

Lake County GE Advisory Committee – Subcommittee 1  
Report of April 27, 2009

**Subcommittee 1 -- Part I**

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**Subcommittee 1 – Part II**

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## Overview and Regulatory Framework: **Food and Drug Administration (FDA)**

Liz Weiss

The U.S. Regulatory Agencies Unified Biotechnology Website states:

*The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through bioengineering. All foods and feeds, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards. Under the Federal Food, Drug, and Cosmetic Act, it is the responsibility of food and feed manufactures to ensure that the products they market are safe and properly labeled. In addition, any food additive, including one introduced into food or feed by way of plant breeding, must receive FDA approval before marketing.*

Consequently, if a food or feed manufacturer states their product is safe, the FDA assumes the manufacturer has done the proper testing. There is no government required long-term safety testing at this time. Industry is in charge of safety.

*The FDA ensures that food and feed manufactures meet their obligations through its enforcement authority under the Federal Food, Drug, and Cosmetic Act. To help sponsors of foods and feeds derived from genetically engineered crops comply with their obligations, the FDA encourages them to participate in its voluntary consultation process. All foods and feeds from genetically engineered crops currently on the market in the U.S. have gone through this consultation process. With one exception, none of these foods and feeds were considered to contain a food additive, and so did not require approval prior to marketing.*

At this time the Food Allergen Labeling and Consumer Protection Act of 2004 requires that food products that contain any ingredients containing protein derived from the eight major allergenic foods (peanuts, wheat, egg,.....) be labeled. In the U.S., no food labeling is required to identify genetically engineered products.

<http://usbiotechreg.nbii.gov/roles.asp>

March 27, 2009 the Department of Health and Human Services Inspector General noted that the government's system for tracing foods is full of potentially dangerous gaps. According to the report, 70 of 118 facilities failed to meet the FDA's record keeping requirements for information pertaining to suppliers, customers and shippers.

There have been several recalls in the past few months including the salmonella outbreak involving peanut products (nine deaths, nearly 700 ill) and a salmonella outbreak from Mexican jalapeno peppers initially blamed on tomatoes.

<http://www.injuryboard.com>

**Overview and Regulatory Framework: Environmental Protection Agency (EPA)**

Marc Hooper

The EPA through a registration process regulates the sale, distribution and use of pesticides in order to protect health, and the environment, regardless of how the pesticide was made or its mode of action. This includes regulation of those pesticides that are produced by an organism through techniques of modern biotechnology. The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), regulates the distribution, sale, use and testing of pesticidal substances produced in plants and microbes. Generally, Experimental Use Permits are issued for field testing. Applicants must register pesticidal products prior to the sale and distribution, and the EPA may establish conditions for use as part of the registration. The EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act.

For further information, please visit <http://www.epa.gov/pesticides/biopesticides>.

Under the Toxic Substances Control Act (TSCA), the EPA acquires information in order to identify and regulate potential hazards and exposures. TSCA applies to the manufacturing, processing, importation, distribution, use, and disposal of all chemicals in commerce, or intended for entry into commerce, that are not specifically covered by other regulatory authorities, (e.g. substances other than food, drugs, cosmetics and pesticides). TSCA's applicability to the regulation of products of biotechnology is based on the interpretation that organisms are chemical substances under TSCA. The EPA's TSCA Biotechnology Program of the Office of Prevention and Toxic Substances currently regulates microorganisms intended for general industrial uses. The Program conducts a pre-market review of "new" microorganisms, i.e. those microorganisms formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera.) Developers must notify the EPA 90 days prior to manufacture or 60 days prior to field testing of a product regulated by TSCA.

For further information, please visit <http://www.epa.gov/oppt/biotech/>.

\* California Department of Pesticide Regulation – no data yet. 4/27/09 MIH

**Overview and Regulatory Framework: United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)**

All

**[U.S. Department of Agriculture \(USDA\) Animal and Plant Health Inspection Service \(APHIS\)](#)**

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act, USDA-APHIS has regulatory oversight over products of modern biotechnology that could pose such a risk. Accordingly, USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering. These are called "regulated articles." USDA-APHIS regulates the import, handling, interstate movement, and release into the environment of regulated organisms that are products of biotechnology, including organisms undergoing confined experimental use or field trials. Regulated articles are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement and disposal.

USDA-APHIS regulations provide a petition process for the determination of non-regulated status. If a petition is granted, that organism will no longer be considered a "regulated article" and will no longer be subject to oversight by USDA-APHIS. The petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically engineered organism, and field test reports. The agency evaluates a variety of issues including the potential for plant pest risk; disease and pest susceptibilities; the expression of gene products, new enzymes, or changes to plant metabolism; weediness and impact on sexually compatible plants; agricultural or cultivation practices; effects on non-target organisms; and the potential for gene transfer to other types of organisms. A notice is filed in the Federal Register and public comments are considered on the environmental assessment and determination written for the decision on granting the petition. Copies of the USDA-APHIS documents are available to the public.

For further information on the petition process, please visit <http://www.aphis.usda.gov/brs/>.

Under the Virus, Serum, Toxin Act, USDA-APHIS Veterinary Services inspects biologics production establishments and licenses veterinary biological substances, including animal vaccines, that are products of biotechnology.

For further information, please visit <http://www.aphis.usda.gov/vs/>.

USDA > AHPIS > Biotechnology and Regulatory Services (BRS), next page.

## Part C – Continued

**APHIS' Role in Biotechnology**

APHIS uses the term biotechnology to mean the use of recombinant DNA technology, or genetic engineering (GE) to modify living organisms. APHIS regulates certain GE organisms that may pose a risk to plant or animal health. In addition, APHIS participates in programs that use biotechnology to identify and control [plant](#) and [animal](#) pests. Below is a list of the regulatory requirements for genetically engineered organisms and facilities.

**Introducing Genetically Engineered Organisms that may be Plant Pests**

APHIS' [Biotechnology Regulatory Services](#) regulates the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms that may pose a risk to plant health.

**Importing or Exporting Genetically Engineered Animals and Animal Products****Importing or Exporting Genetically Engineered Animals and Animal Products****Obtaining Licenses for Veterinary Biologics****Obtaining Registration for Animal Facilities****Obtaining Other Authorizations from APHIS**

See Biotechnology Regulatory Services (BRS) following page.



