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Office of Inspector General
Southwest Region

Audit Report

USDA's Role in the Export of Genetically Engineered Agricultural Commodities

Report No. 50601-14-Te
February 2009



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250



February 20, 2009

REPLY TO

ATTN OF: 50601-14-Te

TO: Katherine Smith
Acting Deputy Under Secretary
for Research, Education and Economics

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

SUBJECT: USDA's Role in the Export of Genetically Engineered Agricultural Commodities

This report presents the results of the subject audit. The Secretary of Agriculture's written response to the report, dated January 27, 2009, is included in its entirety as exhibit C with excerpts and the Office of Inspector General's (OIG) position incorporated into the relevant Findings and Recommendations section of the report.

We appreciate the Secretary's response agreeing to develop a comprehensive strategy relating to the export of genetically engineered agricultural commodities. In order to accept management decision on the recommendations, we need additional information. Documentation and actions needed to reach management decisions for these recommendations are described in the OIG Position sections of the report.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned and the timeframes for implementing those recommendations for which management decision has not been reached. Please note that the regulation requires a management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent 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

USDA's Role in the Export of Genetically Engineered Agricultural Commodities (Audit Report No. 50601-14-Te)

Results in Brief

U.S. producers have adopted new varieties of crops that have been genetically engineered (GE) to possess traits that improve production, reduce costs, protect the environment, and increase revenue. Over the last decade, GE plantings in the United States have increased from 3.6 million acres to 143 million acres. In 2007, American producers alone accounted for 50 percent of GE plantings worldwide. Even as GE varieties of common food crops such as corn and soybeans have become increasingly important to the U.S. agricultural economy, food commodities derived from GE plants face significant export barriers in many markets, including the markets of major U.S. trading partners such as the European Union (EU).

These trade barriers result from different regulatory approaches to this new technology. Nations like those in the EU have argued that governments should approach GE food commodities with caution, treat them differently from non-GE food commodities, and label these products so that consumers can distinguish between them. For those who advocate this “precautionary principle,” governments should regulate GE food commodities, even if there are no demonstrable grounds for concern.

The U.S. approach for regulating biotechnology products directs that GE food products should continue to be regulated according to their characteristics and unique features, not according to their method of production. Thus, Animal and Plant Health Inspection Service (APHIS) grants nonregulated status if the GE organism poses no more of a plant pest risk than an equivalent non-GE organism and the developer provides the information that it believes is adequate to ensure that the product is safe and complies with the relevant provisions of the Food, Drug, and Cosmetic Act. Henceforth, that GE food product is subject to no additional (or no different) regulatory processes.

In 2006, the United States, along with Canada and Argentina, argued before the World Trade Organization (WTO)¹ that the EU had adopted a general moratorium on all new biotech products and separate product-specific moratoria on each new biotech product. The EU also did not implement its own regulations to allow for review of biotech applications to take place. The WTO Panel found that the EU had adopted a moratorium on the final approval of biotech products and that the EU had presented no scientific or regulatory justification for the moratorium. The WTO Panel also identified

¹ In May 2003 the United States, Canada, and Argentina filed a WTO case against the EU over its illegal moratorium on approving agricultural biotech products and EU member states' unjustified bans of previously approved products.

“undue delays” regarding pending product applications. Although the United States and the EU continue to negotiate to remove trade barriers for these commodities, those barriers are still in effect and still act to keep U.S. GE agricultural commodities out of many EU markets.

Given these market conditions, the Office of Inspector General (OIG) initiated this audit to assess the Department of Agriculture’s (USDA) role in promoting the export of GE agricultural commodities. While producers and private companies are the primary economic agents in a free market, they are at a significant disadvantage when dealing with barriers that have been imposed by foreign governments. The U.S. Government and USDA have an important role to play in negotiating with other nations to remove, resolve, or mitigate these barriers.

