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Southwest Region

Audit Report

United States Department of Agriculture
Controls over Importation of Transgenic Plants and Animals

Report No. 50601-17-Te
December 2008

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

December 12, 2008

REPLY TO
ATTN OF: 50601-17-Te

TO: Jeremy Stump
Senior Advisor to the Secretary for International and
Homeland Security Affairs and Biotechnology
Office of the Secretary

THROUGH: Michael Schechtman
Biotechnology Coordinator
Agricultural Research Service

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Controls over Importation of Transgenic Plants and Animals

This report presents the results of our audit of the Department of Agriculture's controls over importation of transgenic plants and animals. Your written response to the official draft report, dated November 26, 2008, is included in its entirety as exhibit C with excerpts and the Office of Inspector General's (OIG) position incorporated into the Findings and Recommendations section of the report. Your response contained sufficient information to reach management decision on Recommendation 2. Please follow your internal procedures in forwarding final-action correspondence to the Director, Planning and Accountability Division, Office of the Chief Financial Officer.

Based on the response, we cannot accept management decision on Recommendations 1 and 3. The information needed to reach management decision is set forth in the OIG Position section after each recommendation. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation for those recommendations for which management decision has not been reached. Please note that the regulation requires a management decision be reached for all recommendations within a maximum of 6 months from the date of report issuance. Final action on the management decisions should be completed within 1 year of the date of each management decision to preclude being listed in the Department's annual Performance and Accountability Report.

We appreciate your timely response and the courtesies and cooperation extended to us by members of your staff during the audit.

Executive Summary

Controls over Importation of Transgenic Plants and Animals (Audit Report No. 50601-17-Te)

Results In Brief

Due to its science-based regulatory system and the willingness of U.S. producers to adopt agricultural biotechnology, the United States has been in the forefront of developing transgenic plants and animals since the 1990s.[1] More recently, however, other nations have started to plant more acres to transgenic crops. They have also begun developing transgenic plants and animals of their own. Some of these new plants and animals will be unknown to, and therefore unapproved by, the U.S. regulatory system. As this trend continues, other nations could begin exporting—inadvertently or deliberately—unapproved transgenic plants or animals into the United States. While the consequences of unapproved transgenic plants or animals entering the U.S. food supply are difficult to foresee, such an event could provoke health and environmental concerns and interfere with commerce.

The Office of Inspector General (OIG) initiated this audit to determine if the Department of Agriculture's (USDA) controls over transgenic imports were effective enough to mitigate any risks from unapproved transgenic plants and animals.[2]

In the United States, the overall control framework for regulating the importation of transgenic plants and animals originated with the Coordinated Framework for the Regulation of Biotechnology of 1986, which assigned regulatory roles to USDA, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Within that framework, USDA has statutory authority over the importation of transgenic plants and animals into the country. The Department's authority is divided among two USDA agencies: the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS). While FSIS regulates the importation of meat, poultry, and egg products, APHIS regulates the importations of plants. The importation of live animals is also regulated by APHIS' Veterinary Services division.[3]

[1] Transgenic organisms are the result of the insertion of genetic material from another organism using genetic engineering techniques.

[2] Throughout this report, when we speak of "transgenic plants and animals," we are referring to the broad range of agricultural commodities that enter the United States and that may be produced from transgenic plants and animals. These commodities could include bulk commodities, processed foods, whole foods, seed, live plants and animals, etc.

[3] Public Law 106-224, "Agricultural Risk Protection Act of 2000," Title IV – "Plant Protection Act," section 402(3), dated June 20, 2000.
"Federal Meat Inspection Act," Title 21, *United States Code* (U.S.C.) - Food and Drugs, chapter 12 - Meat Inspection, sections 603(a) and 620(a).
"Poultry Products Inspection Act," 21 U.S.C. - Food and Drugs, chapter 10 - Poultry and Poultry Products Inspection, sections 455 and 467(b).
"Egg Products Inspection Act," 21 U.S.C. - Food and Drugs, chapter 15 - Egg Products Inspection, sections 1031, 1032, 1034(a), and 1049(a).
"Animal Health Protection Act," as amended through Public Law 108-498, 7 U.S.C. 8301, dated December 23, 2004.

For the importation of transgenic plants, we found that USDA agencies' controls are appropriate for the current risk associated with transgenic biotechnology and the extent to which that technology has been adopted by our trading partners. Importers are required to declare regulated transgenic plants, and they may be fined if they fail to do so. These controls have been adequate to meet the needs of a global market where most transgenic plants were developed in the United States. However, we found that USDA has no controls in place that would identify undeclared, regulated transgenic plants or identify a shipment of undeclared transgenic plants unknown to the U.S. regulatory system. We also found that USDA needs to formalize and consolidate its agencies' controls into an overall, departmental, import control policy.

