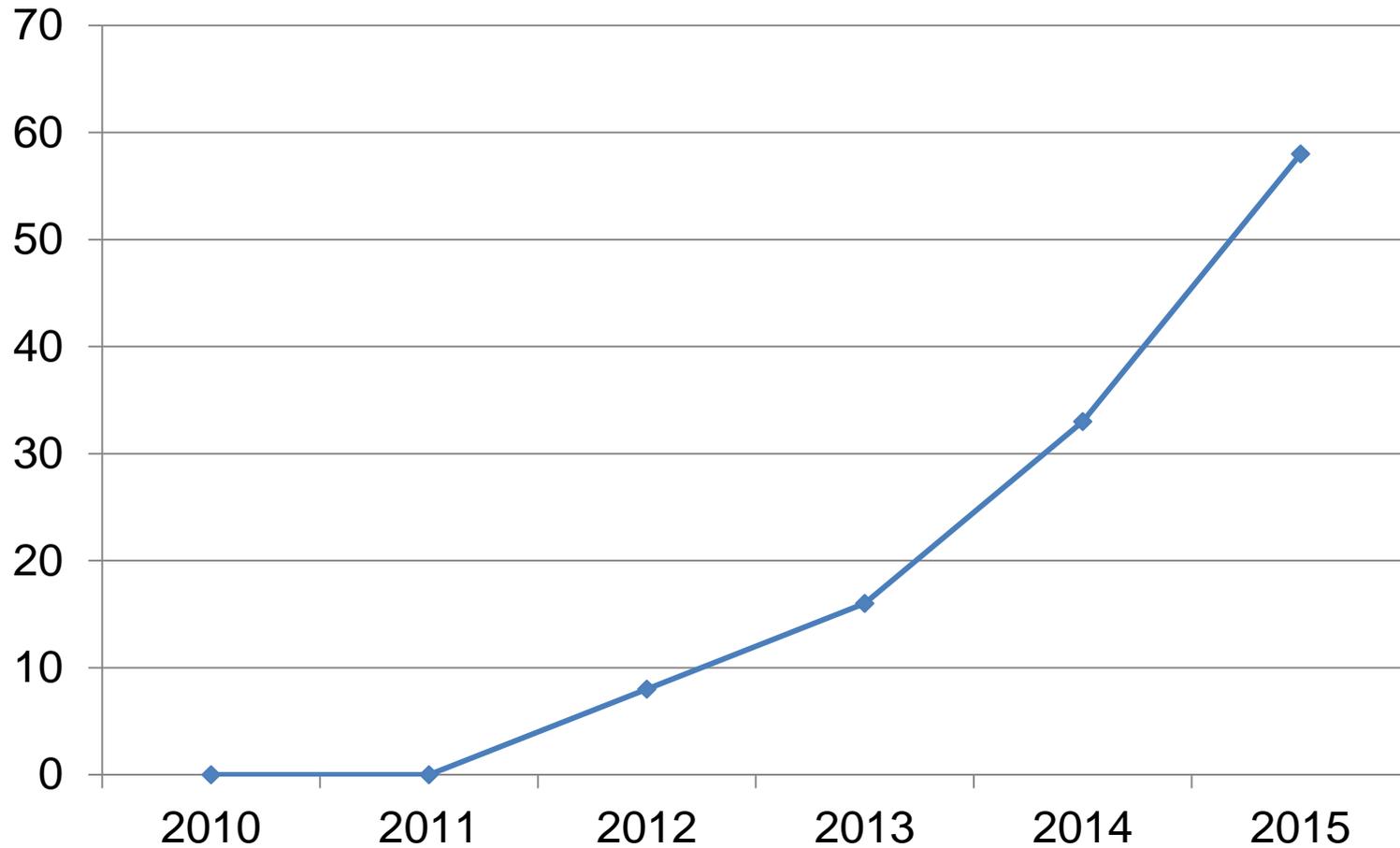
The Am I Regulated (AIR) Process

- A developer who is unsure if their GE product meets the definition of a regulated article is welcome to send a letter of inquiry to USDA-APHIS-BRS.
- Instructions for submitting “Am I Regulated?” inquiries can be found on the [BRS website](#) (hyperlink).
- After BRS responds to the inquiry, both the inquiry and the response are posted on the [BRS website](#) (hyperlink)
- Since July 2011, BRS has responded to 41 “Am I Regulated?” inquiries.

So what about new genome editing technologies?



APHIS authorizations of plants altered with CRISPR-based genome editing tools.



APHIS has determined that some organisms altered using genome editing techniques are outside the scope of our regulations.

Examples:

Waxy Corn



CRISPR Cas9 -
deletion in waxy
(*Wx1*) gene

Anti-browning
Mushroom



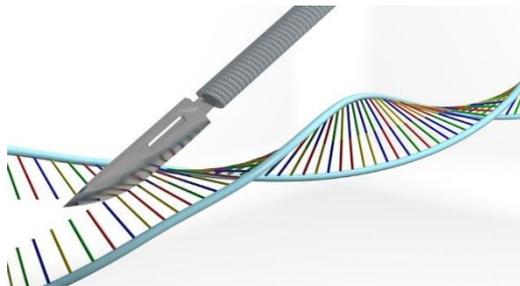
CRISPR Cas9 -
deletion in
polyphenyl oxidase
(*ppo*) gene

Soybean with
higher oleic acid



TALEN - deletion
to fatty acid
desaturase 2
(*fad2*) gene

Genome Editing Tools



Zinc Finger Nucleases

CRISPR Cas9

TALEN

In cases to date where APHIS has determined that genome-edited plants were outside the scope of our regulations, the following have been true:

- The only change to the genome was a deletion
- If any DNA was inserted into the genome, it has been removed through breeding (segregation)

Developers with questions about these or other types of modifications (e.g. edits, gene insertions) using these technologies should contact the agency and may wish to use the “Am-I-Regulated” process.

For more information:

- General:

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

- Petitions – Guidance for new users:



[https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/ct new users petitions](https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/ct_new_users_petitions)

- Extensions:

https://www.aphis.usda.gov/brs/aphisdocs/guidance_ext_nonreg.pdf



United States Department of Agriculture

A close-up photograph of several woven baskets filled with agricultural products. In the foreground, a basket is filled with yellow corn cobs. Behind it, another basket contains red beans. To the right, a basket holds a mix of yellow, red, and black beans. The baskets are made of light-colored, woven material, and the background is dark, making the vibrant colors of the produce stand out.

Thank You!