



United States Department of Agriculture

# Golden Rice

## Deregulatory Pathway

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**USDA-APHIS-BRS**

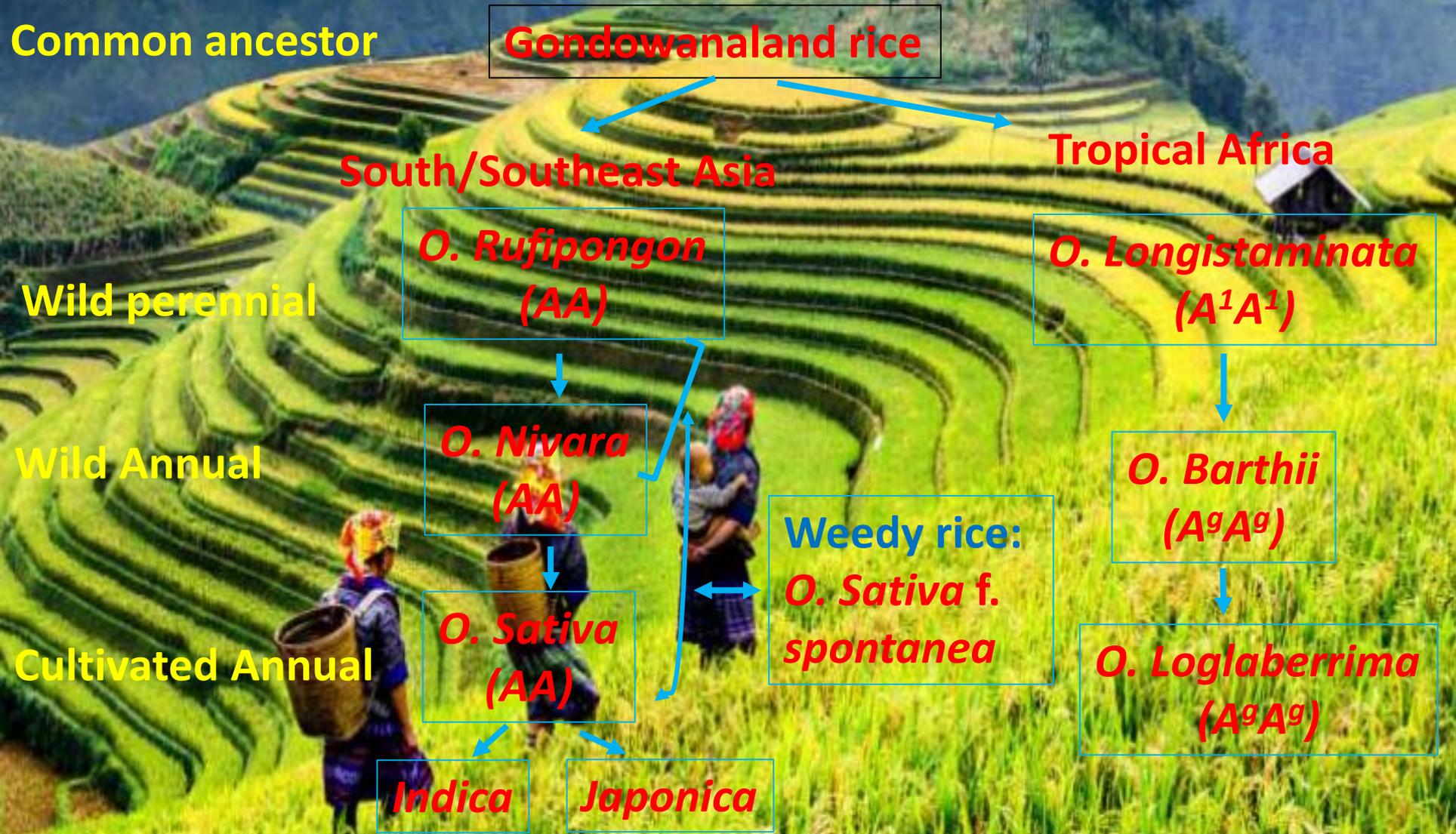
**SCRA Workshop, October 4, 2018**



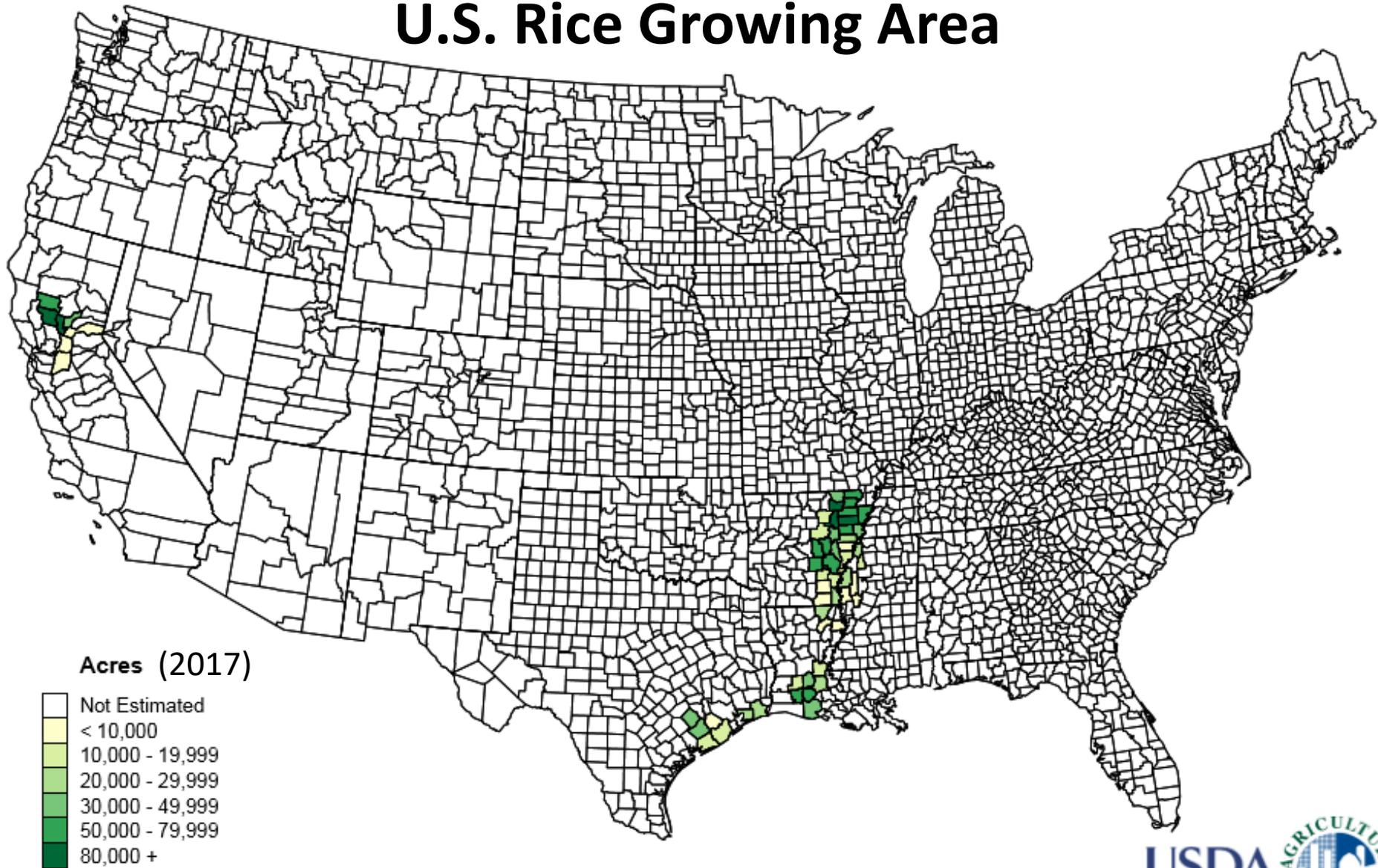
# Outline

- **Origin and Geographic Distribution of Rice**
- **Background Information about Golden Rice**
- **Regulation of GE rice under 7 CFR 340**
- **Petition requirements for a deregulation under 7 CFR 340**