For transgenic animals—both live animals and meat, poultry, and egg products—USDA has not established an import control policy. Concurrent with publication of draft regulatory guidance from FDA, APHIS published on September 19, 2008, a Request for Information on a series of questions regarding research on transgenic animals, any potential impacts on the health of livestock, and potential actions that APHIS should consider to complement FDA's draft guidance. However, according to the Department, no USDA regulations pertaining to transgenic animals have yet been developed. Departmental officials have noted that experimentation with transgenic animals is not as far along as with transgenic plants, and transgenic animals have not been commercialized. By formalizing its import control policy for transgenic animals, USDA could anticipate the import challenges that will arise as the technology for developing transgenic animals becomes more widely accessible.

At present, the Department does not have a strategy for monitoring new transgenic plants and animals that may be developed and imported into the United States. Departmental officials stated that they have not needed such a strategy because most transgenic plants were first developed within the U.S. regulatory system, and it was unlikely that anything unfamiliar would be imported. Recently, however, other nations have begun investing more heavily in biotechnology and developing transgenic plants outside the U.S. regulatory system. China, for example, has committed to investing $500 million in biotechnology by 2010 and has recently announced the creation of a new transgenic rice. To mitigate any risks to the U.S. environment, agriculture, and commerce from unapproved transgenic plants and animals entering the U.S. food supply, USDA will need to monitor such developments closely.

We are recommending that USDA develop and implement a strategy for monitoring the development of transgenic plants and animals abroad. That strategy should integrate the following ongoing, preexisting departmental activities:

- coordinating among USDA agencies and other Federal agencies with authority on this issue, including FDA and EPA;
- working with international entities like Codex Alimentarius (an international food standard-setting body);
- cooperating bilaterally with other countries invested in biotechnology research;
- performing vulnerability assessments so that it can prioritize risks and develop appropriate screening measures; and
- working with, and soliciting input and feedback from, nongovernmental organizations, including various trade organizations.

Over the past several Administrations, there has been an individual within the Secretary's office assigned responsibilities for overall policy leadership on biotechnology for the Department. This individual should take a leadership role in planning and coordinating on USDA-wide activities to assess and address risks posed to U.S. agriculture by a new, foreign transgenic plant or animal.

USDA needs to develop and implement such a monitoring strategy and strengthen its coordination with other Federal agencies to mitigate, or avoid, future risks to the U.S. environment, agriculture, and trade.

Recommendations In Brief

We recommend that the Department:

Formalize, at the departmental level, a control policy for all transgenic imports.

Develop and implement a strategy for monitoring the development of transgenic plants and animals in foreign nations. This strategy should integrate ongoing departmental actions, including (a) coordinating among USDA agencies and other Federal agencies, (b) working with international entities like Codex Alimentarius, (c) cooperating bilaterally with other countries invested in biotechnology research, (d) performing vulnerability assessments so that USDA can prioritize risks and develop appropriate screening measures, and (e) working with, and soliciting input and feedback from, nongovernmental organizations, including various trade organizations.

Develop procedures for regular interagency USDA consultations coordinated by the Office of the Secretary on potential actions that may be appropriate to address any emerging risks that particular new foreign transgenic plants or animals might pose to the United States.

Agency Response

In a memorandum dated November 26, 2008, the Department generally concurred with the findings and recommendations and provided proposed corrective actions. The Department's written response is included as exhibit C of the report.

OIG Position

We generally concur with the Department's response and accept management decision for one of the three recommendations contained in the report. We have explained in the OIG Position section to the recommendations the actions the Department needs to take for acceptance of management decision for each of the two open recommendations.

Abbreviations Used In This Report

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services
Codex	Codex Alimentarius Commission
EPA	Environmental Protection Agency
FAS	Foreign Agricultural Service
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
GAIN	Global Agriculture Information Network
GIPSA	Grain Inspection, Packers, and Stockyards Administration
IFIC	International Food Information Council
OIG	Office of Inspector General
PPQ	Plant Protection and Quarantine
USDA	Department of Agriculture
VS	Veterinary Services

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Background and Objective

Background

In 1986, the U.S. Government established the Federal Coordinated Framework for the Regulation of Biotechnology, which divided the responsibilities for regulating transgenic plants and animals. The Environmental Protection Agency (EPA) monitors transgenic plants designed to produce pesticides; the Food and Drug Administration (FDA) determines the safety of transgenic plants and animals for human consumption; and the Department of Agriculture (USDA) regulates the importation of transgenic plants and animals.[4]

After September 11, 2001, the Customs and Border Protection, within the Department of Homeland Security, assumed responsibility for preventing terrorists and terrorist weapons from entering the United States, while also facilitating legitimate trade and travel. USDA provides the Customs and Border Protection with regulations, policies, and procedures relating to certain agricultural import and entry inspection functions.

Within USDA, the most senior official responsible for biotechnology is currently the Senior Advisor to the Secretary for International and Homeland Security Affairs and Biotechnology, who provides "leadership in the planning, initiation, and execution of biotechnology policy and operations for the Department." Two agencies within the Department exercise controls over the importation of transgenic plants and animals.