**Search APHIS**

**Browse by Audience**

Select an Option

**Browse by Subject**

- ▶ [Animal Health](#)
- ▶ [Animal Welfare](#)
- ▶ [Biotechnology](#)
- ▶ [Emergency Preparedness and Response](#)
- ▶ [Import and Export](#)
- ▶ [International Services](#)
- ▶ [Permits](#)
- ▶ [Plant Health](#)
- ▶ [Regulations and Assessments](#)
- ▶ [Wildlife Damage Management](#)

You are here: [Home](#) > [Biotechnology](#) > BRS

## Biotechnology

### Biotechnology Regulatory Services

In order to protect plant health, Biotechnology Regulatory Services (BRS) implements the APHIS regulations for certain genetically engineered (GE) organisms that may pose a risk to plant health. APHIS coordinates these responsibilities along with the other designated federal agencies as part of the [Federal Coordinated Framework for the Regulation of Biotechnology](#).

#### Biotechnology Permits, Notifications, and Petitions [More](#)

APHIS exercises its regulatory authority through a system that includes both [permits and notifications](#). A researcher or developer may also request that APHIS no longer regulate an organism by submitting a petition for nonregulated status.

[Check the status of a permit, notification, or petition](#)

#### Compliance and Inspections [More](#)

BRS uses inspections and other procedures to maintain compliance with the federal regulations and requirements.

[Report an unauthorized/accidental release of a regulated article or compliance issue](#)

#### News and Information [More](#)

Find [news](#), such as documents available for public review and comment, announcements of public meetings, and Agency decisions. Also learn about some current [hot topics](#), such as outreach activities and regulatory changes.

#### BRS Organization and Functions [More](#)

Discover more information about program, functions, and the mission of APHIS BRS at the [About BRS](#) page.

Last Modified: November 16, 2007

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- [Introducing Genetically Engineered Organisms that may be Plant Pests](#)
- [About BRS](#)
- [About Permits, Notifications, and Petitions](#)
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ISO 9001:2000  
 FM 535173

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## GAO Review of Regulation of GE Crops

At the request of the U. S. Senate Committee on Agriculture, Nutrition and Forestry, the Government Accountability Office (GAO) carried out a review of the USDA, the FDA and the EPA regulation of GE crops. The full review is available at the Web site listed in Reference 1 below.<sup>1</sup> The “Highlights” section of this study is attached. A few brief comments on the report are included here. (See the following page for this attachment.)

As the report states, there have been six known unauthorized releases of GE crops into food, animal feed or the environment beyond farm fields, but the total number of releases is unknown. “In 2007, USDA analyzed its record of over 700 violations or potential violations that occurred from January 2003 through August 2007 and found 98 that indicated a possible release into the environment.”<sup>2</sup>

In the highlights section the GAO report recommends several actions which could be taken by USDA, FDA and the EPA to improve their oversight and present more transparency to their work. The agencies have agreed to implement part of the recommendations. The GAO replies “We stand by the recommendations.” They also note that The FDA proposed in 2001 “to require that food developers notify the agency before marketing their products. However, as of July 2008, FDA had not taken action to finalize the proposed rule, believing its current approach calling for voluntary notice is sufficient.”

Of particular concern for growers in Lake County, are observations on proximity of GE and non-GE crops:

“Another concern stemming from the widespread use of GE crops is the economic impact they might have on farmers growing conventional or organic crops. For example, some growers of no-GE crops fear that seeds or pollens containing engineered traits from neighboring fields may commingle with their crops, thereby making those crops harder to sell to customers who prefer not to consume GE products. In this regard, the U.S. District Court of the District of Northern California ruled that USDA needed to conduct an environmental impact statement to analyze, among other things, the impact that deregulating a particular GE alfalfa might have on farmers growing organic or conventional alfalfa. In a 2008 report to the Secretary of Agriculture, USA’s Advisory Committee on Biotechnology and 21<sup>st</sup> Century Agriculture concluded that fostering coexistence between GE and non-GE crops is an important and worthwhile goal and acknowledged that the proximity of GE crops to conventional and organic crops sometimes cause commingling, preventing some retail consumers from finding products that are free of GE crops. The committee recommended that the Secretary ‘take note’ of several factors that can cause commingling, such as the failure to adequately contain regulated GE crops.

Despite these recommendations and observations from various sources, we found that USDA, EPA and FDA do not have a mechanism to monitor, evaluate and report on the impact of the commercialization of GE crops following the completion of the agencies’ evaluation procedures. USDA, the agency with the most comprehensive authority regarding GE crops, has no systematic program of post market oversight....Without monitoring, undesirable agricultural and environmental problems could result from the unintended transfer of genetic material from deregulated GE crops to non-GE crops and other plants, and these problems could have significant financial implications.”<sup>3</sup>

### References

1. GAO-09-60 <http://www.gao.gov/new.items/d0960.pdf>
2. GAO-09-60, pages 16-17
3. GAO-09-60, pages 31-32

Attachment: GAO Highlights “Genetically Engineered Crops” – next page.

November 2008



Highlights of [GAO-09-60](#), a report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate

## Why GAO Did This Study

Genetically engineered (GE) crops—including crops engineered to resist pests or tolerate herbicides—are widespread in the United States and around the world. Taking direction from the 1986 *Coordinated Framework for Regulation of Biotechnology*, the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) regulate GE crops to ensure that they are safe. The unauthorized mixing of some GE crops with non-GE crops has caused controversy and financial harm. GAO examined (1) unauthorized releases of GE crops, (2) coordination among the three agencies, and (3) additional actions they have proposed to improve oversight. GAO gathered data from agencies and stakeholders; used criteria from prior GAO work to assess coordination; and reviewed agency proposals.

## What GAO Recommends

GAO recommends that (1) FDA make public the results of its early food safety assessments of GE crops; (2) USDA and FDA develop an agreement to share information on GE crops with traits that, if released into the food or feed supply, could cause health concerns; and (3) USDA, EPA, and FDA develop a risk-based strategy for monitoring the widespread use of marketed GE crops. FDA agreed with the first recommendation, and, with USDA, agreed in part with the second. The agencies agreed in part with the third recommendation. We stand by the recommendations.