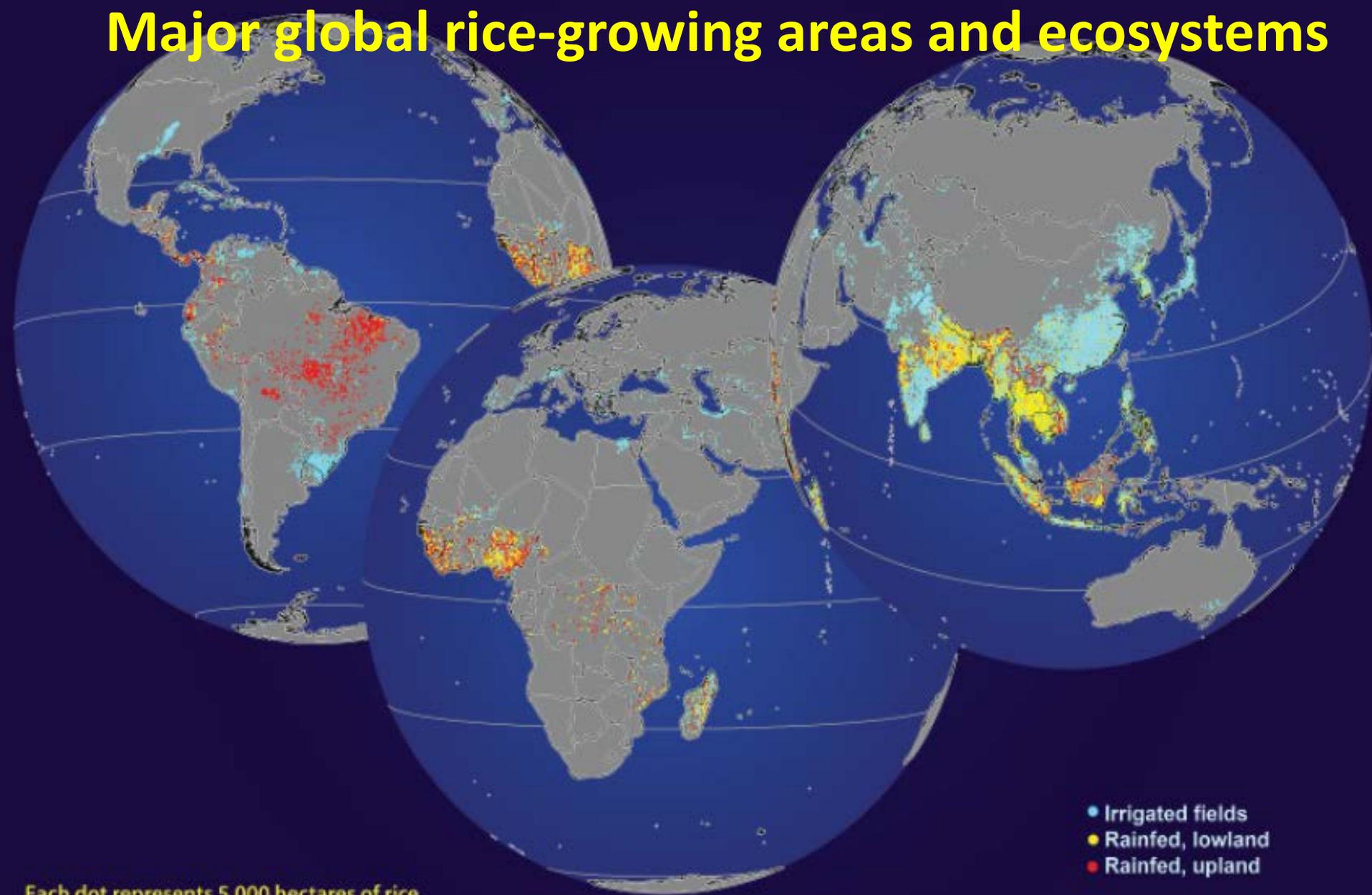
# Origins of Cultivated Rice



# U.S. Rice Growing