Animal and Plant Health Inspection Service (APHIS)

APHIS regulates imports of transgenic plants and live animals.[5] APHIS has three program offices with responsibilities over transgenic food and agricultural imports—Biotechnology Regulatory Services, Plant Protection and Quarantine, and Veterinary Services. APHIS coordinates these responsibilities along with the other designated Federal agencies.

Biotechnology Regulatory Services (BRS)

BRS derives its authority to regulate items that might be plant pests from the Plant Protection Act.[6] Under this authority, BRS regulates introductions of transgenic organisms, which include

[4] Public Law 106-224, "Agricultural Risk Protection Act of 2000," Title IV – "Plant Protection Act," section 402(3), dated June 20, 2000.
"Federal Meat Inspection Act," Title 21, United States Code (U.S.C.) – Food and Drugs, chapter 12 – Meat Inspection, sections 603(a) and 620(a).
"Poultry Products Inspection Act," 21 U.S.C. – Food and Drugs, chapter 10 – Poultry and Poultry Products Inspection, sections 455 and 467(b).
"Egg Products Inspection Act," 21 U.S.C. – Food and Drugs, chapter 15 – Egg Products Inspection, sections 1031, 1032, 1034(a), and 1049(a).
"Animal Health Protection Act," as amended through Public Law 108-498, 7 U.S.C. 8301, dated December 23, 2004.
[5] Title 7, *Code of Federal Regulations*, chapter III, part 340, section 340.3(b), January 1, 2005, edition.
[6] Public Law 106-224, "Agricultural Risk Protection Act of 2000," Title IV – "Plant Protection Act," section 402(3), dated June 20, 2000.

imports, interstate movements, and field tests.[7] BRS is responsible for regulating the introduction of transgenic plants that are regulated articles. According to APHIS, most transgenic plants are regulated by BRS, and they fall under regulations to enable BRS to determine if they pose a risk as plant pests. If a transgenic plant has been deregulated, then BRS exercises no controls over its importation, as that plant may be freely commingled with its nontransgenic equivalent.

When importers bring regulated transgenic plants into the United States, they are required to declare the regulated nature of the import. BRS has the authority to issue permits, notifications, and shipping labels for imports of these regulated articles.

In fiscal year (FY) 2007, BRS issued 36 permits and 237 notifications for the importation of regulated transgenic plants into the United States.

Plant Protection and Quarantine (PPQ)

PPQ's mission is to safeguard the Nation's agricultural and natural resources from the risks associated with the entry, establishment, or spread of exotic plant pests, diseases, pathogens, and noxious weeds. PPQ carries out this important mission by regulating, according to international standards, the importation of plants, seeds, and other plant products into the United States.

PPQ is responsible for issuing permits for the importation, transit, and domestic movement of plants and plant parts. It is responsible for performing inspections of propagative seeds and plants, and also inspects regulated items for BRS.

Veterinary Services (VS)

VS' mission is to protect and improve the health, quality, and marketability of our Nation's animals, animal products, and veterinary biologics by preventing, controlling, and eliminating animal diseases, and monitoring and promoting animal health and productivity. One of the tools it uses to accomplish this mission is the inspection of imports. VS maintains ports of entry dedicated to the importation of animals. Of the 65 VS ports, 35 are located along the Canadian and Mexican borders.

[7] Title 7, *Code of Federal Regulations*, chapter III, part 340, January 1, 2005, edition.

Imports are divided into three categories—live animals, animal products, and pets. The live animal restrictions apply mainly to birds, dogs, cattle, horses, sheep, and fish. Each type of animal has its own import restrictions varying from written certifications for sheep to 60-day quarantines for some horses. VS must also notify FDA of live food animal imports.

Food Safety and Inspection Service (FSIS)

FSIS is responsible for ensuring that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS operates under the Federal Meat Inspection Act,[8] the Poultry Products Inspection Act,[9] and the Egg Products Inspection Act.[10] FSIS evaluates foreign inspection practices to ensure that they are equivalent to U.S. practices.

Additionally, USDA participates in the Codex Alimentarius Commission (Codex), which is an international food standard-setting body. According to departmental officials, Codex standards are based on international scientific expert consensus. Codex standards have become the benchmarks against which national food measures and regulations are evaluated within the legal parameters of World Trade Organization agreements. There are eight Codex standards relating to transgenic food and agricultural imports (see exhibit A).

Participation in the Codex process is important because, through such participation, the United States can try to ensure that international standards are based on science and do not become artificial trade barriers. The Codex process also ensures consistency across borders and provides assurance that each country signing the agreement is in accordance with the agreed-upon standards. While Codex standards do not have a binding effect on national legislation, member countries can use these standards as support during trade dispute resolution. For example, according to the Department, the existence of Codex standards was helpful to the United States and co-complainants in their successful challenge of European Union trade practices regarding import of transgenic plant products, although the case was not based strictly on adherence to Codex guidelines.

