



Petition for the Determination of Nonregulated  
Status For Sclerotinia Blight Resistant (aka  
Blight Blocker) Transgenic Peanut Events N70,  
P39, and W171

Applicants: E. A. Grabau & P.M. Phipps, Virginia Tech, VA

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**USDA/APHIS/BRS**  
**SCRA Workshop, Dec 6-8, 2011**

# Justification for Deregulation

## *Statement of Grounds*

A person must present a full statement explaining the factual grounds why the organism should not be regulated under 7 CFR part 340. The petitioner shall include,

- copies of scientific literature,
- copies of unpublished studies, when available, and
- data from tests performed upon which to base a determination.

## *Data Collection*

- APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations.
- A person may follow an APHIS guideline or follow different procedures, practices, or protocols.
- When different procedures, practices, or protocols are followed, a person may, **but is not required to**, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

# Nonregulated/Not a Regulated Article

## Regulated Article

Any organism,

- which has been altered or produced through **genetic engineering**, and
- if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in §340.2, and meets the definition of **plant pest**...



United States Department of Agriculture  
Animal and Plant Health Inspection Service



Biotechnology  
Regulatory  
Services

# Plant Pest

**Section 403 (14) of the Plant Protection Act (7USC Sec 7702(14)) defines plant pest as:**

**Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:**

- a protozoan
- a nonhuman animal
- a parasitic plant
- a bacterium
- a fungus
- a virus or viroid
- an infectious agent or other pathogen
- any article similar to or allied with any of the articles specified in the preceding subparagraphs

# BB Peanut is a Regulated Article

because,

- It's a product of **genetic engineering** (biolistic transformation to introduce the transgene Oxalate oxidase or Oxox), and
- the donor organisms (Cauliflower mosaic virus & Tobacco etch virus) belong to taxa designated in §340.2, and meet the definition of **plant pest**

# Timeline

- 2003 (T1 - T2 generations): Greenhouse
- May 2004- May 2009 (T3 - T7): Field tests
- January-September 2009: Applicant met twice with the ERAP staff and presented the preliminary data (pre-submission consultation)
- March 2010: Petition for deregulation submitted to USDA/APHIS/BRS
- April-July 2010: A team of BRS staff reviewed the petition for the technical completeness
- August, 2010: A draft copy of BRS' review comments shared with the applicant
- October, 2010: A formal 'Letter of Technical Completeness' was provided to the applicant





# Field Tests

- **Two types of APHIS/BRS applications-Notifications and Permits**
- **BB peanut lines were field tested using notification applications between 2004-2009.**
- **Field tests were conducted to generate data for**
  - **expression levels of the transgene (Oxox),**
  - **evaluation of resistance to Sclerotinia blight,**
  - **desirable agronomic traits, and**
  - **human and environmental safety.**



# Pre-submission Discussion

- A brief presentation by the applicant
  - molecular genetic data, crop composition, agronomic data
- BRS input
  - gene flow experiment, nontarget impacts, change in agricultural practices, etc.

# Petition Review

- Review team— three biotechnologists and a NEPA specialist
- A two-part review process
  - Whether BB peanut lines likely to pose a plant pest risk (7 CFR 340 regulatory requirement)
  - Whether BB peanut cultivation has (a) any significant impacts, individually or collectively, on the quality of the human environment (NEPA 7 CFR 372), and any effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitats (ESA 16 U.S.C. §1531 et seq.) (Federal Action)

# Plant Pest Risk

Rationale: Examine the known and potential differences between BB peanut lines and unmodified parental line(s) to test whether the BB peanut lines are likely/unlikely to pose a greater plant pest risk than the unmodified recipient organism from which they were derived.

Types of comparative data (BB and Control) 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/Infectious agent**);
- whether the introduced genes produce any new enzymes or changes to plant metabolism (**leading to plant pest risk**);
- whether the introduced genes make BB plant a weed (**pest plant**);
- whether gene flow from BB peanut lines to any sexually compatible species impart weediness to those taxa (**pest plant**);

## Plant Pest Risk (contd.)

- whether BB peanut lines impact agricultural and cultivation practices (effects on disease and pest susceptibilities);
- whether BB peanut lines affect nontarget organisms (effects on beneficial organisms);
- whether BB peanut lines have any indirect plant pest effects on other agricultural products; and (plant pest risk)
- whether BB peanut lines have the potential to transfer introduced genes to organisms with which it cannot interbreed (Horizontal gene transfer).

# Draft Letter of Technical Completeness

(a few examples)

## ➤ Clarifications

- What are LSK and FM in Tables 17-21?
- “In 2006, our results showed zero or low outcrossing..... in the 5B row in the W59 line.” What is the W59 line?
- P 110. iii. Protein extraction. What was the standard protein against which you quantitated amount of protein?

## ➤ Suggestions

- Formatting, Guidance document, Typos, Use of acronyms

## ➤ Request for data

- P 81: Compositional analysis: The last statement does not have any supporting data in the petition.

# Letter of Technical Completeness

(a few examples)

- Please provide data separately for both lines W171 and W73.
- APHIS/BRS needs to know for which **transformation events you are seeking deregulation**, and will review data for only those lines, unless data for other lines is relevant to this petition (i.e. N99, P53, W59, etc.).
- One of the data requirements for petitions seeking deregulation is to establish the **stability of the inserted gene** in transgenic lines. What data do you have to support gene stability?
- Please provide agronomic data such as germination rate, plant height, yield, flowering time, seed dormancy, etc. All agronomic data should be analyzed and presented in comparison to the nontransgenic parental line (**to analyze weediness characteristics of the genetically engineered plant**).
- Information on volunteer monitoring results from previous field trials must be included. This provides data regarding **weediness**.
- Analysis for **effects on non-target organisms** needs to be provided. Since this is a plant incorporated protectant (PIP), and you are in discussion with EPA...If new data are required by EPA, please be prepared to provide a summary of these results to APHIS/BRS.



# NEPA Compliance—Request for Information



## Rationale

- As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) APHIS prepares an environmental assessment (EA) to consider the potential environmental effects of granting nonregulated status to the proposed peanut lines 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 Sclerotinia blight resistant peanuts.

## Request for Information

- APHIS is requesting additional information to assist in preparing the required NEPA documentation.
- The types of information requested are not specifically cited in the regulations.
- If you are unable to locate the requested information, please identify this lack of information and APHIS will attempt to secure the required information from other available sources.



# NEPA Compliance—Request for Information

(contd.)

- Present a comprehensive analysis of Sclerotinia incidence and of fungicide amelioration of the disease from Tables 8-11, including yield impacts (**Socioeconomic Impacts**)
- What is the incidence of Sclerotinia blight in other peanut growing regions? According to the petition, a 50% decline in yields due to Sclerotinia blight is noted—is this a maximal value or an average? How has acreage declined due to blight over time? Why do you not expect the introduction of Sclerotinia resistant peanut to increase current acreage? Please provide details. (**Affected Environment**)
- What is the source of the information for the decline in market prices for Virginia peanuts? Or, the reference for the effects on other businesses such as buying stations, shelling and warehouses for Virginia type peanuts? (**Socioeconomic Impacts**)



# Overall Review Comments



- **Formatting** - Address the 'issues' in a logical order.
- **Presentation** - Data analyses and presentation require more clarity.
- **New data request** – None/very little