Area



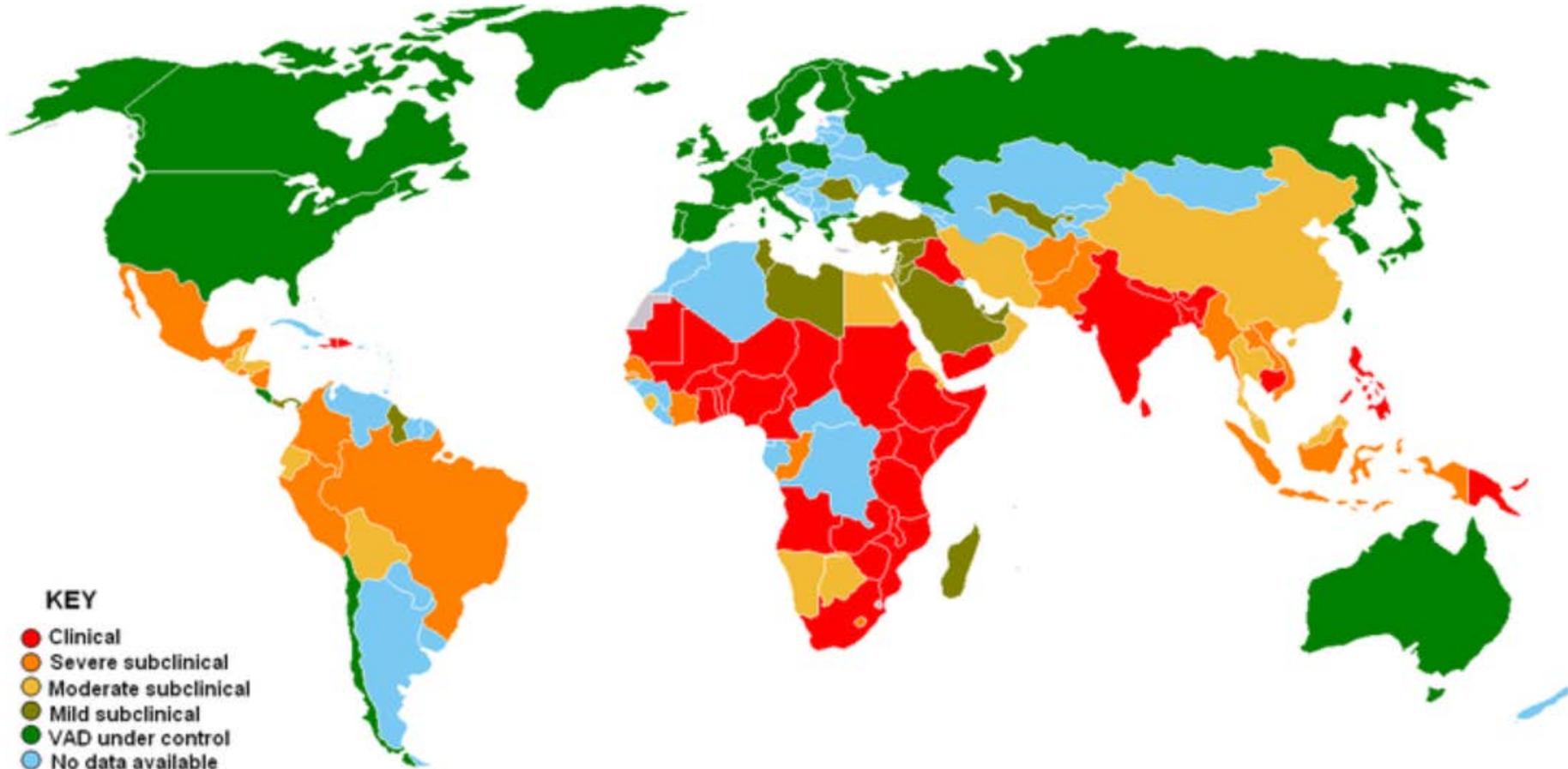
# Major global rice-growing areas and ecosystems