USDA has identified promoting the international competitiveness of American agriculture as a strategic goal. USDA’s 2006 Annual Performance and Accountability Report stated that “[e]xpanding global markets for agriculture products is critical for the long-term economic health and prosperity of the domestic food and agriculture sector.” Congress also recognized the importance of global trade in the 2002 Farm Bill and included provisions specifically relating to agriculture biotechnology because of its growing importance to trade. The 2002 Farm Bill required USDA to develop a global marketing strategy and a biotechnology and agricultural trade program designed to remove, resolve, or mitigate barriers to the export of U.S. commodities. It also required USDA to fund public education on the benefits of agricultural biotechnology, as well as research into the effects of biotechnology on the environment and how biotechnology can be used in developing countries. The recently enacted 2008 Farm Bill still required most of the 2002 Farm Bill provisions dealing with biotechnology; however, it did repeal the biotechnology and agricultural trade program and the program to fund public education on the benefits of agricultural biotechnology.

Numerous USDA agencies, public and private groups, and committees appointed by the Secretary of Agriculture have discussed the impact of agriculture biotechnology on American agriculture, the environment, and trade since at least 2000 (see exhibit B). Outside USDA, the Office of Science and Technology Policy (OSTP),² the Congressional Research Service (CRS),³ and the Government Accountability Office (GAO)⁴ published papers and reports identifying the challenges producers face when planting and exporting GE crops. They also identified the specific challenges USDA must address to assist producers in expanding trade opportunities (see Findings 1 and 2).

² OSTP, “Food and Agricultural Biotechnology Initiatives: Strengthening Science-Based Regulation,” May 3, 2000.

³ CRS, “U.S. Agricultural Biotechnology in Global Markets: An Introduction,” June 19, 2003.

⁴ GAO-01-727, “International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports,” June 2001.

Despite these discussions, USDA has not developed a coordinated, comprehensive strategy for addressing the various challenges to the trade in agricultural commodities, including GE commodities, and there is limited evidence that USDA has made measurable progress in fulfilling the various biotechnology goals of the 2002 Farm Bill. USDA's research and public information accomplishments relating to exporting these commodities are limited, and are not targeted towards any specific goal or trade challenge. We could not determine the progress made in, or the effectiveness of, USDA's biotechnology trade-related activities because USDA has not developed performance measures tied to any specific goal or objective.⁵

Departmental officials responsible for providing leadership and direction on biotechnology-related activities within USDA advised that they have not developed such a strategy because they believe that USDA should not be involved in controlling the market and, instead, should focus on facilitating the operation of the market. Department officials have argued that private entities are more responsive to market conditions, and that responding to the market should be left to them. Other representatives of industry and Government we interviewed disagreed and stated that a USDA strategy for promoting the export of GE agricultural commodities is essential. We agree that such a strategy should not be geared to controlling the market, but, as the Department states, to facilitate trade opportunities.

We found that market conditions for U.S. agricultural commodities have varied significantly over the past several years. Although the U.S trade balance in agricultural goods was declining from 1996 to 2006, the weakening of the dollar, poor harvests due to adverse weather conditions and strong demand in the world economy have combined to strengthen U.S. agricultural exports. In 2007 agricultural exports increased to \$82.2 billion and USDA is currently forecasting agricultural exports totaling \$114 billion in 2008. Even some nations formerly reluctant to import U.S. GE commodities have found the increased demand and shortage of supply a strong incentive to do so. However, the market for these commodities has proved to be especially volatile, and is subject to sudden shifts in demand, such as when types of GE rice and corn not intended for human consumption were found in the food supply.

Developing a coordinated, comprehensive strategy for promoting the export of U.S. GE crops should prove beneficial to U.S. producers in such volatile market. As a recent release from USDA's Economic Research Service noted, U.S. producers have adopted GE crops "notwithstanding uncertainty about consumer acceptance." Given that uncertainty, the Department has a responsibility to assist producers by designing a strategy serving not only to soften downturns in the market, but also to help increase exports when market conditions are more favorable. Additionally, this strategy should help

⁵ The Government Performance and Results Act of 1993 is a results-oriented process that requires the development of a strategic plan, as well as annual reporting, and that sets specific measurable targets of performance and a data-based assessment of success.

the Department focus proactively on opening markets to these types of commodities, instead of dealing reactively with individual trade disputes as they arise.

**Recommendations
In Brief**

Develop and implement a coordinated, comprehensive strategy for promoting the export of U.S. GE crops.