To view the full product, including the scope and methodology, click on [GAO-09-60](#). For more information, contact Lisa Shames at (202) 512-3841, or [shamesl@gao.gov](mailto:shamesl@gao.gov).

## GENETICALLY ENGINEERED CROPS

### Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring

#### What GAO Found

Unauthorized releases of GE crops into food, animal feed, or the environment beyond farm fields have occurred, and it is likely that such incidents will occur again. While there is no evidence that the six known releases into the food or feed supply or into crops meant for the food or feed supply affected human or animal health, some resulted in lost trade opportunities. Moreover, the total number of unauthorized releases into the environment is unknown. USDA and EPA have the authority to inspect fields in which GE crops are tested, but crop developers have detected most violations. USDA and EPA have taken enforcement actions in response to violations, ranging from warning letters to significant penalties. The agencies have used lessons learned from unauthorized releases to make regulatory and policy changes. For example, USDA increased inspections of field trial sites for GE crops producing pharmaceutical compounds; EPA discontinued a policy under which a GE crop containing a pesticidal agent could be approved for animal feed, but not for food; and FDA established a voluntary early food safety evaluation program for certain GE crops intended for food use to help mitigate the impact should unauthorized releases occur during field trials, although it has not made these evaluations available to the public.

USDA, EPA, and FDA routinely coordinate their oversight and regulation of GE crops in many respects, but could improve their efforts. Specifically, USDA and FDA do not have a formal method for sharing information that could enhance FDA's voluntary early food safety review for certain GE crops in the field trial stage and support USDA's oversight. Also, the three agencies do not have a coordinated program for monitoring the use of marketed GE crops to determine whether the spread of genetic traits is causing undesirable effects on the environment, non-GE segments of agriculture, or food safety, as recommended by the National Research Council and others.

USDA, EPA, and FDA have proposed regulatory changes intended to improve their oversight of GE crops. In 2007, USDA assessed a wide array of regulatory alternatives that could redefine, on the basis of risk, which GE crops it regulates and how it will respond to unauthorized releases. USDA's fiscal year 2009 budget request also seeks funding for a voluntary system to help GE crop developers employ best management practices to reduce the risk of unauthorized releases. Furthermore, the 2008 Farm Bill required USDA to take actions on lessons learned from its investigation of an unauthorized release of GE rice. EPA has proposed several changes to its regulations for GE crops that produce pesticides, including one change that would distinguish between pesticidal agents produced in GE crops and those applied topically to crops. In 2001, FDA proposed to require that GE food developers notify the agency before marketing their products. However, as of July 2008, FDA had not taken action to finalize the proposed rule, believing its current approach calling for voluntary notice is sufficient.

Overview and Regulatory Framework: **California Department of Food and Agriculture (CDFA)**

Lorrie Gray

The California Department of Food and Agriculture (CDFA) is charged with protecting and promoting agriculture. Part of that function is to review APHIS notification and permit applications for genetically engineered crop field trials in the state, and to comment upon them.

CDFA laboratories do not have access to manufacturer's proprietary information, usually claimed to be Confidential Business Information (CBI).

California Assembly Bill 541, signed into law in September 2008 requires the CDFA or a CDFA designated independent third party to carry out any sampling activity as specified in California See Law regulations.

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## USDA National Organic Regulations

In order to sell a crop as organic, the producer must be certified as organic by a certifier licensed by the USDA National Organic Program (NOP) unless annual sales are less than \$5,000. A certifying company often used is the California Certified Organic Farmers (CCOF) which was founded before the national program was started. All certifiers must follow the guidelines in the NOP (see Reference 1 for a link to the web USDA NOP web site).

Regarding GE substances the NOP guidelines include the following sections:

### “(NOP 205.2) Excluded methods.

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

### NOP 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;
- (b) Non-synthetic substances prohibited in § 205.602 or § 205.604;
- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;
- (e) Excluded methods, except for vaccines, provided that the vaccines are approved in accordance with § 205.600(a);
- (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
- (g) Sewage sludge.”

On the basis of these sections, no GE modified inputs whatsoever may be used in organic production.

The question of the possible contamination of an organic crop by drift of an excluded material has been addressed in a letter from Bill Hawks, Under Secretary, Department of Agriculture<sup>2</sup>:

“The presence of a detectable residue of excluded methods alone does not necessarily constitute a violation of this regulation (NOP 205.2). As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods will not affect the status of the organic operation. As to the status of the commodity, USDA’s position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship.”

Thus, the “contaminated” crop could still be sold as “organic.” A letter from Neal MacDougall of the San

Luis Obispo Chapter of CCOF addresses the attitude of a buyer of a “contaminated” product.<sup>3</sup>

“...while a grower would still be allowed to sell genetically contaminated product as being certified organic, it is highly unlikely that a buyer of that product (especially if the organic product is an input into a processed organic product) would be willing to buy that product. If it became widely known that a grower’s certified organic product is contaminated, the organic status of the product would not be enough to convince buyers that the product is truly equivalent to other organic products that were not similarly contaminated. When such a product is to be exported or it is to be incorporated into an organic product that is to be exported, the danger becomes even greater since foreign buyers and processors are hesitant to purchase product that their customers might think is contaminated.”

The NOP provides that buffers should be provided between the organic crop area and conventionally farmed crops. The buffers can prevent or at least minimize drift of non-organic sprays on the organic crop. Such buffers could also be utilized between GE crops and organic crops. The situation is somewhat different in the latter case. While the spray material will only have a transient effect on the organic crop, the GE crop could cause transformation of the crop because of, for example, pollen drift. A study of this effect has been published in the peer-reviewed article by Ellstrand<sup>4</sup>. In studies of hybridization of wild and cultivated radishes he found that hybridization at a level of about 2% occurred when the plants were separated by 0.62 mile (1 kilometer). He also studied the hybridization of two distinct species, sorghum bicolor and Johnson Grass, “one of the world’s worst weeds.” Hybridization by pollen drift could be detected at a separation of 330 feet (100 meters). This study indicates that it could be very difficult to furnish an adequate buffer between GE and organic crops to allow the latter to have non-detectable levels of GE traits.