Each dot represents 5,000 hectares of rice

- Irrigated fields
- Rainfed, lowland
- Rainfed, upland

# Worldwide prevalence of vitamin A deficiency



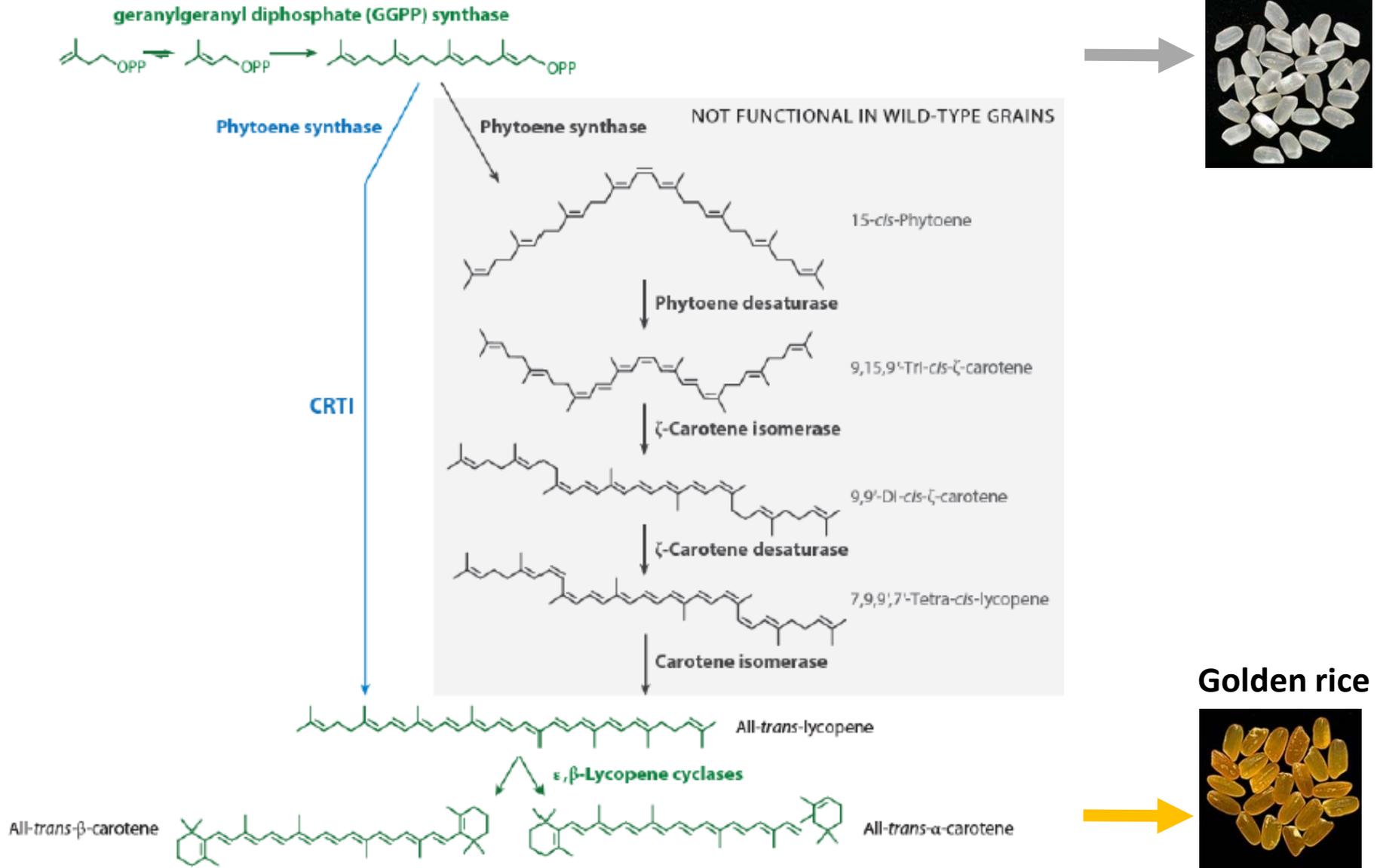
**Vitamin A deficiency is a global health problem, primarily in developing countries in Africa and South-East Asia**

*Data collected by WHO between 1995 and 2005 in populations at risk of vitamin A deficiency.*

## Source of vitamin A

- Vitamin A from animal products
- Provitamin A from Certain fruits, vegetables and grains
  - Provitamin A is converted in our bodies into vitamin A
  - Rice plants produce provitamin A in the leaf but **NOT** in the polished white rice grain.
- Population groups with a rice-based diet are therefore at risk of vitamin A deficiency

# Golden Rice was Genetically engineered (GE) to Produce Provititamin A in Grains



# Regulations of GE products by USDA-BRS

**Plant Protection Act; National Environmental Policy Act; Threatened and Endangered Species Act**

**Regulations:**

**7 CFR 340**

**“Regulated article” (7 CFR part 340)**

- **The organism has been altered or produced through genetic engineering (recombinant DNA techniques), and**
- **The organism poses a plant pest risk**
  - **Produced using plant pest sequences (the donor, recipient or vector), or**
  - **There is a reason to believe that it is a plant pest**

