



# Ultra-low Gossypol Cottonseed

## Deregulatory Pathway

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# 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...

# 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

# Ultra-low Gossypol Cotton is a Regulated Article

because,

- It's a product of **genetic engineering**, and
- the vector and the donor organism (*Agrobacterium tumefaciens*) belongs to taxon designated in §340.2, and meet the definition of **plant pest**

# 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- copies of unpublished studies, when available, and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.

# Guidelines



[https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa\\_guidance\\_documents/ct\\_cottonguidance](https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/sa_guidance_documents/ct_cottonguidance)

## **Additional Guidance on Agronomic Performance Data of Cotton** (Last Modified: Jan 26, 2016)

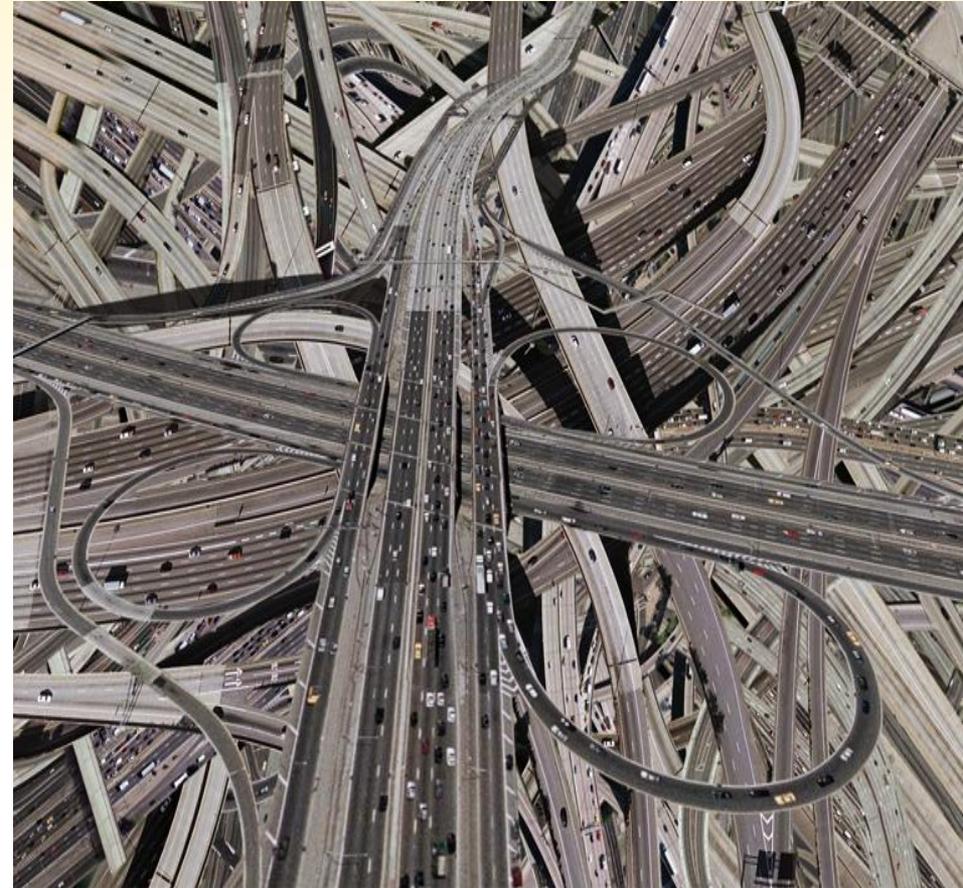
### Number of Sites and Years

- The above data should be collected on a number of sites sufficient to represent the major growing regions to be targeted by the product... One way to increase the likelihood that plants are exposed to varied environmental conditions is through multi-year testing.
- In general, APHIS recommends 6 sites minimum per year in multi-year (at least 2) data packages in which these sites would represent the major producing states in the target area for the product.
- If data are to be all from a single year, the geographic range should be expanded to include minor growing regions such that more varied environmental conditions are likely to be encountered.
- In general, a minimum of 12 sites representing both the major producing states and other climatologically varied regions is recommended if all data are from a single year.
- More sites can provide a better context in which to interpret field data, especially when anomalous data are encountered.