### References

1. Reference Web address:  
<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateF&navID=RegulationsNOPNationalOrganicProgramHome&rightNav1=RegulationsNOPNationalOrganicProgramHome&topNav=&leftNav=NationalOrganicProgram&page=NOPRegulations&resultType=&acct=noprulemaking>.
2. Letter from Bill Hawks, Under Secretary, Marketing and Regulatory Programs, December 21, 2004, USDA to Gus Douglass, Commissioner, The National Association of State Departments of Agriculture,.
3. Appendix E, Committee Report-Evaluation of Growing GE Crops in San Luis Obispo County, July 19, 2004.
4. Elstrand, Norman C., “When crop transgenes wander in California, should we worry?,” 2006, California Agriculture Volume 60 Number 3, page 116.

Overview and Regulatory Framework: **Pre- and Post- Market Gaps in Regulatory Oversight**

All

Overview and Regulatory Framework: **Other California GE Legislation**  
All

Appendix 1 -- List of Registered Plant-incorporated Protectants

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U.S. DEPARTMENT OF AGRICULTURE  
 ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
 BIOTECHNOLOGY REGULATORY SERVICES

**BRS NOTIFICATION - INTRODUCTION OF GENETICALLY ENGINEERED PLANTS**

<b>1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT</b> Name: Lorraine Gray Position: Organization: Organization Unique ID: Address:  County/Province: Township/Island:  Day Telephone: FAX: Alternate:  Email 1: bgray191@mchsi.com Email 2:	<b>2. INTRODUCTION TYPE</b> <input type="checkbox"/> Importation <input type="checkbox"/> Interstate Movement <input type="checkbox"/> Interstate Movement and Release <input type="checkbox"/> Release
<b>3. APPLICANT REFERENCE NUMBER</b> 241394	

**4. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**  
 Does this application contain CBI?  Yes  No

**CBI Justification:**  
 N/A

**5. REGULATED ARTICLE**  
 Scientific Name:  
 Common Name:  
 Cultivar and/or Breeding Line:

**6. PHENOTYPIC DESIGNATION**

**7. INTRODUCTION**

**8. ADDITIONAL INFORMATION**  
 None

I, *Lorraine Gray*, certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

If there are any changes to the information disclosed in this application, I will contact APHIS.

<b>9. SIGNATURE OF RESPONSIBLE PERSON</b>	<b>10. DATE</b>
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The collection of this information is authorized by the Plant Protection Act of 2000. The information will be used to determine eligibility to receive all types of permits. No permit will be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE  
 ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
 BIOTECHNOLOGY REGULATORY SERVICE  
**APPLICATIONS FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340**  
*(Genetically Engineered Organisms or Products)*

<b>1. NAME, ADDRESS, TELEPHONE, AND EMAIL OF APPLICANT</b> Name: Lorraine Gray Position: Organization: Organization Unique ID: Address:  County/Province: Township/Island:  Day Telephone: FAX: Alternate:  Email 1: bgray191@mchsi.com Email 2:	<b>2. INTRODUCTION TYPE</b> <input type="checkbox"/> Importation <input checked="" type="checkbox"/> Interstate Movement <input type="checkbox"/> Interstate Movement and Release <input type="checkbox"/> Release	<b>3. PERMIT TYPE</b> <input checked="" type="checkbox"/> Standard Permit <input type="checkbox"/> Courtesy Permit
<b>4. PURPOSE OF PERMIT</b> <input type="checkbox"/> Industrial Product <input type="checkbox"/> Pharmaceutical Product <input type="checkbox"/> Phytoremediation <input checked="" type="checkbox"/> Traditional		

**5. CONFIDENTIAL BUSINESS INFORMATION VERIFICATION (CBI)**  
 Does this application contain CBI?  Yes  No  
 CBI Justification:  
 N/A

**6. REQUEST TYPE**  
 New  Amendment  Renewal  Variance  Amendment, Renewal and/or Variance  
 Amendment/Renewal Description:  
 Previous Permit Number(s):

**7. MEANS OF MOVEMENT**  
 Truck

**8. VARIANCE VERIFICATION**  
 Have you previously applied for variance(s) that you wish to apply to this permit?  Yes  No  
 Variance Number(s):  
 If so, describe in a brief summary how the variance will be applied:  
 N/A

**9. REGULATED ARTICLE**  
 Scientific Name:  
 Common Name:  
 Any biological material (e.g., culture medium, or host material) accompanying the regulated Article during movement:  
 Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed, and produced:  
 Processes, Procedures, and Safeguards Description:

**10. ARTICLE SUPPLIER AND/OR DEVELOPER**

**11. PHENOTYPES/GENOTYPE**

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**12. INTRODUCTION**  
Point of Origin

WARNING: Any use of ePermits to make materially false, fictitious, or fraudulent statements or representations is subject to civil penalties of up to \$250,000 (7 U.S.C. § 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. §1001).

**Destination**

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**13. DESIGN PROTOCOLS**

**Production Design**

A detailed description of the purpose for the introduction of the regulated article including detailed description of the proposed experimental and/or production design:

N/A

**Destination or Release Description**

A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location):

**Confinement Protocols**

A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations:

**Final Disposition Method:**

- Destruction/Devitalization     Other     Storage in Contained Facility

**Final Disposition Description:**

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**14. ATTACHMENTS**

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**15. ADDITIONAL INFORMATION**

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**16. COURTESY JUSTIFICATION**

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I, *Lorraine Gray*, hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

I acknowledge this is not an application to move or import select agents, the genes expressing select agents, or the toxins made by the select agents, as described in 9 CFR 121.

I will not introduce the regulated articles described in this application until APHIS has deemed the application complete and has granted the permit. By signing this permit, I agree to comply with any and all state, local, and tribal laws and regulations that may apply to the introduction of the articles described in this applications.

If there are any changes to the information disclosed in this application, I will contact APHIS.