Assist program agency officials in developing plans to implement the 2002 and 2008 Farm Bill provisions in line with the Department's and program agencies' strategic plans and priorities, and in requesting funds to implement each of those provisions.

Develop performance measures to evaluate the effectiveness of biotechnology trade-related activities.

Formalize and better document existing processes to effectively coordinate and utilize USDA's various biotechnology-related activities in developing its strategies for resolving or mitigating GE trade barriers.

Agency Response

In a prior response to the draft audit report, dated January 15, 2009, the former Deputy Chief of Staff (DCS) stated that the Department would not develop a separate strategy for emphasizing biotech crops. In general, the DCS felt that existing programs and performance measures were adequate to meet the international challenges faced by U.S. biotech agriculture (see exhibit D).

In a response, dated January 27, 2009, the current Secretary of Agriculture stated that he had reviewed the report and recognized the report's merit. He further stated that he has directed the Acting Under Secretary for Research, Education and Economics to lead the Department's effort to develop a comprehensive strategy relating to the export of GE commodities, and directed that the framework for such a strategy be completed within 6 months of this report's issuance (see exhibit C).

OIG Position

We acknowledge the Secretary's plan for corrective action. To reach management decision, however, additional information is needed describing the Department's comprehensive strategy and the specific actions that will be taken in response to Recommendations 1 through 5, as well as timeframes for implementation.

Abbreviation Used in This Report

AC21	Advisory Committee on Biotechnology and 21 Century Agriculture
APEC	Asia Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
BCG	Biotechnology Coordinating Group
BPG	Biotechnology Policy Group
BRAG	Biotechnology Risk Assessment Grant
BRS	Biotechnology Regulatory Services
CRS	Congressional Research Service
CSREES	Cooperative State Research, Education, and Extension Service
DCS	Deputy Chief of Staff
EPA	Environmental Protection Agency
EU	European Union
FAS	Foreign Agricultural Service
FDA	Food and Drug Administration
GAIN	Global Agriculture Information Network
GAO	Government Accountability Office
GE	Genetically Engineered
GIPSA	Gain Inspection, Packers and Stockyards Administration
GPRA	Government Performance and Results Act
IICA	Inter-American Institute for Cooperation on Agriculture
NABI	North American Biotechnology Initiative
OIG	Office of Inspector General
OSTP	Office of Science and Technology Policy
P.L.	Public Law
SASB	Special Assistant to the Secretary for Biotechnology
U.S.	United States
USDA	Department of Agriculture
USTR	U.S. Trade Representative
WTO	World Trade Organization

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Background and Objective

Background

Recent technological advances have allowed scientists to modify plants' genetic coding and produce new plant varieties with new traits. This practice has accelerated the development of new crops, a tendency that has been part of agriculture since human beings first learned to cultivate crops. In the United States, life science companies have taken advantage of this new technology to engineer many new varieties of crops, some with useful traits such as herbicide tolerance, insect and disease resistance, and altered nutritional content. Many of these new genetically engineered (GE) plants are also profitable since they can result in better yields and lower costs.

The United States has responded to this scientific advance with a science-based regulatory structure that controls new GE plants while they are under development. So long as a new variety of GE plant is under development, it is regulated and subject to controls to prevent its accidental introduction into the environment and the food supply. Since 1986, biotechnology products have been regulated under a coordinated framework of laws administered primarily by three agencies—the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Department of Agriculture (USDA). The central premise of the coordinated framework was that the process of biotechnology itself poses no unique risks and that products engineered by biotechnology should therefore be regulated under the same laws as conventionally produced products with similar compositions and intended uses. A second and no less important conclusion was that existing laws were adequate to meet regulatory needs.

After a new GE plant is determined to be “safe to grow,” Animal and Plant Health Inspection Service (APHIS)' Biotechnology Regulatory Services (BRS) can deregulate it when petitioned by the life science company or public entity that conducted the field test. In the United States, GE grains that have been deregulated may be freely sold and commingled with non-GE grains.

Under this system, U.S. producers have adopted several varieties of GE plants. As of 2007, GE varieties accounted for about 91 percent of soybeans and 73 percent of corn planted. Moreover, these GE crops are used extensively in many processed foods, such as corn syrup and soybean oil, which are also major U.S. export commodities.