# Road to Deregulation



- Ask for directions from regulators (early consultations)
- Field trials-permit or notification
- Confinement protocols
- Multilocation field trials
- Type of data required for deregulation





# Field Trials



- **Two types of APHIS-BRS applications- Notification and Permit**
- **GE cotton was field tested using notification applications between 2009-2016, because it satisfies all 6 eligibility criteria and 6 performance standards.**



# Notification



## Eligibility Criteria

- Plant species (not a noxious weed)
- Genetic sequence stably integrated
- Function is known
- Doesn't act like an infectious agent, no non-target impact, not a PMPI
- Plant virus sequence: non-coding or endemic
- No plant or animal pathogen sequence

## Performance Standard

- Shipment: No release during movement or at destination
- Release: No mixing with non-regulated crops
- Identity is known all the time & devitalize when no longer in use
- No viable vector
- No persistence
- Volunteer management after harvest

# Field Trials



INSTITUTION	Location	ARTICLE	EFFECTIVE DATE	EXPIRE DATE
Texas A&M University	TX	Cotton	04/08/2016	04/08/2017
Texas A&M University	TX	Cotton	04/01/2015	04/01/2016
Texas A&M University	MS, NC, TX	Cotton	04/01/2015	04/01/2016
Texas A&M University	TX	Cotton	04/01/2014	04/01/2015
Texas A&M University	MS, NC, TX	Cotton	04/01/2014	04/01/2015
Texas A&M University	TX	Cotton	04/15/2013	04/15/2014
Texas A&M University	MS, NC, TX	Cotton	04/01/2013	04/01/2014
Texas A&M University	TX	Cotton	04/17/2012	04/17/2013
Texas A&M University	TX	Cotton	04/16/2011	04/16/2012
Texas A&M University	TX	Cotton	04/01/2010	04/01/2011
Texas A&M University	TX	Cotton	04/20/2009	04/20/2010



# Pre-submission Discussion



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

# Petition Review

- Review team— 2-3 biotechnologists and a NEPA specialist
- A two-part review process
  - Whether the GE ULG cotton lines likely to pose a plant pest risk (7 CFR 340 regulatory requirement)
  - Whether the ULG cotton 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.) (NEPA)

# Plant Pest Risk

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

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**);
- whether the introduced genes produce any new enzymes or changes to plant metabolism (**leading to plant pest risk**);
- whether the introduced genes make ULG cotton plant a weed (**pest plant**);
- whether gene flow from ULG cotton to any sexually compatible species impart weediness to those taxa (**pest plant**);