<b>17. SIGNATURE OF RESPONSIBLE PERSON</b>	<b>18. DATE</b>
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Appendix 3 – Freedom of Information Act (1) Request and (2) Response

Steve Devoto

**Current California GE Research on Lake County Food Crops**

Food Crops Grown in Lake County Crops <sup>*1</sup>	Total Acres	Organic	Crops Deregulated by USDA Commercialized or Not <sup>*5</sup> 6/2/1992 thru 3/26/2009 (17 yrs)			Field Test <sup>*6</sup> Releases 2008 Permits-APHIS#	Research and Case Study Stage
			Pending	Withdrawn	Approved		
References >			<a href="http://www.nbiap.vt.edu">www.nbiap.vt.edu</a>			<a href="http://www.isb.vt.edu">www.isb.vt.edu</a>	<a href="http://www.ncfap.org">www.ncfap.org</a>
<b>Fruit &amp; Nut Crops</b>							
Pears	2,208	33					
Walnuts	2,702	1,708					
Misc. Fruit & Nuts <sup>*2</sup>	70	3					
Wine Grapes	8,345	126					
Total Acres	13,325	1,870					
<b>Vegetables</b>							
Vegetables <sup>*3</sup>	50						
Chicory				1	1		
Melon				1			
Potato				3	5		
Squash					2		
Tomato				2	11		
Total Acres	50	17					
<b>Nursery</b>							
Nursery - Greenhouse (sq. ft.)	69,900						
Nursery - Field	77						
Total Acres	79	10					
<b>Timber</b>							
Timber Yield (Board Feet: MBF <sup>2</sup> )	3,684						
Total Board Feet (MBF <sup>2</sup> )							
<b>Field and Seed Crops</b>							
Irrigated Pasture	1,800						
Range	90,000						
Miscellaneous <sup>*4</sup>	2,100						
Alfalfa			1		1		
Corn (Field and Sweet Corn)			4	7	20		
Rice					2		
Wheat				3			
<b>Total Value</b>	\$ 68,766,520						

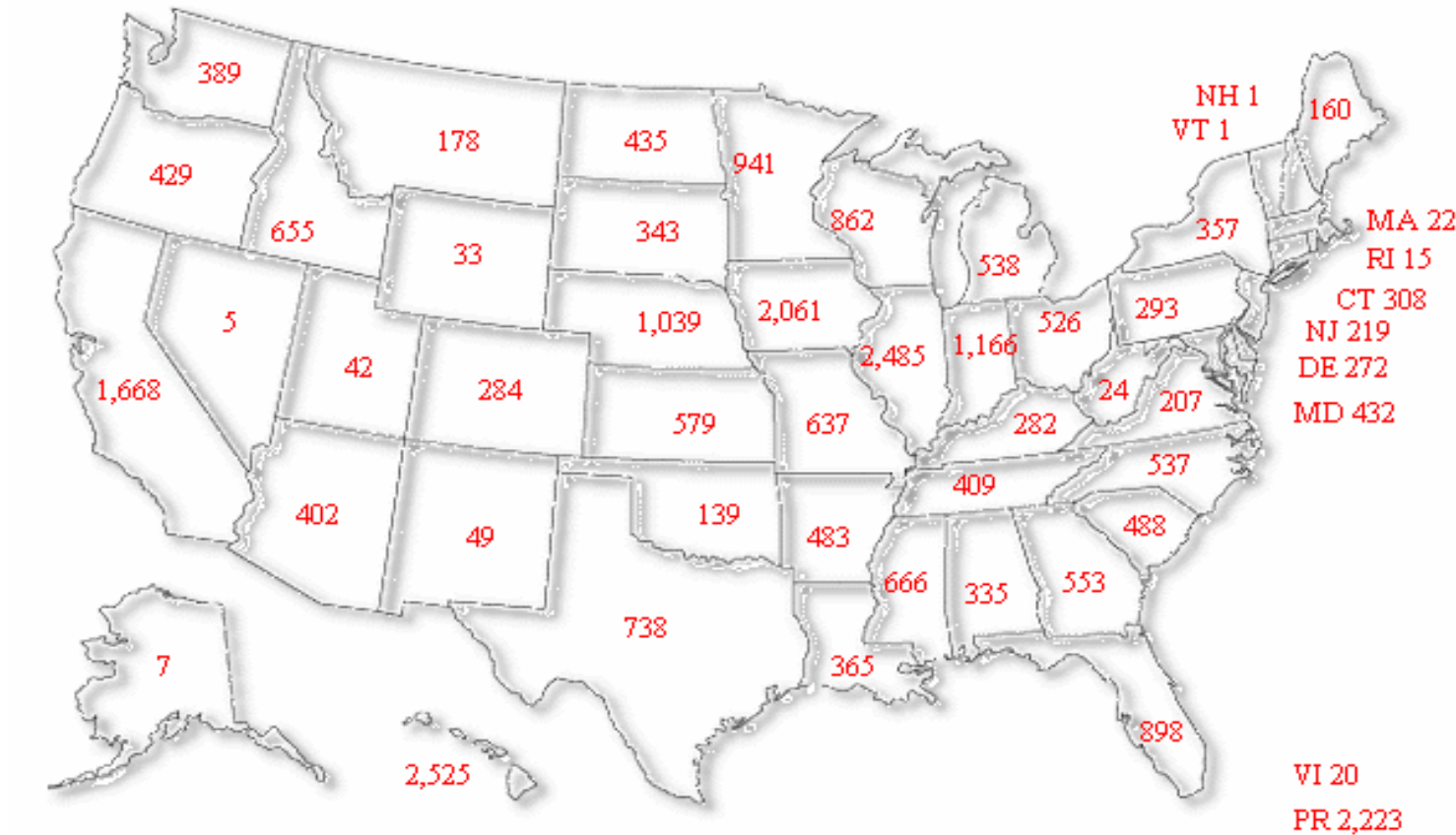
Working

<sup>\*1</sup> Crops, acreages and values based the Ag Commission's 2007 Lake County Crop Report.  
<sup>\*2</sup> Includes apples, peaches, strawberries, melons, dried fruits, olives, etc.  
<sup>\*3</sup> Includes beans, peas, tomatoes, squash, pumpkins, etc.  
<sup>\*4</sup> Includes Wild rice, oat hay, alfalfa, grass hay.  
<sup>\*5</sup> Source of information - Web query at: <http://www.nbiap.vt.edu/cfdocs/biopetition3.cfm> for date range shown > Permit action: Pending, Withdraw, Approve.  
<sup>\*6</sup> Field Test Release Applications in the US, APHIS Database -- through 3/30/2009: Notifications 13,935 records; Full Release Permits Only 1,563 records.