A widespread international consensus on how these new GE plant varieties should be regulated has not emerged, however. Other nations—especially the European Union (EU)—have created regulatory systems that differ from the U.S. model. These regulatory systems are based on what has come to be

known as the “precautionary principle” for regulating new varieties of GE plants. According to the “precautionary principle,” governments should regulate GE plants aggressively until definitive scientific proof is available that a new GE plant will have no long-term, negative consequences on public health and the environment. Foreign governments that have established regulatory structures according to the “precautionary principle” have declined to approve some varieties of GE plants that are widely harvested in the United States. Department officials responded that “there is a unified U.S. Government position about the principle and about the supposed reliance on that principle by Europe and others,” which according to the Department has been “an *ex post facto* justification for political decisions.” This difference in how the United States and other countries regulate the development of GE crops has effectively resulted in a number of trade barriers to the export of U.S. GE agricultural commodities.

Trade Barriers to the Export of U.S. GE Agricultural Commodities

Foreign countries have established different types of recognized nontariff trade barriers affecting exports of U.S. GE agricultural commodities—moratoria on the approval of new varieties of GE plants, mandatory labeling requirements for GE commodities, traceability requirements, and thresholds for trace amounts of GE material that may be found in non-GE food commodities. These barriers are common throughout the global marketplace. As of 2004, the Foreign Agricultural Service (FAS) identified 50 countries with mandatory labeling laws, 31 with traceability requirements, and 54 with thresholds for trace amounts of GE material in non-GE commodities (see exhibit A).

Moratoria on the Approval of New Varieties of GE Plants

Even though the EU had established a science-based regulatory approval process for GE plants, the EU imposed, beginning in 1998, a moratorium on the approval of any new GE plants for its markets. A majority of EU states—France, Belgium, Luxembourg, the Netherlands, Germany, Austria, Italy, Greece, Spain, Portugal, and Finland—effectively banned GE plants from entering their markets.

In 2003, the United States, Canada, and Argentina responded to this moratorium by filing suit in the World Trade Organization (WTO). These countries argued that the EU had adopted a general moratorium on all new biotech products and separate product-specific moratoria on each new biotech product. The EU also did not implement its own regulations to allow for review of biotech applications to take place. The moratorium imposed undue delay on the more than 25 products then in the EU’s regulatory pipeline and the member state bans on products already approved were not supported by scientific evidence and were thus illegal

under WTO rules. The WTO Panel upheld the co-complainants' claim and found that the EU adopted a moratorium on the final approval of biotech products starting in 1999 through August 2003. The WTO also found that the EU had presented no scientific or regulatory justification for the moratorium and thus the moratorium resulted in undue delay which is in violation of WTO rules. The WTO also identified specific WTO-inconsistent "undue delays" with regard to 24 of the 27 pending product applications listed in the complaint. Also, with respect to each of the EU member state bans on biotech crops approved by the EU prior to the adoption of the moratorium, the WTO Panel upheld the claim that in light of positive safety assessments issued by the EU's own scientists, the member state bans were not supported by scientific evidence and were thus inconsistent with WTO rules. Although the EU has taken some approval actions it has not met WTO requirements for lifting the moratorium.

In January 2008, the U.S. Trade Representative's (USTR) office commented on the expiration of the reasonable period of time for EU compliance with the WTO ruling. The USTR's office announced that, in light of this expiration, "[w]e are taking steps necessary under WTO rules to preserve our right in the WTO to suspend trade concessions." The United States agreed with the EU to suspend, for a limited period, the U.S. request for authority to suspend concessions so that the EU could demonstrate meaningful progress on the approval of biotech products. The office added that the goal was to normalize trade in biotech products, not to impose trade sanctions on EU goods. Negotiations to reach this goal are still ongoing.

Mandatory Labeling Requirements for GE Commodities

Many foreign countries—including most EU nations, as well as other significant markets such as China, Australia, Japan, South Korea, and others—have established mandatory labeling requirements for foods derived from approved GE plants.