# Plant Pest Risk (contd.)

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

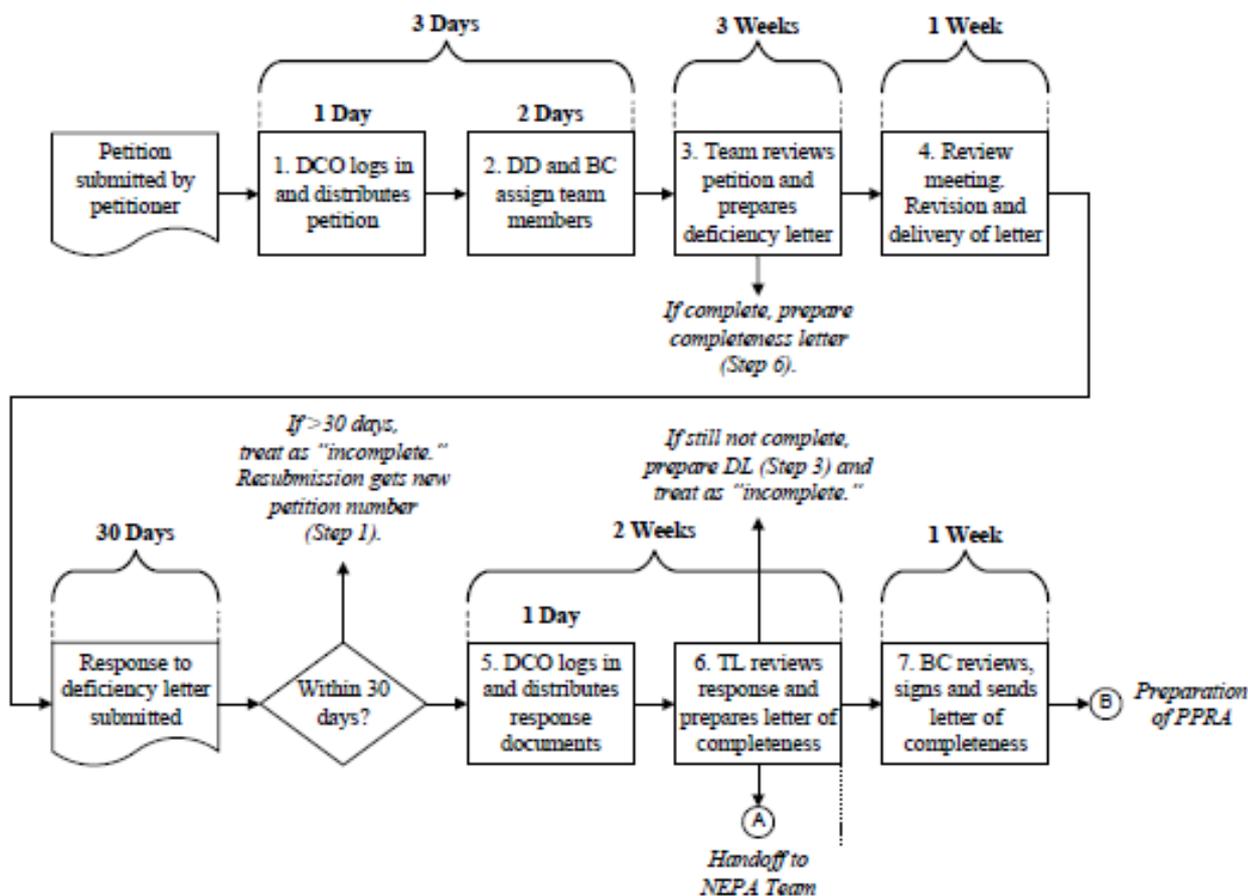
# Letter of Technical Completeness

Within 30 days the petitioner receives a letter:  
Complete or Deficient

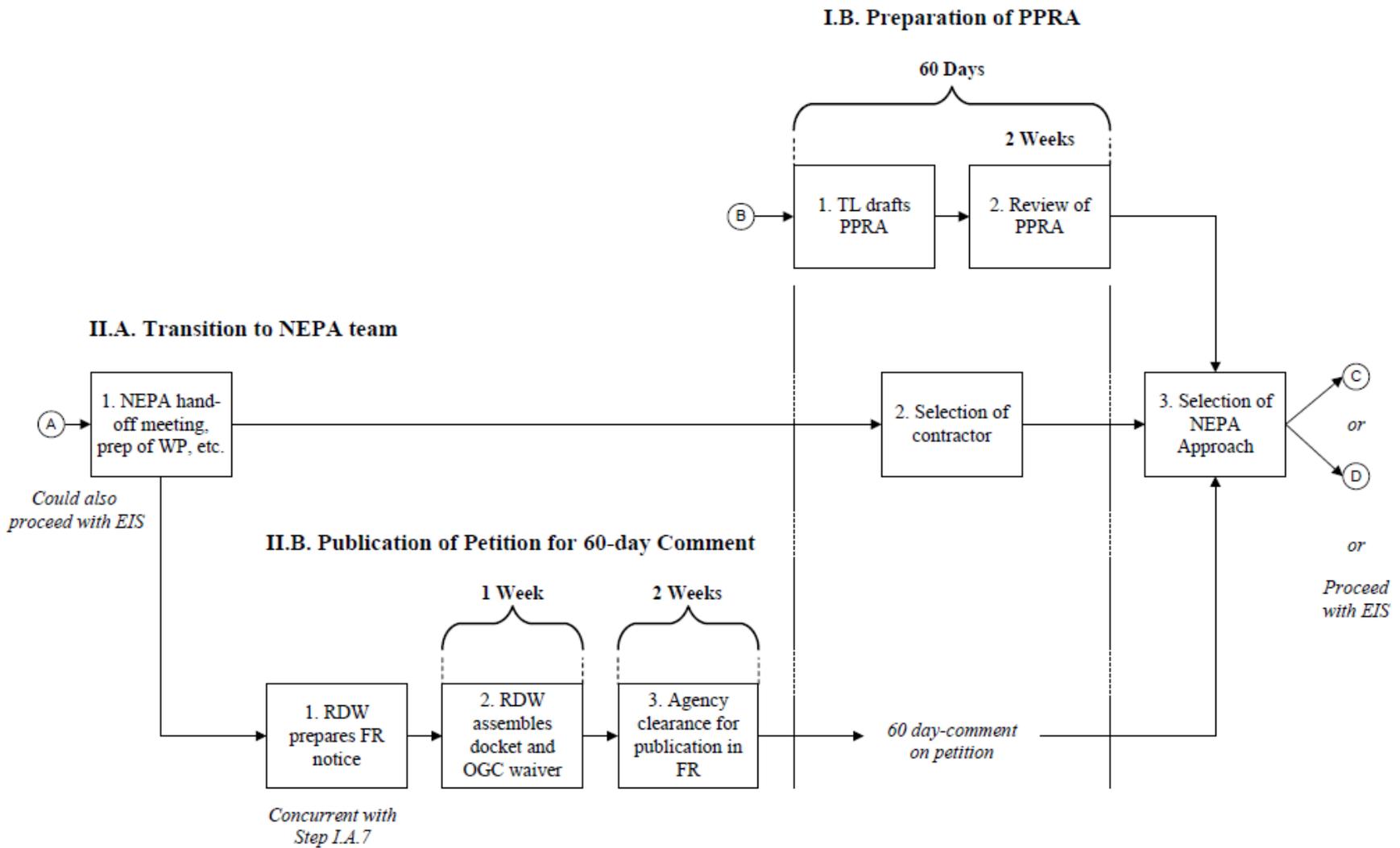
- Clarifications
- Request for more data
- Suggestions