<http://www.isb.vt.edu/cfdocs/biocharts1.cfm>

### Number of Field Tests by State in the U.S.

(To March 30, 2009)



## Appendix 5 -- Other Countries' Requirements for GE Crops and Dates Enacted

Liz Weiss

Country	Labeling	Ban or Moratorium on Commercialization	Ban on Imports
Albania		2003	2003
Algeria		2000	2000
Angola			2004
Australia	2001		
Benin		2002	2002
Bolivia		2005	
Brazil	2004	1999-2003	1999-2003
Bulgaria	2005	2005	
Cameroon	2003		
Chile	2000		
China	2002		
Costa Rica	1998		
Croatia	2003	2005	
Ecuador	2001		2006
European Union (25 Countries)	2004	1998-2004	
Georgia		1996	1996
Ghana			2005
Hong Kong	2000		
India	2000		
Indonesia	1996		
Japan	2003		
Malawi			2002
Mali	2005		
Mauritius	2004		
Mexico	2003		
Namibia			2002
New Zealand	2001		
Norway	1997		
Paraguay	2002		
Phillippines	2001		
Russia	2005		
Saudi Arabia	2001	2001	2001
South Africa	2004		2005
Sough Korea	2002		
Sri Lanka			2000-2001
Switzerland		2005	
Taiwan	2001		
Thailand	2002	2005	1964
Uganda		2004	
Vietnam	2005		
Yugoslavia	2005		
Zambia		2005	2002
Zimbabwe			2002

Reference:

Appendix 6 – Seed Industry Structure 2009

Marc Hooper

Searching for updated information.

Appendix 7 – Directory of Non-GMO's

Steve Devoto

Appendix to be removed



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## Biotechnology

### Noncompliance History

The following is a summary of major incidents of noncompliance with APHIS biotechnology regulations from 1995 through present. In each case, APHIS and the companies took remedial actions in order to protect agriculture, the food supply, and the environment and no adverse effects were reported. Investigative and Enforcement Services (IES) thoroughly investigated each incident. None of the incidents, except those by one company, included field tests of plant-made pharmaceuticals or industrials.

#### 2008

**Company/Institution: Syngenta Seeds, Inc.**

On April 2, 2008, Syngenta Seeds, Inc. entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR 340). The incident involved regulated corn seed and it occurred in December, 2006. Specifically, APHIS alleges that Syngenta:

- Failed to notify APHIS of an accidental/unauthorized release within the required time period.
- Failed to contain or devitalize 29 pounds of regulated corn seed when it was no longer in use. This corn seed was subsequently misidentified and disseminated in transit.
- Was responsible for an unauthorized introduction that occurred when corn seed was accidentally released into the environment while in transit.

The regulated parental line was granted non-regulated status in March, 2007.

**Resolution:**

Under the settlement agreement, Syngenta Seeds, Inc. agrees to pay a civil penalty of \$13,125.

#### 2007

**Company/Institution: The Scotts Company LLC**

On November 26, 2007, in response to an administrative complaint filed against it, The Scotts Company, LLC entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR 340). Specifically, APHIS alleges that Scotts:

- Failed to comply with performance standards for field trials of glyphosate-tolerant creeping bentgrass (GTCB) conducted under notifications from 1999 to 2005 at multiple test sites located in 19 states,
- Violated supplemental permit conditions for a 2005 Idaho field trial of GTCB by failing to remove immature seed heads, and
- Failed to conduct a 2003 Oregon field trial in a manner that ensured the GTCB and/or its offspring would not persist in the environment.
- In a related incident, APHIS also alleges that Scotts improperly moved GE Kentucky bluegrass seed heads.

**Resolution:**

Under the settlement agreement, Scotts agrees to pay a civil

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ISO 9001:2000  
 FM 535173

penalty of \$500,000. In addition, Scotts agrees to conduct three public workshops within 1 year to present best management practices and technical guidance for other potential developers of GE plants and all interested parties on the identification and prompt resolution of biotechnology incidents. The workshops will take place:

- In Oregon, to address current and ongoing efforts to monitor and destroy GTCB in and around the Oregon Control District,
- At a national conference of seed producers or turfgrass specialists, and
- At a location selected by Scotts, with APHIS approval.

Scotts has already implemented measures to comply with performance standards and permit conditions related to these allegations. In addition, Scotts is carrying out monitoring and mitigation actions in Oregon to locate and remove the regulated GE material that was accidentally released during the 2003 field trial. These actions were required by APHIS beginning in 2004 to address past allegations that Scotts failed to notify APHIS of the accidental release of the GTCB in 2003. The current allegations address the ongoing persistence in the environment related to the accidental release.

**Company/Institution: Bayer CropScience**

APHIS' Investigative and Enforcement Services (IES), in coordination with USDA's Office of the Inspector General (OIG), conducted an investigation into the release of regulated genetically engineered (GE) material detected in 2 varieties of commercial long-grain rice. APHIS initiated the investigation in August 2006 after Bayer CropScience reported that regulated GE LLRICE601 had been detected in the long-grain rice variety Cheniere. This investigation was expanded in February 2007 to include the discovery of regulated GE material, later identified as LLRICE604, in the long-grain rice variety Clearfield 131 (CL131). Both GE rice lines have the same added protein which has been safely used in other deregulated products for more than 10 years.

**Resolution:**

Investigators were able to determine that the presence of LLRICE601 was limited to the long-grain rice variety of Cheniere and that the presence of LLRICE604 was limited to the long-grain variety CL131. No short- or medium-grain rice varieties tested positive for either LLRICE601 or LLRICE604. Investigators had hoped to identify how each GE rice line entered the commercial rice supply, but the exact mechanism for introduction could not be determined in either instance. However, direct cross-pollination was probably not a factor for LLRICE604's entry point into CL131.

Based on the findings of the investigation, APHIS is not taking any enforcement action against Bayer. Given the lack of available information and evidence, APHIS was unable to make any definitive determinations that could have resulted in enforcement action. LLRICE601 was deregulated in November 2006, and as such no longer falls under APHIS oversight. In March 2007, APHIS issued emergency action notifications to stop the further distribution and planting of CL131 rice seed to minimize the spread of LLRICE604. The investigation is now closed.