# Golden Rice is a Regulated Article

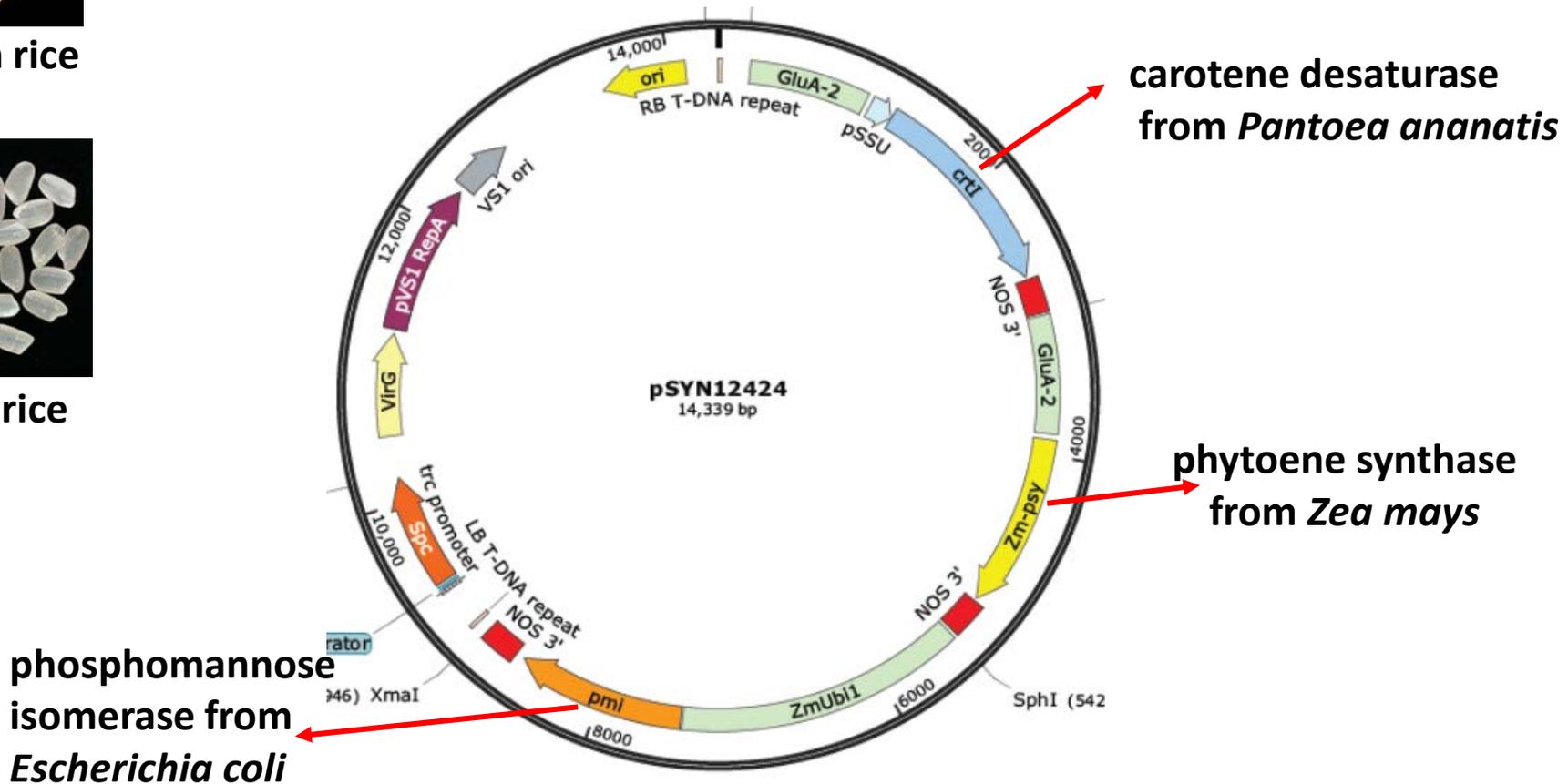


Golden rice



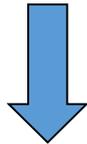
White rice

- ❖ Golden rice was developed through genetic engineering
- ❖ The genes were delivered by *Agrobacterium tumefaciens*, a plant pest
- ❖ Some of the gene donors are also plant pest: *A. tumefaciens*



# Regulation of Genetically Engineered Plants

**Laboratory and Greenhouse**



**Environmental Release for field tests**

**Importation & Interstate Movement**

**Not Regulated by  
USDA -APHIS  
(Follow NIH Guidelines)**

**Regulated by  
USDA -APHIS  
(Permit & Notification)**

# Petition for determination of non-regulated status

**Anyone can petition APHIS to seek a determine “nonregulated” status. If granted, then regulated article is no longer subject to APHIS regulations.**