Finally, USDA participates in workgroups and committees that meet on worldwide various transgenic topics (see exhibit B). As with Codex workgroups, new developments in transgenic plants and animals may be discussed at these workgroups, but there is no mechanism for monitoring such developments, assessing any potential risk, and reporting to the

[8] "Federal Meat Inspection Act," 21 U.S.C. - Food and Drugs, chapter 12 - Meat Inspection, sections 603(a) and 620(a).
[9] "Poultry Products Inspection Act," 21 U.S.C. - Food and Drugs, chapter 10 - Poultry and Poultry Products Inspection, sections 455 and 467(b).
[10] "Egg Products Inspection Act," 21 U.S.C. - Food and Drugs, chapter 15 - Egg Products Inspection, sections 1031, 1032, 1034(a), and 1049(a).

Secretary on unapproved transgenic agricultural commodities that may be imported into the United States.

Objectives

Our audit objectives were to identify USDA's controls for minimizing the risk of importing unapproved transgenic plants and animals, and assess the effectiveness of those controls.

Findings and Recommendations

Section 1. USDA Needs a Strategy for Monitoring the Importation of Transgenic Plants and Animals Developed Outside the U.S. Regulatory System

Finding 1

USDA does not have a strategy for monitoring transgenic plants and animals that are developed outside the U.S. regulatory system and may be imported into the United States. Departmental officials have stated that USDA does not have such a strategy because, in the past, it has not needed one—most transgenic plants and animals have been developed within the United States and under the U.S. regulatory system. As these circumstances change and other nations start to develop transgenic plants and animals—the number of biotech countries, crops, and traits is expected to double between 2006 and 2015—USDA will need to closely monitor these developments to prevent any risks to the U.S. environment, agriculture, and commerce.

One goal of USDA's strategic plan is to enhance protection of the Nation's agricultural and food supply. The coordinated framework[11] is interpreted by USDA officials to give USDA the lead role in assessing the potential effects of nonpesticidal transgenic plants on other plants and animals in both agricultural and nonagricultural environments.[12] Likewise, USDA has statutory authority over the movement of live animals or meat into, within, or through the United States, including animals developed through genetic engineering.[13]

At this time, USDA's controls over the importation of transgenic plants are appropriate for the current risk associated with transgenic biotechnology and the extent to which that technology has been adopted by our trading partners throughout the world. Deregulated transgenic plants—those that the appropriate regulatory agency has determined are no different from their nontransgenic equivalents—are subject to no additional controls at the point of entry apart from routine phytosanitary certification, as is appropriate under the U.S. regulatory system. Regulated transgenic plants must be declared by the importer, and APHIS' BRS then provides labels for the shipment. (See sample label on the following page.)

[11] "Coordinated Framework for the Regulation of Biotechnology," dated June 26, 1986.
[12] National Research Council, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulations*, National Academy Press, Washington, D.C., 2002, p. 19.
[13] "Federal Meat Inspection Act," 21 U.S.C. - Food and Drugs, chapter 12 - Meat Inspection, sections 603(a) and 620(a). "Animal Health Protection Act," as amended through Public Law 108-498, 7 U.S.C. 8301, dated December 23, 2004.

Example: Import Label (Shipping) for Genetically Engineered Organisms

If the importer fails to disclose regulated transgenic plants, USDA may assess penalties, including civil penalties up to $50,000 or twice the gross gain of any violation.[14]

Although controls relating to the importation of regulated, transgenic plants exist at the agency level, USDA needs to formalize and consolidate its control policy at the departmental level. Similarly, USDA has not formally established a control policy for the importation of transgenic animals, both live animals and meat, poultry, and egg products. The regulation concerning the importation of transgenic animals dates from the Coordinated Framework for Regulation of Biotechnology in 1986. Concurrent with publication of draft regulatory guidance from FDA, APHIS published on September 19, 2008, a Request for Information on a series of questions regarding research on transgenic animals, any potential impacts on the health of livestock, and potential actions that APHIS should consider to complement FDA's draft guidance.

However, according to the Department, no USDA regulations pertaining to transgenic animals have yet been developed. Departmental officials have noted that experimentation with transgenic animals is not as far along with transgenic plants—no transgenic animals have been deregulated and commercialized. Although transgenic animals are not currently being imported and exported like transgenic plants, agency officials have indicated that eventually they will be. By formalizing its import control policies—for all transgenic imports—the Department could identify the challenges that will arise as transgenic plants and animals are developed in foreign regulatory systems.

In the United States, when scientists develop a transgenic plant and intend to use it outside the laboratory in which it was developed, it is regulated and tested within the Government's science-based regulatory system until it is

[14] Public Law 106-224, "Agricultural Risk Protection Act of 2000," Title IV - Plant Protection Act, section 402(3), dated June 20, 2000.

determined that the new plant is not substantially different from its nontransgenic equivalent. At this point, the transgenic plant may be deregulated and commercialized if the developer so requests.