**Company/Institution: ProdiGene**

On July 26, 2007, ProdiGene, Inc., and APHIS entered into a settlement agreement regarding alleged violations of 7 CFR 340.4 (f), which states that a person who is issued a permit must comply with those permit conditions. Specifically, APHIS alleged that ProdiGene failed to monitor for volunteers associated with a 2004 GE field test of a corn variety modified to produce pharmaceutical compounds. APHIS also alleged that the company did not manage the fallow zone properly and allowed oats being grown in the fallow zone to be harvested and baled for use as on-farm animal feed. These alleged violations arose from APHIS inspections of the field test, in which the inspector found volunteer corn growing and flowering within the fallow zone surrounding the field trial and in a nearby sorghum field planted within a 1-mile isolation distance. An APHIS inspector and compliance officer also discovered that oats growing in the border rows immediately surrounding the regulated article had been cut and baled.

**Resolution:**

ProdiGene destroyed all volunteers in the 1-mile isolation zone, and plowed under the sorghum field. All suspect oat bales were

quarantined and later destroyed. An APHIS inspector supervised the destruction of the regulated plant material. The case was referred to IES for investigation. In addition to paying a civil penalty, ProdiGene, Inc., has agreed that it and its successors in interest will never again apply to BRS for a notification or permit to introduce GE organisms.

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**2006****Company/Institution: BASF**

On June 15, 2006, BASF, Research Triangle Park, NC and APHIS entered into a stipulation to settle alleged violations of 7 CFR Part 340.4(f)(4). APHIS alleged that BASF failed to maintain the regulated article only in areas and premises specified in the permit. These alleged violations arose from an APHIS inspection of the field test, in which the inspector noted that the corn was planted in a different location from what was approved in the permit.

**Resolution:**

The case was referred to IES. BASF paid a civil penalty.

**Company/Institution: ArborGen, LLC**

On July 17, 2006, ArborGen, LLC, Summerville, SC, and APHIS entered into a settlement agreement regarding alleged violations of 7 CFR 340.3(c)(3) and 340.3(d)(2)(ii)(b). APHIS alleged that ArborGen, LLC failed to maintain the identity of trees of a genetic construct introduced in field trials and failed to follow procedural requirements for notifying APHIS of identification of a regulated article in the notification. These alleged violations arose from a self disclosure by the company that several trees were of a genetic construct not listed on their notification.

**Resolution:**

The trees have been cut and removed from the location. The stumps are being monitored for re-sprouting and will be treated as appropriate. The case was referred to IES. In addition to paying a civil penalty, ArborGen, LLC employed a third-party consultant to review quality control measures for the management of product identity and inventory. Based on this consultation, ArborGen, LLC presented a written plan to BRS describing how ArborGen, LLC will improve and implement quality control measures. The measures will enhance the genotypic and phenotypic identification of all products that are, will, or may, be regulated articles subject to 7 CFR 340 regulations, including those received from outside contractors.

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**2005****Company/Institution: Syngenta Seeds, Inc.**

On March 24, 2005, Syngenta Seeds, Inc., Research Triangle, NC, and the Animal and Plant Health Inspection Service (APHIS) entered into a Stipulation Agreement to settle alleged violations of 7 CFR Part 340.4 (b) (c). APHIS alleged that Syngenta planted and moved interstate genetically engineered corn seed without obtaining USDA APHIS permits. These alleged violations arose from a disclosure made by the company to APHIS. Specifically, Syngenta mistakenly produced and distributed a limited amount of its genetically engineered Bt 10 corn, which had not complete the Federal government's full regulatory review.

**Resolution:**

EPA and USDA reviewed the scientific information and concluded that there are no human or animal health or environmental concerns with Bt10 corn due to the limited amount in the environment, the results of the review of product characterization information, and the close similarity of the Bt10 corn line and another Bt corn line which had cleared regulatory review. EPA and USDA coordinated their investigative efforts. All plants of Bt10 corn were destroyed, seed stocks were quarantined, and their disposal was then overseen by USDA. In addition to paying a civil penalty, the Stipulation Agreement required Syngenta to sponsor a training conference for other members of the regulated community that focused on compliance with APHIS rules regulating biotechnology crops (7 CFR Part 340). The conference goals were:

1. Develop best management practices or technical guidelines for insuring no contamination or cross contamination of biotech genes

in the seed development and breeding program; and  
2. Develop best management practices or technical guidelines to identify, promptly address, and implement corrective measures to resolve unintended biotech releases.

## 2004

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### **Company/Institution: Seminis Vegetable Seeds, Inc.**

On September 30, 2004, Seminis Vegetable Seeds, Inc., Oxnard, CA, and APHIS entered into a stipulation to settle alleged violations of 7 CFR Part 340.3 (c) (1). APHIS alleged that Seminis shipped small amounts of genetically engineered tomato seeds to the University of California (UC), Davis, without proper identification. APHIS also alleged that UC inadvertently shipped these seeds to multiple US and international investigators. Seminis retrieved seeds and documented seed locations. In addition to paying a civil penalty, the company was required to implement training and procedures to prevent future violations.

### **Company/Institution: The Scotts Company**

On August 3, 2004, the Scotts Company of Marysville, OH, and APHIS entered into a stipulation to settle alleged violations of permit conditions requiring the immediate notification upon discovery of accidental or unauthorized releases of regulated articles. [7 CFR 340.4 (f)(10)(i)]. APHIS alleged that, on two occasions, Scotts failed to notify APHIS about the accidental release of glyphosate-tolerant, or Roundup Ready, Creeping Bentgrass (GTCB), which resulted from unanticipated wind events at a field test site in Jefferson County, OR that carried dried GTCB seed heads beyond the field test location.

#### **Resolution:**

Scotts provided a mitigation plan and committed to additional control measures outlined in a Compliance Agreement with BRS. In addition to paying a civil penalty, Scotts was required to implement training and procedures to prevent future violations.

## 2003

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### **Company/Institution: Pioneer Hi-Bred International, Inc.**

IES initiated an investigation in May of 2003 after tests required by the Environmental Protection Agency indicated a small amount of genetically engineered corn had cross contaminated surrounding genetically engineered corn being grown at the research nursery. Of the 337,000 leaf and seed samples collected from the surrounding research fields, 12 leaf samples indicated cross contamination had occurred. All of the corn planted at the Pioneer nursery was for use in research breeding trials and was not to be used for food or feed.