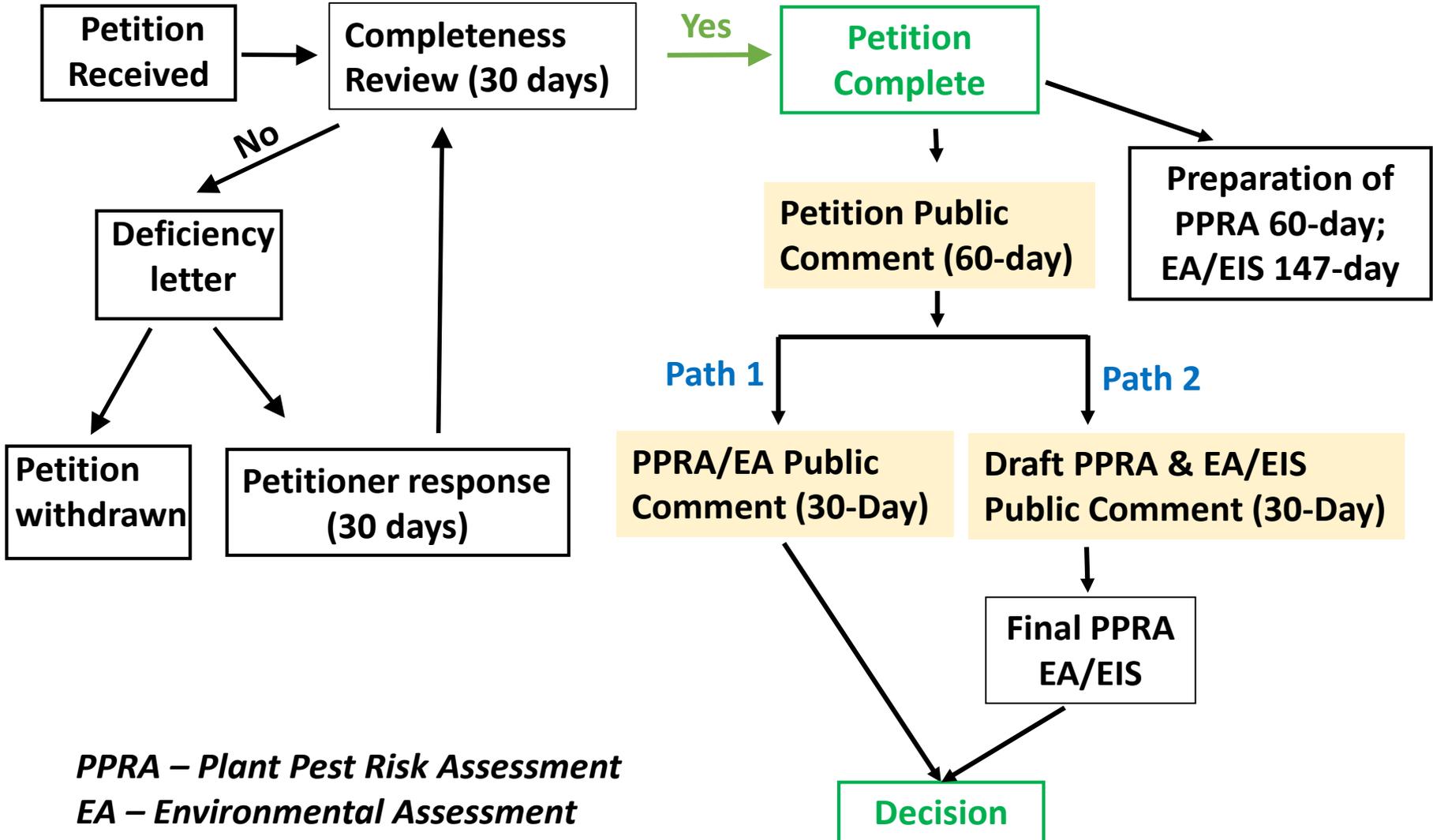
- ❖ Petition information should support conclusion that the GE organism is not a plant pest**
- ❖ APHIS bases its decisions, actions, and recommendations on the best science available.**
- ❖ Public reviews petition and APHIS evaluates petition and public review comments before final APHIS determination**

# Petition Procedure for Nonregulated Status

Using the best science available, APHIS does two types of evaluations:

1. **Regulatory Authority: Plant pest risk assessment to determine if the GE organism is a plant pest or poses plant pest risk (Plant Protection Act; PPA)**
2. **Obligation: Environmental Assessment to evaluate the potential environmental impacts arising from the APHIS decision (National Environmental Policy Act; NEPA)**

# Petition Process



*PPRA – Plant Pest Risk Assessment  
 EA – Environmental Assessment  
 EIS – Environmental Impact Statement*

# Petition Planning

- **Pre-consultations with BRS are encouraged**
  - **We encourage applicants to come in early and often to discuss data requirements and field testing**
- **Get expert assistance when needed**
- **Understand the petition submission process**
- **Field trials-permit or notification/multilocation and multiyear field trials**
- **Confinement protocols**
- **Submit a complete and well-written document**



# **Petition: Data and Information Requirements (7 CFR 340.6(c))**

- **Description of the rice biology and taxonomy**
- **Relevant experimental data and publications**
- **Genotype difference between the GE rice and the nonmodified recipient rice cultivar.**
- **Phenotype differences.**
- **Field test reports for all trials conducted under permits or notifications.**

