



United States Department of Agriculture

# **Myths and Truths of Plant Regulation Processes**

## ***SCRA Workshop***

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# Plant Regulation Processes Involve Different Agencies

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## Gene-edited CRISPR mushroom escapes US regulation

Emily Waltz

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**A fungus engineered with the CRISPR-Cas9 technique can be cultivated and sold without further oversight.**



The common white button mushroom (*Agaricus bisporus*) has been modified to resist browning.  
 Credit: Jose A. Bernat Bacete/Getty Images

# Outline

- Who regulates what?
- Current regulatory jargon
- Misconceptions about current regulatory processes and clarification of procedures



# Who Regulates What?

New GE Trait/Organism	Regulatory Review By	Reviewed to Ensure
Insect resistance in a food crop ( <i>e.g.</i> , Bt corn)	APHIS	Safety for agriculture and the environment
and	EPA (plant/herbicide)	Safety for the environment and food and feed safety of PIPs
Herbicide resistance in a food crop ( <i>e.g.</i> , glyphosate-resistant corn)	FDA	Safety for food and feed use
Modified oil content in a food crop ( <i>e.g.</i> , oleic acid in soybean seed)	APHIS	Safety for agriculture and the environment
	FDA	Safety for food and feed use
Herbicide resistance in an ornamental crop ( <i>e.g.</i> , glyphosate-resistant marigold)	APHIS	Safety for agriculture and the environment
	EPA (herbicide)	Safe use of companion herbicide
Modified flower color in an ornamental crop ( <i>e.g.</i> , blue carnation)	APHIS	Safety for agriculture and the environment



# Regulatory Jargon

## Legacy regulations

**Am I Regulated (AIR) letters of inquiry:** Submitted by developers seeking verification that their organism developed using genetic engineering (modified organism) is considered **not regulated** pursuant to 7 CFR part 340 based on absence of inserted sequences and/or no use of a plant pest

# Regulatory Jargon

## Revised regulations

**CR (Confirmation Request):** Submitted by developers seeking confirmation that their modified organism is considered not regulated based on:

(A) 7 CFR § 340.1(b) (1-3) **exemption from part 340** because plants could otherwise have been developed through conventional breeding techniques

(B) 7 CFR § 340.1(c ) exemption is based on previously deregulated events through petition process or RSR

**RSR (Regulatory Status Review):** If a plant does not qualify for an exemption, then it can be reviewed under RSR, based on the characteristics of the plant rather than on the use of a plant pest in its development. If a plausible pathway to increased plant pest risk is not identified, the plant is **not subject to part 340**

# Clarification of Regulatory Processes

## Myth

A product which would have not been regulated under the legacy regulations is exempt under the revised regulation

## Truth – it depends

- (A) A specific plant which APHIS affirmed was not subject to legacy regulations for a specific developer, is exempt from the revised regulations.
- (B) If another line of the same species is recreated, it may or may not be exempt under the revised regulations.



# Clarification of Regulatory Processes

## Myth

A single modification to **more than two copies** of an allele (in a polyploid species) is eligible for exemption under the revised regulations

## Truth

A single modification to **two copies** of an allele on a pair of homologous chromosomes in any plant species is eligible for exemption under the revised regulations under 340.1(b)



# Clarification of Regulatory Processes

## Myth

A plant with the same trait and MOA as **another plant species** which was determined to be not regulated is exempt

## Truth

A plant-trait-MOA combination which is the same as another plant of **the same species** which was determined to be not regulated is exempt under 340.1(c)

# Clarification of Regulatory Processes

## Myth

A comprehensive data package needs to be submitted for RSR, similar to petitions, including agronomic data.

## Truth

A minimal data package is needed for an initial RSR: description of the comparator plant, genotype of the modified plant and a detailed description of the new trait(s) of the modified plant



# Clarification of Regulatory Processes

Please email [RSRrequests@usda.gov](mailto:RSRrequests@usda.gov)  
with questions on submissions

Guidance for applicants will be posted  
on the APHIS website soon

# Additional Resources

- [APHIS-BRS Homepage](#)
- [Revised Rule \(7 CFR part 340\)](#)
- [Unified Website for Biotechnology Regulation](#)
- [2017 Update of the Coordinated Framework](#)



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**Thank you**