Foreign countries have different systems for regulating the development of new transgenic plants. These systems can vary from countries with strict, science-based processes for approving transgenic plants and animals to countries with less stringent standards. If a company develops a transgenic plant abroad and wishes to import that commodity into the United States, it can apply to the appropriate U.S. regulatory agency, which would determine whether the transgenic plant meets U.S. standards and is as safe as its nontransgenic equivalent.[15] A transgenic plant that meets these standards could be imported and would not be subject to additional regulation.

According to USDA officials, this relationship between the United States and foreign regulatory systems has worked well. According to the 2006 Pew report, "[f]or more than a decade, the United States has led the world in developing and cultivating genetically engineered . . . plants for agricultural applications."[16] U.S. producers have planted more acres to transgenic plants than any other nation. In 2007, U.S. producers planted 142.5 million acres to transgenic crops, which was 50 percent of the global biotech acreage. When producers in other countries have planted transgenic crops, they have usually tended to plant varieties developed under the U.S. regulatory system. Our analysis showed that the top five transgenic crops from the top five transgenic-producing countries had been deregulated in the United States.

As transgenic plants win broader acceptance and transgenic technologies become more widely available, other nations have begun to plant more and more acres to transgenic crops. From 2006 to 2007, developing nations switched to biotech production at a much higher rate (21 percent growth in total hectares planted to biotechnology) than industrial countries (6 percent). Rising commodity prices have also persuaded formerly reluctant markets to import transgenic products. Japan and South Korea have, for example, recently agreed to import U.S. transgenic corn for manufacturing sweeteners and starch, and China is moving towards approving transgenic rice for human consumption.

More importantly from a regulatory standpoint, researchers in other countries have begun to experiment with new varieties of transgenic plants. China, for example, has committed to investing $500 million in biotechnology from 2006 to 2010, and this investment has begun to show results. On March 19, 2008, scientists at Zhejiang University in Hangzhou, China, published a paper describing a new method to control the unintended

[15] The appropriate regulatory agency would be USDA, FDA, or EPA, depending on the transgenic plant or animal and its intended use.
[16] Pew Initiative on Food and Biotechnology Report entitled "Commercial, Safety and Trade Implications Raised by the Importation of Genetically Engineered Ingredients, Grain or Whole Foods for Food, Feed or Processing" from roundtable discussion held September 7-8, 2006.

spread of transgenic rice through inadvertent pollen or seed dispersal. To keep conventional rice production segregated from transgenic rice planted for pharmaceutical or industrial protein production, Chinese scientists have used genetic engineering to make rice susceptible to bentazon, a common herbicide used to kill weeds in rice fields. (Conventional rice is highly tolerant of bentazon.) Using the new process, producers will spray conventional rice fields with bentazon which will kill both normal weeds and any genetically engineered rice that had been altered for drug or industrial uses. Only conventional rice plants will live. Potentially, this development could help address many environmental and food safety concerns relating to transgenic crops. However, this transgenic rice has not been developed inside the U.S. regulatory system and is not approved and deregulated under that system.

In the future, foreign scientists will continue to develop transgenic plants and animals—like the bentazon-susceptible rice—which will need to be reviewed and approved by the U.S. regulatory system. Those unapproved transgenic plants and animals could be imported into the United States, perhaps inadvertently, or perhaps deliberately. While USDA's controls for monitoring the importation of unapproved transgenic plants and animals are appropriate for a market where most transgenic commodities are developed in the United States, they will not be adequate for a globalized market where scientists in a number of foreign countries are developing new plants and animals.

Any monitoring or regulation of an unapproved transgenic plant or animal is greatly complicated by the fact that any given transgenic commodity appears identical to its nontransgenic equivalent, and there is no simple test to identify a transgenic plant or animal. Simple tests for identifying a transgenic plant rely on proprietary information concerning unique proteins in that plant's genetic sequence. These tests are inexpensive and quick, but one must obtain the specific test for the transgenic plant in question—the scientists responsible for making the new transgenic commodity usually also develop such a test. Since unapproved transgenic plants might very well be unknown in the country into which they are being imported, obtaining these tests could be extremely difficult, or even impossible.

At present, the risks associated with the importation of unapproved transgenic plants or animals into the United States are unknown. However there is a risk that such an event could potentially adversely impact the U.S. environment, food supply, and trade. For example, U.S. producers lost trade because domestically produced transgenic plants unapproved for human consumption were discovered in shipments thought to contain only nontransgenic plants. When Liberty Link (LL601) transgenic rice was found

in U.S.-grown, nontransgenic rice, U.S. rice producers lost approximately 41 percent of their export market due to concerns about the safety of this rice.