# Petition Completeness Review (8 Weeks)

## I.A. Petition Completeness Review



# NEPA Hand Over (12-13 weeks)





# NEPA Compliance—Request for Information



## Rationale

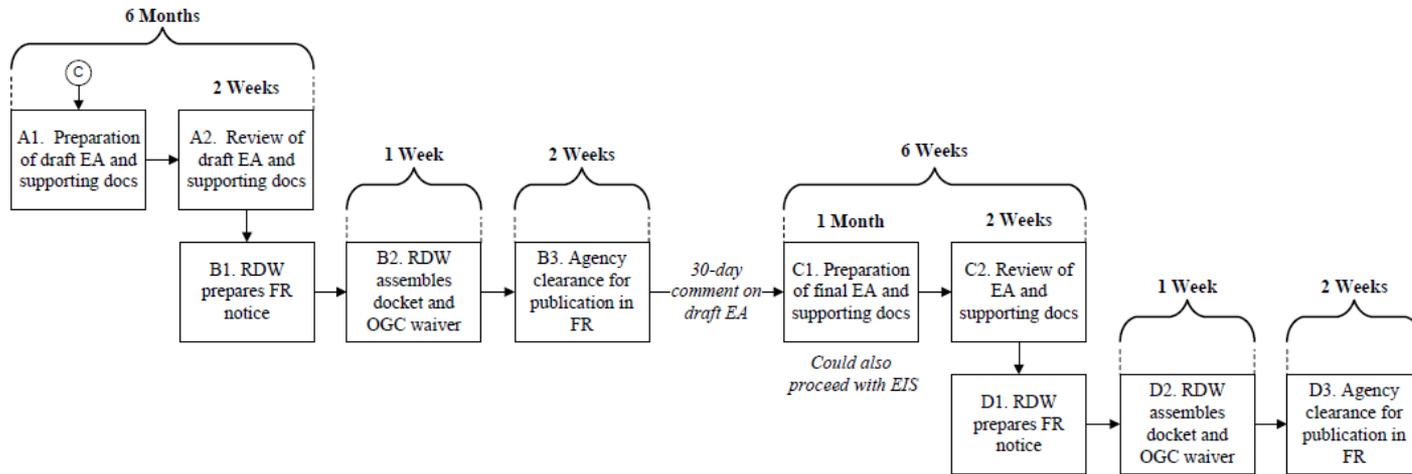
- As a Federal agency subject to compliance with the National Environmental Policy Act (NEPA) APHIS prepares an environmental assessment (EA) to consider the potential environmental effects of granting nonregulated status to the proposed peanut lines consistent with NEPA regulations and the USDA and 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 ULG cotton.