# **Petition: Data and Information Requirements**

## **- *Broad categories***

- **Crop Biology (Taxonomy, genetics, use, growing region, pollination, weediness, invasiveness)**
- **Genotype and phenotype difference between the GE rice and the nonmodified recipient rice cultivar**
- **Potential plant pest and disease impacts**
- **Potential impacts on non-target organisms beneficial to agriculture**
- **Potential for enhanced weediness**
- **Potential for enhanced weediness of sexually compatible relatives**
- **Potential changes to agricultural or cultivation practices**
- **Potential impacts from transfer of genetic material to organisms with which the GE organism cannot interbreed**

# Petition: Data and Information Requirements

*- A detailed description of the phenotype of the regulated article to assess plant pest risk characteristics*

- **Rationale: Examine the known and potential differences between the Golden rice and unmodified parental line(s) to assess whether the Golden rice are likely to pose a greater plant pest risk than the unmodified parental line(s)**
- **Types of comparative data generally looked at to assess plant pest characteristics:**
  - **whether the introduced plant pest sequences (introduced genes or sequences) cause or promote disease, damage or injury to plants (plant pest risk);**
  - **whether the introduced genes are stably integrated (stable phenotype/not an Infectious agent);**



# Petition: Data and Information Requirements

***- A detailed description of the phenotype of the regulated article to assess plant pest risk characteristics (contd.)***

- whether the introduced genes produce any new enzymes or changes to plant metabolism (leading to plant pest risk);**
- whether the introduced genes make Golden rice plant a weed (pest plant);**
- whether gene flow from Golden rice to any sexually compatible species impart weediness to those taxa (pest plant);**
- whether Golden rice impacts agricultural and cultivation practices (effects on disease and pest susceptibilities);**
- whether Golden rice affect nontarget organisms (effects on beneficial organisms);**
- whether Golden rice has any indirect plant pest effects on other agricultural products; and (plant pest risk)**
- whether Golden rice has the potential to transfer introduced genes to organisms with which it cannot interbreed (Horizontal gene transfer).**



# National Environmental Policy Act (NEPA) Compliance

## Rationale

- As a Federal agency subject to compliance with NEPA APHIS prepares an environmental assessment (EA) to consider the potential environmental effects of granting nonregulated status to the proposed GE rice consistent with NEPA regulations and the USDA and APHIS NEPA implementing regulations and procedures.
- The EA is going to be prepared in order to specifically evaluate the effects on the quality of the human environment that may result from the deregulation of Golden rice.

## The Scope of Environmental Assessment:

- **Agricultural Production**  
Areas of rice production and agronomic Practices
- **Physical Environment**  
Soil, water and air quality
- **Biological Resources**  
Animal & Plant Communities; Soil Microorganisms; Biodiversity; Gene flow and weediness
- **Human Health**  
Public Health; Worker Health and Safety
- **Animal Health**  
Animal Feed; Livestock Health
- **Socioeconomics**  
Domestic Economic Environment; Trade Economic Environment



# Petitions for Determination of Nonregulated Status

Petition Number	Docket Number	Applicant	Crop	Phenotype/Event	Status	Documents
<a href="#">+</a> 17-321-01p	APHIS-2018-0014	BASF	Canola	Altered Oil Profile and Resistance to an Imidazolinone	Pending	<a href="#">View Documents</a>
<a href="#">+</a> 17-236-01p	APHIS-2017-0096	Nuseed Americas	Canola	Altered Oil Profile	Deregulated	<a href="#">View Documents</a>
<a href="#">+</a> 17-292-01p	APHIS-2017-0097	Texas A&M	Cotton	Low Gossypol	Pending	<a href="#">View Documents</a>
<a href="#">+</a> 17-223-01p	APHIS-2017-0075	Verdeca	Soybean	High Yield	Pending	<a href="#">View Documents</a>
<a href="#">+</a> 17-138-01p	APHIS-2017-0073	Bayer	Cotton	Resistance to Glyphosate and Isoxaflutole	Deregulated	<a href="#">View Documents</a>
<a href="#">+</a> 16-235-01p (Extension of 98-278-01p)	APHIS-2017-0015	Bayer	Canola	Male Sterile, Glufosinate-Ammonium Resistant/MS11	Deregulated	<a href="#">View Documents</a>

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



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## Additional Information

### Permits, Notifications, & Petitions

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



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**Thank You**

**Questions ?**