USDA has begun to prepare for challenges that will arise as more nations begin to experiment with biotechnology and develop their own varieties of transgenic plants and animals. In its draft environmental impact statement,[17] APHIS has considered updating its current regulations "to address current and future technological trends resulting in GE plants with which [APHIS] is less familiar." Some of these considered updates are related to transgenic commodities developed in other nations and under other regulatory systems. For example, APHIS is proposing:

- Creating a tiered system to classify transgenic plants based on their risk and familiarity so that Government oversight can vary by category;

- Regulating nonviable plant material (e.g., cell debris, leaves, stems, roots seeds) from transgenic field tests if those materials might pose environmental or human health risks;

- Codifying agency actions should regulated transgenic plant material be found in commercial shipments of commodities; and

- Determining how the United States will handle transgenic plants that have received all necessary approval in their country of origin.

APHIS had proposed publishing these regulations in the Federal Register in 2008. Once the public has had an opportunity to comment on these proposed regulations, they could be finalized.

While OIG agrees that these proposed regulations are positive and necessary steps for responding to international advances in biotechnology, each of these proposed regulations depends on USDA's knowledge of new transgenic plants and animals. Unless international developments in transgenic plants and animals are closely monitored, USDA could be unaware of potential threats that particular new transgenic plants or animals might pose to the Nation's food supply should those plants or animals enter the country.

For this reason, we are recommending that USDA develop and implement a strategy for monitoring the development of transgenic plants and animals abroad. That strategy should integrate the following ongoing, preexisting departmental activities:

[17] "Introduction of Genetically Engineered Organisms Draft Programmatic Environmental Impact Statement," dated July 2007.

- coordinating among USDA agencies and other Federal agencies, such as FDA and EPA;
- working with international entities like Codex Alimentarius;
- cooperating bilaterally with other countries invested in biotechnology research;
- performing vulnerability assessments so that it can prioritize risks and develop appropriate screening measures; and
- working with, and soliciting input and feedback from, nongovernmental organizations, including various trade organizations.

Over the past several Administrations, there has been an individual within the Secretary's office assigned responsibilities for overall policy leadership on biotechnology for the Department. This individual should take a leadership role in planning and coordinating on USDA-wide activities to assess and address risks posed to U.S. agriculture by a new, foreign transgenic plant or animal.

USDA has a number of resources that it could draw upon as it implements such a monitoring strategy. Employees working for USDA routinely attend international Codex meetings, where they participate in discussions that may mention varieties of transgenic plants and animals being developed abroad. Other scientists working for USDA also participate in international activities where they may learn of such developments. Finally, the Foreign Agricultural Service (FAS) receives more than 3,000 Global Agriculture Information Network (GAIN) reports annually from its foreign service officers in 80 countries. These GAIN reports often contain information relating to biotechnology and are widely distributed to those in USDA concerned with biotechnology affairs. However, summaries from multiple reports are not routinely prepared for policymakers.

Although USDA participates in numerous departmental, interagency, and international working groups with interests in biotechnology, there is no mechanism for monitoring new developments in transgenic plants and animals, assessing any potential risk, and reporting to the Secretary on unapproved transgenic agricultural commodities that may be imported into the United States. USDA should, as part of its strategy for monitoring the importation of unapproved transgenic commodities, develop and implement a process for collecting, summarizing, and distributing information from USDA scientists and other personnel.

When we discussed with USDA's Biotechnology Coordinator the possibility of the Department monitoring the development of unapproved commodities, he offered the view that there could be instances where specific monitoring may have a role in regulation or trade in the future. OIG believes that, by developing such a strategy, USDA can help mitigate, or avoid, potential risks to the U.S. environment, agriculture, and trade.

Recommendation 1

Formalize, at the departmental level, a control policy for all transgenic imports.

Agency Response

The Department's written response, dated November 26, 2008, stated the USDA, as a whole, supports this recommendation. The Department recognizes there may be a benefit in making the policy more transparent, thereby enhancing public confidence. However, to act upon this recommendation, the incoming Administration, with key appointments, will need to be in place and thoroughly briefed before adequately vetting such a policy.

OIG Position

We cannot accept the management decision for Recommendation 1. Although the Department agreed with the concept of making a control policy more transparent, it provided no information or specificity as to the direction or content of this policy statement. The specific information as to what the control policy would incorporate, as well as an estimated date for issuance of the policy, needs to be provided.

Recommendation 2

Develop and implement a strategy for monitoring the development of transgenic plants and animals in foreign nations. This strategy should integrate ongoing departmental actions, including (a) coordinating among USDA agencies and other Federal agencies, (b) working with international entities like Codex Alimentarius, (c) cooperating bilaterally with other countries invested in biotechnology research, (d) performing vulnerability assessments so that it can prioritize risks and develop appropriate screening measures, and (e) working with, and soliciting input and feedback from, nongovernmental organizations, including various trade organizations.