## Request for Information

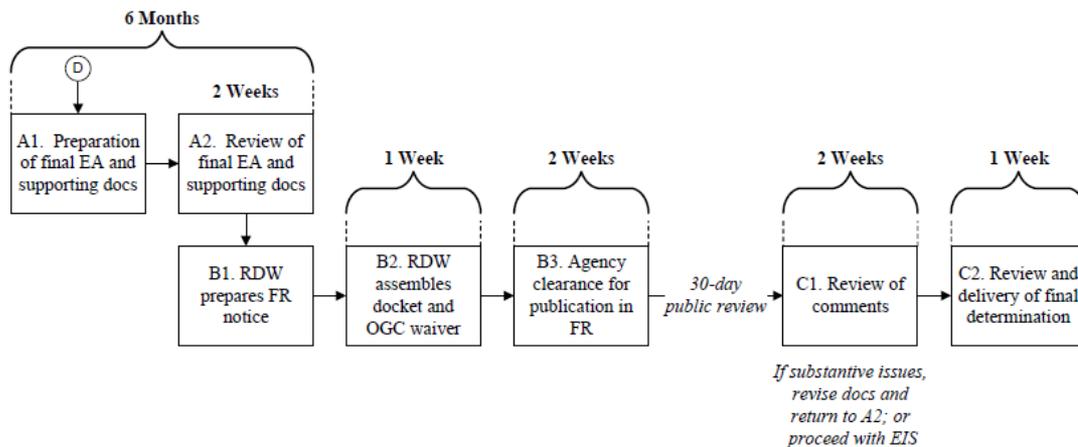
- APHIS is requesting additional information to assist in preparing the required NEPA documentation.
- The types of information requested are not specifically cited in the regulations.
- If you are unable to locate the requested information, please identify this lack of information and APHIS will attempt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

# Environmental Assessment (40 weeks)

## III. If EA Published as Draft for Public Comment



## IV. If EA Published as Final for Public Review



# Additional Information



Permits, Notifications, & Petitions

[https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/ct\\_submissions\\_home](https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/ct_submissions_home)



**United States Department of Agriculture**  
Animal and Plant Health Inspection Service



**Biotechnology  
Regulatory  
Services**

# Petitions for Determination of Nonregulated Status

[https://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml](https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml)

## Petitions for Determination of Nonregulated Status

	Petition No.	Applicant	Crop	Phenotype/Event	Petition and Preliminary Assessment	Final Assessment and Decision	Effective Date of Determination
123	15-218-01p Extension of 11-244-01p	Syngenta	Corn	Insect and Glufosinate-Resistant/SYN-00098-3	↓	↓	March 23, 2015
122	15-140-01p Extension of 13-022-01p	J.R. Simplot	Potato	Low-Acrylamide Potential, Reduced Black Spot Bruise/SPS-00V11-6	↓	↓	January 13, 2015
121	15-124-01p Extension of 11-244-01p and 11-342-01p	Syngenta	Corn	Glufosinate and Glyphosate Tolerant/MZHG0JG	↓	↓	November 30, 2014
120	15-113-01p	Monsanto	Corn	Dicamba and Glufosinate Resistant/MON-87419-8	↓	↓	March 23, 2015
119	14-213-01p	Monsanto	Corn	Increased Ear Biomass/ MON-87403-1	↓	↓	December 8, 2014
118	14-093-01p	J.R. Simplot	Potato	Late Blight Resistant, Low-Acrylamide Potential, Reduced Black Spot Bruise, Lowered Reducing Sugars/Russet Burbank Event W8	↓	↓	September 2, 2014
117	13-290-01p	Monsanto	Corn	Rootworm-Resistant/Glyphosate-Tolerant/MON-87411-9	↓	↓	October 27, 2014
116	13-337-01p Extension of 09-082-01p	Monsanto	Soybean	Lepidopteran-Resistant Soybean/MON 87751	↓	↓	October 17, 2014
115	13-262-01p	Dow	Cotton	2,4-D and Glufosinate-Tolerant/DAS-81910-7	↓	↓	July 23, 2014
114	13-022-01p	J.R. Simplot	Potato	Low-Acrylamide Potential, Reduced Black Spot Bruise/E12, E24, F10, F37, J3, J55, J78, G11, H37, H50	↓	↓	November 10, 2014
113	12-321-01p	Monsanto/Forage Genetics	Alfalfa	Reduced Lignin/ KK179	↓	↓	November 10, 2014
112	12-185-01p	Monsanto	Cotton	Dicamba and Glufosinate Tolerant/ MON-88701-3	↓	↓	January 20, 2015
111	12-272-01p	Dow	Soybean	Insect Resistant/ DAS-81419-2	↓	↓	April 17, 2015
110	12-215-01p	Bayer/Syngenta	Soybean	HPPD and Glufosinate Tolerant/ SYHT0H2	↓	↓	July 18, 2014