Traceability Requirements for Imported Agricultural Commodities

Mandatory labeling laws often require the "traceability" of food products throughout the system of production. Traceability means that the marketing system must have documentable ability to trace the presence or absence of GE materials through each step from farm to point of sale. Since the U.S. supply of corn and soybeans may contain approved varieties of GE corn and soybeans, traceability requirements are difficult for U.S. companies to meet. Industry representatives have argued that "any regulatory measure that would lead to segregation [of the production process for GE and non-GE grains] would raise handling

costs and potentially undermine the efficiency and competitiveness of th[e] system.”⁶

Thresholds for the Trace Presence of GE Material in non-GE Commodities

Many foreign countries have also imposed labeling thresholds for the unintended presence of a small amount of GE material in seed, grain, or feed and food products. The EU, for example, has threshold limits for grain containing more than .9 percent of approved GE varieties. Since, in the United States, grains of approved GE corn and soybeans may be commingled with non-GE corn and soybeans, all shipments of corn and soybeans may contain enough GE material to trigger EU’s regulations on labeling threshold limits.

U.S. producers thus confront an array of nontariff trade barriers when they attempt to export commodities that contain GE material.

Objective

The objective of this audit was to assess USDA’s role in promoting the export of GE agricultural commodities.

⁶ Government Accountability Office (GAO)-01-727, “International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports,” p. 12, June 2001.

Findings and Recommendations

Section 1. A Coordinated, Comprehensive Strategy is Needed to Address Challenges U.S. Producers Face When Exporting GE Agricultural Commodities

While U.S. producers have embraced the agricultural potential of new GE plant varieties, they have encountered numerous nontariff trade barriers preventing them from exporting commodities derived from these plants, especially in established markets, such as the EU and Japan. Faced with this long-term challenge to the health of U.S. exports, USDA has not developed a coordinated, comprehensive strategy for promoting the trade of agricultural commodities (including GE commodities), nor is there evidence that USDA has made significant progress in fulfilling the various biotechnology goals of the 2002 Farm Bill. USDA's research and public information accomplishments relating to exporting these commodities are limited and are not targeted towards any specific goal or trade challenge.

USDA has established many different groups, offices, and positions with interests in agricultural biotechnology, yet biotechnology-related efforts at the departmental level have remained ad hoc, uncoordinated, or undocumented. Departmental officials responsible for providing leadership and direction on biotechnology-related activities within USDA advised they do not believe that USDA should be involved in controlling the market and that private entities are more responsive to market conditions. However, OIG maintains that USDA has a legitimate and necessary role to play in coordinating its many activities and in responding, on behalf of American producers, to barriers to the export of agricultural commodities.

Finding 1

USDA Needs a Strategy Addressing the Challenges of Exporting GE Agricultural Commodities

While U.S. agricultural producers have embraced biotechnology—planting around 143 million acres with GE crops, or 50 percent of the total global biotechnology derived acreage in 2007—many of our trading partners have erected stringent nontariff trade barriers regarding the importation of GE commodities.⁷ Among its many activities related to biotechnology, USDA has responded to specific trade disputes; most notably, the Department has sought to remove barriers to the importation of U.S. GE commodities through a successful WTO suit against the EU. However, USDA has not developed a comprehensive trade strategy that includes addressing the challenges of exporting GE agricultural commodities and coordinating all of the many biotechnology-related activities pursued within the Department. Developing

⁷ See exhibit A for a comprehensive list of nations with such barriers.

such a strategy is critical because the global market in GE agricultural products is especially volatile. During a downturn, planning is necessary to improve the competitiveness of American agriculture; during an upswing, planning will enable the United States to profit from markets favorable to U.S. producers' interests.

The 2002 Farm Bill required the Secretary of Agriculture to develop a global marketing strategy that identifies opportunities for the growth of agricultural exports to overseas markets; ensures that all the resources, programs, and policies of the Department are coordinated with those of other agencies; and remove barriers to agricultural trade in overseas markets.⁸ Since GE commodities are an increasingly important part of the U.S. agricultural sector, a well-designed global marketing strategy would include consideration of these commodities. This legislative requirement remains in effect under the 2008 Farm Bill.