Agency Response

The Department's written response, dated November 26, 2008, stated this recommendation will involve compiling information from a number of ongoing USDA activities. It may also require expanding some existing activities, which may in turn require some new assignments of responsibilities and reprioritizations of resources, and bringing other agencies outside USDA on board with the recommendation. USDA will compile the results of ongoing activities in these areas through its

biotechnology coordination group (or a successor group under a new Administration) and will provide OIG with an agenda for the first meeting at which this task will be discussed. USDA will also provide an overall summary of results from a first survey of these activities and an overall strategy with implementation plan cleared by the Office of the Secretary. The Department expects to have these actions completed by November 30, 2009.

OIG Position

We accept the management decision for Recommendation 2.

Recommendation 3

Develop procedures for regular interagency USDA consultations coordinated by the Office of the Secretary on potential actions that may be appropriate to address any emerging risks that particular new foreign transgenic plants or animals might pose to the United States.

Agency Response

The Department's written response, dated November 26, 2008, stated USDA supports this recommendation and will develop a plan for holding the recommended consultations on a regular basis, utilizing information gathered under the response to Recommendation 2, identifying when actions may be necessary, and describing appropriate procedures to address any risks. Meaningful progress on this recommendation will need to await the arrival of a new USDA Secretary and appointment of key senior staff, including the incoming Secretary's designated coordinator for biotechnology issues, briefing these key personnel on the topic of emerging risks, and developing appropriate procedures for consultants.

OIG Position

We cannot accept the management decision for Recommendation 3. Although we agree with the planned corrective action, an estimated date for issuance of the procedures needs to be provided.

Scope and Methodology

Our audit covered USDA's controls over transgenic agricultural imports. Fieldwork began on October 1, 2007, and ended on April 7, 2008. USDA agencies reviewed were APHIS, AMS, FAS, FSIS, and the GIPSA.

To accomplish our audit objective, we interviewed officials and reviewed supporting documentation obtained from these agencies. These interviews were conducted in Washington, D.C., and Riverdale, Maryland. We did not interview APHIS VS officials, but obtained information from the Biotechnology Coordinator for the Department. We also interviewed EPA, FDA, and Customs and Border Protection officials, along with officials from three nongovernmental organizations—the Union of Concerned Scientists, the Center for Science and Public Interest, and the American Seed Trade Association—and two USDA scientists to gain their perspectives on transgenic agricultural imports.

We reviewed Federal regulations, agency policies and procedures, and other documentation, such as reports from transgenic work groups and attaché reports from countries producing transgenic agricultural products. After the familiarization and identification phases,

- We analyzed FY 2007 data for 273 regulated articles and databases containing information on transgenic crops. Our analysis showed that only 36 permits were issued for regulated articles entering the U.S during FY 2007—notifications were issued for the remaining 237 regulated articles that were imported. According to BRS, notifications are issued for items it has determined to have lower risk and have extensive experience regulating.

- We judgmentally selected for further analysis the top five transgenic crops from the top five transgenic-producing countries based on acreage. We found that all of the crops we selected had already been deregulated in the United States.

- We selected a sample of at least one regulated transgenic crop variety for each of the top transgenic crops for analysis. We determined that, for all five, the crops and the traits were the same as those that have already been approved in the United States.

We conducted this performance audit in accordance with generally accepted Government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. The evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995) - Food inspection and certification systems should be used wherever appropriate to ensure foods and their production systems meet requirements in order to protect consumers against food-borne hazards, deceptive marketing practices, and to facilitate trade on the basis of accurate product description.

Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) - Guidelines provide a framework for the development of import and export inspection and certification systems consistent with the *Principles for Food Import and Export Inspection and Certification.* They are intended to assist countries in the application of requirements and the determination of equivalency.

Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food (CAC/GL 27-1997) - Guidelines provide a framework for the implementation of quality assurance measures to ensure the competence of testing laboratories involved in the import and export control of foods. These guidelines are intended to assist countries in the application of requirements for trade in food stuffs in order to protect the consumers and to facilitate fair trade.

Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34 –1999) - Document provides practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems.

Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) - Risk analysis process for foods derived from modern biotechnology should be consistent with the Codex Working Principles for Risk Analysis. These principles discuss elements of risk assessment, risk management, and risk communication as related to foods derived from modern biotechnology.

Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) - Describes recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists. Guidelines also identify the data and information that are generally applicable to making such assessments.

Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003) - Recombinant-DNA microorganisms that are used to produce foods are typically derived using the techniques of modern biotechnology from strains that have a history of safe, purposeful use in food production. In instances where the recipient strains do not have this history, safety will have to be established.

Guidelines for Food Import Control Systems (CAC/GL 47-2003, REV.1-2006) - Guidelines provide a framework for the development and operation of an import control system to protect consumers and facilitate fair practices in food trade while ensuring unjustified technical barriers to trade are not introduced.