#### **Resolution:**

The cross-contaminated research corn was destroyed immediately upon discovery. Following a thorough investigation into Pioneer Hi-Bred International, Inc.'s adherence to BRS-imposed confinement conditions, IES determined that no conditions of the APHIS permit were violated. In addition, no unapproved corn plants entered the food or feed supply. The investigation is now closed.

## 2002

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### **Company/Institution: ProdiGene**

**Location 1:** APHIS inspectors found volunteer corn growing within a soybean field that had been a field test site for a pharmaceutical-producing plant in the previous season. Commercial corn surrounded the site within the appropriate isolation distance. ProdiGene failed to notify APHIS of volunteers with tassels within 24 hours of discovery.

#### **Remedial measures:**

ProdiGene destroyed all corn seed and plant material within 1320 feet of the previous year's test plot. APHIS inspectors supervised the destruction of the regulated corn seed and plant material.

**Location 2:** At a second location, APHIS inspectors found volunteer corn from the previous year's test sites with tassels growing in a

soybean field. APHIS required the company to remove all the volunteer corn to prevent its harvesting, along with the soybeans. Despite APHIS notification of appropriate volunteer corn removal, the soybean field was harvested with volunteer corn plants standing in the field. The soybeans were sent to a grain elevator where they were mixed with 500,000 bushels of soybeans.

**Remedial measures:**

APHIS and the company stopped movement of all the soybeans at the elevator. USDA destroyed the 500,000 bushels of soybeans.

**Joint Resolution:**

IES investigated both incidents and through a formal administrative proceeding, ProdiGene is paying a \$250,000 penalty to resolve the allegations. ProdiGene also entered into a consent decision with USDA. ProdiGene agreed to reimburse USDA for the cost of moving and destroying 500,000 bushels of soybeans and provided proof of financial responsibility of \$1 million trust fund. In addition, the company agreed to develop a new compliance implementation program and engage in an audit by a third party; ProdiGene must comply with the auditor's requirements.

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**2001**

**Company/Institution: North Carolina State University**

USDA's Office of the Inspector General (OIG) inspected field test sites of transgenic tobacco engineered for virus resistance and determined that the N.C. State researcher did not have a current permit. The field test was near completion when OIG discovered the infraction.

**Resolution:**

APHIS required the researcher to monitor the site in the following year. IES investigated the case and North Carolina State University paid a stipulated penalty of \$1,250.

**Company/Institution: Monsanto**

Monsanto failed to monitor for corn volunteers in the year following a GE crop field test on an insect-resistant corn variety. The company allowed the volunteers to release pollen within commercial corn planted over the field test site. Consultants and other field workers reported the issue of corn planted on the previous test site to Monsanto, but the company failed to take immediate action or report the situation to APHIS.

**Resolution:**

Monsanto destroyed all the corn planted on the site of the previous years' test crop. Monsanto also purchased and destroyed all the corn growing within the isolation distance. IES investigated and Monsanto paid stipulated penalty of \$12,500. Patriot Seed, their cooperator, paid a stipulated penalty of \$3,750.

**Company/Institution: Monsanto**

Monsanto did not follow APHIS' permit conditions for border rows of cotton. The border rows on this field test were too small.

**Resolution:**

Once the infraction was detected, Monsanto destroyed all of the cotton. IES investigated and Monsanto paid a stipulated penalty of \$25,000. Monsanto's cooperators paid the following stipulated penalties: University of Tennessee \$3,750; Delta and Pine Land \$15,000; University of Georgia \$3,750.

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**1998**

**Company/Institution: University of Hawaii**

Contrary to assigned permit conditions, 15 papaya plants genetically engineered for virus resistance were allowed to grow on an experimental plot. APHIS was notified after the plants had been present for 3 to 5 months. Pollen from these 15 plants would have been able to fertilize nontransgenic trees. An APHIS inspector was sent to the site to investigate and determined that the nearest papaya trees were one-quarter of a mile away, which is an adequate isolation distance to prevent fertilizing nontransgenic

plants. The inspector also took immediate steps to cut down the 15 plants and remove all flowering parts containing pollen.

**Resolution:**

IES investigated the case and the University of Hawaii paid a stipulated penalty of \$500. A written warning had already been sent to the permit holder for infractions at another test site.

**Company/Institution: Monsanto**

Monsanto planted three GE crop field tests in Puerto Rico and one GE crop field test in Illinois without notifying APHIS. Several field tests included plants engineered with insect resistance. Other field tests included plants engineered with glyphosate resistance. The company also moved regulated GE material without notifying APHIS.

**Resolution:**

Monsanto accounted for all the GE corn seed. All the GE corn seed was either in storage or planted as a regulated article under a new APHIS permit. Monsanto destroyed any regulated articles in the field not under an APHIS permit. Monsanto improved their experimental tracking database and provided training for the relevant field personnel. IES investigated and Monsanto paid a stipulated penalty of \$2,500.

**1997**

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**Company/Institution: Monsanto**

Monsanto failed to monitor for canola volunteers in the year following a GE crop field test that modified the corn's oil profiles at numerous locations. The company also failed to notify APHIS within 24 hours once the lapse in monitoring was detected.

**Resolution:**

Monsanto removed the canola using herbicides. At one location, the volunteers were located within the isolation distance of a commercial birdseed canola crop. APHIS required the company to purchase and destroy the crop that could have been pollinated by the volunteers. APHIS also required Monsanto to monitor the sites for one year and destroy any additional volunteers. IES investigated the case and Monsanto paid a stipulated penalty of \$3,300.

**1995**

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**Company/Institution: Harvey Campbell and Associates, Inc.**

The company planted cotton seed with genetically engineered herbicide resistance in California without obtaining a permit or requesting permission to release the cotton into the environment. In addition, the company had received APHIS permission to move the cotton, but provided inaccurate information about the name and address of the person receiving the GE cotton seed. The 40-foot border rows of nontransgenic cotton surrounding the field test were harvested and pressed for oil, which was used in animal feed.

**Resolution:**

An APHIS officer visited the site to verify that all of the GE cotton plants were destroyed. All of the cotton seed and lint that was harvested from the GE crop was also ordered to be seized and destroyed. As a result of cross pollination, the 40-foot border rows of nontransgenic cotton could have contained some GE material, however, the cotton seed oil would have been free of all GE proteins. The case was referred to IES, and Harvey Campbell and Associates paid a stipulated penalty of \$500.

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Last Modified: May 29, 2008