According to GAO, an effective national strategy—i.e., one that offers policymakers and implementing agencies a management tool that can help ensure accountability and more effective results—includes the following six elements: (1) a clear purpose, scope, and methodology; (2) a detailed discussion of the problems, risks, and threats the strategy intends to address; (3) the desired goals and objectives, and outcome-related performance measures; (4) a description of the U.S. resources needed to implement the strategy; (5) a clear delineation of the U.S. Government's roles, responsibilities, and mechanisms for coordination; and (6) a description of how the strategy is integrated internally among U.S. agencies and externally among the relevant international entities, such as the WTO.

We found, however, that USDA has not developed such a strategy for U.S. agricultural products as a whole or for the subset of U.S. agricultural products developed with biotechnology. In a prior audit, we reported that USDA had not developed a focused global marketing strategy that would allow it to identify and react to changing trends in global markets for all U.S. agricultural commodities.⁹ USDA officials did not agree that such a strategy was necessary and asserted that the Department's practices and procedures related to market development were consistent with its strategic goals.

Senior departmental officials explained that USDA has not developed such a strategy because they believe the Department should not be involved in controlling the market and that private entities are more aware of, and quicker to react to, market conditions than USDA. While this may be true, OIG maintains that, since trade barriers affecting GE commodities have been

⁸ Public Law (P.L.) 107-171, "Farm Security and Rural Investment Act of 2002," Title III - Trade, subtitle C - Miscellaneous, sec 3206 - "Global Market Strategy," May 13, 2002.

⁹ OIG Audit Report No. 50601-12-At, "FAS Implementation of the Trade Title of the 2002 Farm Bill and the 2002 President's Management Agenda," March 2007.

established by foreign governments, private entities have limited tools at their disposal for responding to such barriers. The U.S. Government thus has a legitimate role to play in dealing with other governments and furthering the interests of U.S. producers.

USDA's strategic goals recognize the Department's responsibility to plan for market volatility, as well as intercede with foreign governments to promote the interests of American agriculture. USDA's first strategic goal is to "enhance [the] international competitiveness of American agriculture," including working to expand "market access through reduction of nontariff barriers."¹⁰ In order to accomplish this goal, the Department states the need for actionable strategies for "monitoring trade partner compliance with existing trade agreements and working with USTR to enforce those agreements;" "developing strategies to avoid and resolve individual problems, such as technical barriers to trade;" "interven[ing] with international Governments on behalf of U.S. agriculture;" and "researching and analyzing the effects of trade agreements, political and economic structural changes, and technological developments on the comparative and competitive advantages of U.S. agriculture."

Such planning is critical for promoting GE commodities because biotechnology is new to the marketplace and is subject to dramatic shifts in demand. GE crops represent only a fraction of U.S. agriculture production, but they represent an increasingly important fraction. Over the last decade, GE plantings in the United States increased from 3.6 million acres to 143 million acres. For agricultural commodities such as soybeans and corn, U.S. production has largely become GE—the percentage of GE soybeans planted in the United States increased from 7 percent of the total acreage of soybeans planted in 1996 to 91 percent in 2007; during the same period the percentage of GE corn planted increased from 1 percent of the total acreage of corn planted to 73 percent. While many other food crops remain non-GE, scientists are continually experimenting with new plants, and scientific and commercial developments are ongoing.

U.S. producers' adoption of this new technology has complicated agricultural trade with other nations, as several significant foreign markets have been reluctant to import GE agricultural commodities. Ultimately, this reluctance has become a trade dispute based on different notions of how GE food plants should be regulated, a dispute most clearly illustrated by the difference between positions taken by the United States and the EU. The U.S. position is that scientific studies of GE crops indicate that there is no difference between modified crops approved for commercialization in the United States and their unmodified equivalents; given their fundamental similarity, these products should be regulated no differently than their nonmodified equivalents, nor

¹⁰ USDA Strategic Plan 2005-2010.

subjected to mandatory labeling. The EU position—known as the “precautionary principle”—is that until definitive scientific proof is available that a new GE plant will have no long-term, negative consequences on public health and the environment, governments should regulate GE commodities aggressively.