Exhibit B – Examples of Workgroup Participation

Pew Initiative on Food and Biotechnology was a nonprofit food and biotech project that was created in 2001 by The Pew Charitable Trusts. Pew concluded its work in 2007. The initiative was established as an independent and objective source of credible information on agricultural biotechnology for the public, media, and policymakers. It produced over 20 reports, fact sheets, and briefings that covered safety issues and the social, economic, political, or ethical impacts of genetically manipulated flora and fauna.

The Interagency Working Group on Import Safety, made up of senior administration officials, was established by Executive Order on July 18, 2007, to conduct a comprehensive review of current import safety practices and determine where improvements can be made. The working group, chaired by the Secretary of Health and Human Services, reviewed what is being done and what can be done to promote import safety at three stages: in the exporting country, by companies importing into the United States, and by Federal, State, and local governments.

The International Food Information Council (IFIC) Foundation is the educational arm of IFIC. IFIC's mission is to communicate science-based information on food safety and nutrition to health and nutrition professionals, educators, journalists, Government officials, and others providing information to consumers. IFIC is supported primarily by the broad-based food, beverage, and agricultural industries. Biotechnology activities include the brochure "Food Biotechnology: Enhancing Our Food Supply," various articles in *Food Insight Magazine*, and a chapter in the 2007-2009 IFIC Foundation Media Guide on Food Safety and Nutrition about food biotechnology.

USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Washington, DC 20250

MEMORANDUM

NOV 26 2008

TO: Robert W. Young
Assistant Inspector General
for Audit

FROM: Cindy J. Smith
Administrator

SUBJECT: Response on OIG Report, "United States Department of Agriculture Controls over Importation of Transgenic Plants and Animals" (50601-17-TE)

Thank you for the opportunity for the United States Department of Agriculture (USDA) to provide comment on the above-titled Office of Inspector General (OIG) report. We believe that this audit provides a fair representation of the issues surrounding the importation of genetically engineered (GE) animal and plants and their products. USDA appreciates OIG's careful work on this audit.

This response has been discussed and vetted with representatives of a number of USDA agencies, including the Animal and Plant Health Inspection Service; Agricultural Research Service; Cooperative State Research, Education and Extension Service; Economic Research Service; Food Safety and Inspection Service; Foreign Agricultural Service; Forest Service; and Grain Inspection, Packers and Stockyards Administration; as well as coordinated with the Secretary's office on International and Homeland Security Affairs and Biotechnology, now the Deputy Chief of Staff.

Recommendation 1: Formalize, at the department level, a control policy for all transgenic imports.

USDA, as a whole, supports the Recommendation to formalize a control policy for all transgenic imports which could assist in anticipating any import challenges. We recognize there may be a benefit in making the policy more transparent, thereby enhancing public confidence. We also note that OIG acknowledges "For the importation of transgenic plants, we found that USDA agencies" controls are appropriate for the current risk associated with transgenic biotechnology and the extent to which that technology has been adopted by our trading partners. Importers are required to declare regulated transgenic plants, and they may be fined if they fail to do so. These controls have been adequate to meet the needs of a global market where most transgenic plants were developed in the United States."

It should be noted however, that in order to act upon this Recommendation, the incoming Administration, with key appointments, will need to be in place and thoroughly briefed before adequately vetting such a policy.

Recommendation 2: Develop and implement a strategy for monitoring the development of transgenic plants and animals in foreign nations. This strategy should integrate ongoing departmental actions, including (a) coordinating among USDA agencies and other Federal agencies, (b) working with international entities like Codex Alimentarius, (c) cooperating bilaterally with other countries invested in biotechnology research, (d) performing vulnerability assessments so that it can prioritize risks and develop appropriate screening measures, and (e) working with, and soliciting input and feedback from, nongovernmental organizations, including various trade organizations.

As OIG noted, this Recommendation will involve compiling information from a number of ongoing USDA activities. It may also require expanding some existing activities, which may in turn require some new assignments of responsibilities and reprioritization of resources, and bringing other agencies outside USDA on board with the OIG recommendation. USDA will compile the results of ongoing activities in these areas through its Biotechnology Coordination Group (BCG) (or a successor group under a new Administration) and will provide OIG with an agenda for the first meeting at which this task will be discussed. USDA will also provide an overall summary of results from a first survey of these activities and an overall strategy with implementation plan cleared by the Office of the Secretary. We expect to have these actions completed by November 30, 2009.

Recommendation 3: Develop procedures for regular interagency USDA consultations coordinated by the Office of the Secretary on potential actions that may be appropriate to address any emerging risks that particular new foreign transgenic plants or animals might pose to the United States.

USDA supports this Recommendation and will develop a plan for holding the recommended consultations on a regular basis, utilizing information gathered under the response to Recommendation 2, identifying when actions may be necessary, and describing appropriate procedures to address any risks. Meaningful progress on this Recommendation will need to await the arrival of a new USDA Secretary and appointment of key senior staff, including the incoming Secretary's designated coordinator for biotechnology issues, briefing these key personnel on the topic of emerging risks, and developing appropriate procedures for consultations.