GE Peanut with Reduced Level of Allergens

Specialty Crop Regulatory Assistance Workshop
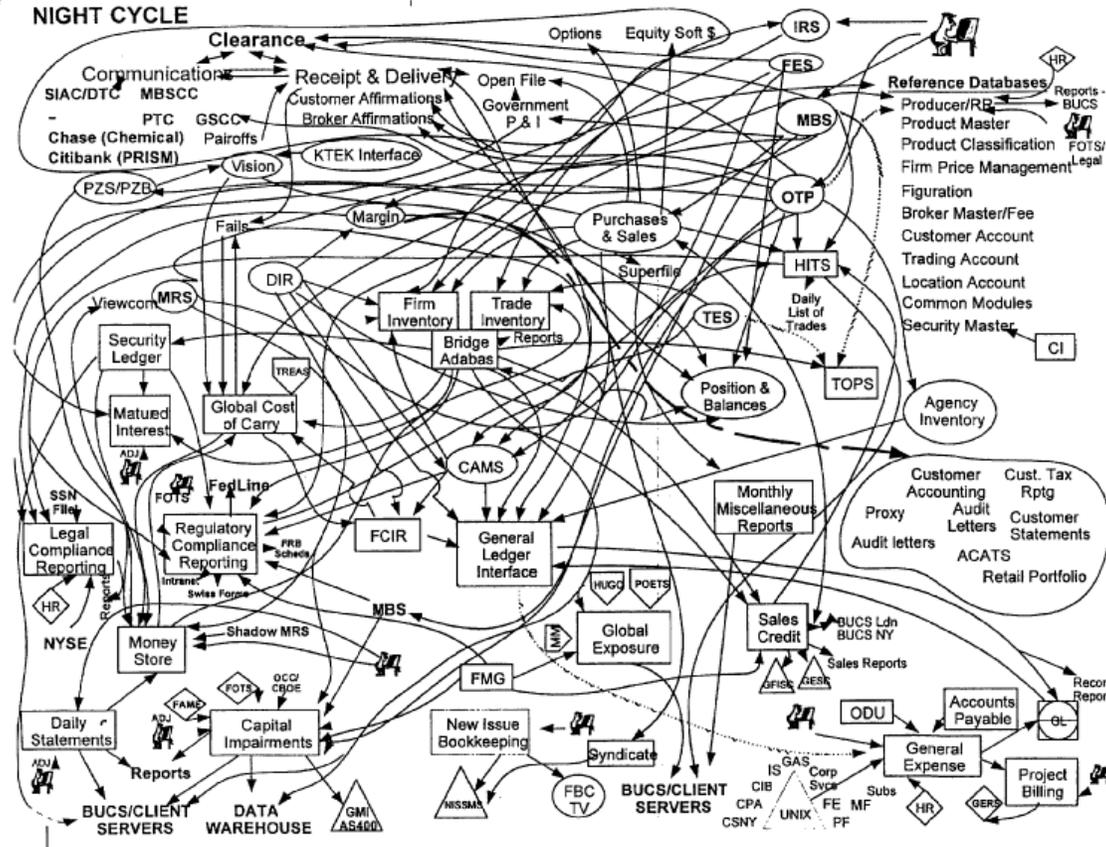## Riverdale, MD
October 3-5, 2018

Subray Hegde

United States Department of Agriculture

Regulatory Language

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…**

Low Allergen Peanut is a Regulated Article

➢ **It's a product of genetic engineering, and**

➢ **the donor organisms (*Cauliflower mosaic virus & Agrobacterium tumefaciens*) and the transformation vector (*Agrobacterium tumefaciens*) belong to taxa designated in §340.2, and meet the definition of plant pest**

Petition Data Requirement

Rationale: Examine the known and potential differences between regulated peanut lines and unmodified parental line to test whether the regulated 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 (Regulated vs 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);

Petition Data Requirement (contd.)

➢ **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 regulated plant a weed (pest plant);**

➢ **whether gene flow from regulated plant to any sexually compatible taxa impart weediness to those taxa (pest plant);**

Petition Data Requirement (contd.)

➤ **whether the regulated plant impacts agricultural and cultivation practices (effects on disease and pest susceptibilities);**

➤ **whether the regulated plant affect nontarget organisms (effects on beneficial organisms);**

➤ **whether the regulated plant has any indirect plant pest effects on other agricultural products (plant pest risk); and**

➤ **whether the regulated plant has the potential to transfer introduced genes to organisms with which it cannot interbreed (Horizontal gene transfer).**

Petition Supporting Data

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.**

➢*Field Test*

• **Regulated peanut plant was field tested between 2011-2014 under USDA authorization.**

USDA Guidance on 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.**

Pre-submission Discussion

➢ **Presentation by the applicant**

     --molecular genetic data, crop composition, agronomic data

➢ **BRS input**

     - multiplication trials, molecular data, nontarget impacts, etc.

Petition Review

➢ ***Review team***— A Team Lead (for technical completeness) and members, & a NEPA Lead

➢ ***A two-part review process***
(i) Whether the regulated plant is likely to pose a plant pest risk (7 CFR 340 regulatory requirement)

(ii) Whether the cultivation of regulated plant 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.) (Obligation due to Federal Action)

Deficiency Letter or Letter of Completeness

First Step: Plant Pest Risk Assessment

➢ **Clarifications**

> e.g. Protein extraction. What was the standard protein against which you quantitated amount of protein?

➢ **Request for Data**

> e.g. There are no data supporting the stable inheritance of the introduced gene.

NEPA Compliance

Rationale

➤ As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) USDA 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 low allergen peanuts.

NEPA Compliance

Request for Information

➢ USDA 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 USDA will attempt to secure the required information from other available sources.

Time Line

On average 13-15 months for a petition that is deemed technically complete and that does not require an Environmental Impact Statement.

United States Department of Agriculture Animal and Plant Health Inspection Service

Biotechnology Regulatory Services (BRS)

Regulations

Permits, Notifications, and Petitions

Compliance and Inspections