Senior USDA officials have stated that “[w]e believe that adherence to this so-called [precautionary] ‘principle’ is not in fact what has motivated the EU government to act as it has.” Instead, they stated that the EU has used the “precautionary principle” as “an *ex post facto* justification for political decisions.” Political considerations—as well as consumers’ perceptions of these commodities—may have influenced decisions made by those governments. However, part of developing a coordinated, comprehensive strategy for promoting the export of U.S. crops, including GE crops, would include devising appropriate means to overcome perceptions not based on sound science.

In any case, following the “precautionary principle,” member states of the EU established nontariff trade barriers preventing the importation of U.S. GE commodities, including requirements that foods made from GE plants be labeled; that the marketing system must have the ability to document the presence or absence of GE material through each step from farm to point of sale; and that trace amounts of GE material found in non-GE commodities be severely limited.¹¹ EU states have also declined to approve new varieties of GE plants, even though the EU has a science-based regulatory process for doing so.

The adoption of regulatory systems that may impede or discourage trade in GE commodities is not restricted to the EU. Other nations—including significant trading partners such as Japan and South Korea—have erected trade barriers against the importation of U.S. GE agricultural commodities that resemble the EU’s. As of 2004, FAS identified 50 countries with mandatory labeling laws, 31 with traceability requirements, and 54 with thresholds for trace GE material present in non-GE imports (see exhibit A).¹² If the 58 other countries without regulatory systems develop systems similar to those in the EU, U.S. exports could be negatively affected.

From 1996 to 2006, the U.S. trade surplus in agricultural goods decreased from \$27 billion to just \$4.7 billion. Beginning in 2007, however, a number of economic factors—rapid growth in demand in developing countries like China and India, poor harvests due to adverse weather conditions, and the declining value of the dollar—converged to reverse these trends. In 2007, the U.S. trade surplus in agricultural goods rebounded to \$12.1 billion, and is projected to reach \$35 billion in 2008.

¹¹ These trade barriers are discussed more fully in the Background.

¹² After 2004, FAS no longer tracked this information.

High food prices have meant that nations formerly reluctant to import U.S. GE food commodities have reconsidered their position. Japan and South Korea recently agreed to import U.S. GE corn for manufacturing sweeteners and starch.

The reversal of this economic data should not, however, be taken as final. All markets rise and fall and, as we have already noted, this market has experienced a number of especially dramatic shifts in demand. In 2005, for instance, USDA learned that a regulated variety of GE corn was inadvertently harvested and exported. Major U.S. trading partners such as Japan and the EU reacted negatively and adopted emergency measures requiring testing of all U.S. corn. This incident could have adversely impacted an export market worth \$1.9 billion.

Similarly, on August 18, 2006, USDA announced that trace amounts of the regulated GE rice, LLRICE601, were detected in commercial long-grain rice, even though this rice had not been deregulated by USDA. According to a rice industry official, about 63 percent (\$807 million) of the \$1.28 billion export market was affected by importers' reaction to the presence of LLRICE601. The official further advised that the GE events in rice commerce have destroyed prior market gains and will take years to repair.¹³ USDA officials recently advised us that the U.S. continues to expand long-grain rice sales. World-wide shipments to date in 2008 on a volume basis are almost 23 percent ahead of the same period last year, while the value of exports is 60 percent above last year.

Despite the volatility of the international market in GE agricultural commodities, USDA has not developed a plan for responding to market developments. The challenges of this market were recognized as early as 2000, when the Office of Science and Technology Policy (OSTP) published a report addressing the challenges U.S. producers face when planting GE crops. That report stated that USDA should (1) support an expanded research program focused on biotech safety issues, (2) develop reliable testing procedures for differentiating GE commodities, (3) enhance public education concerning biotechnology, and (4) provide farmers with reliable information on access to foreign markets.

There have been a series of reports identifying biotechnology-related export challenges. In June 2001, GAO published a report discussing trade barriers preventing the export of U.S. producers' GE food commodities, especially in Europe. GAO identified several key challenges facing these commodities. GAO saw the regulatory conflict between the United States and the EU as problematic, and observed the rising tide of foreign trade barriers to these commodities and concluded that these barriers "could significantly increase

¹³ This is testimonial evidence obtained from a representative from the rice industry; OIG did not validate the assessment of damage to the U.S. rice export markets.

production costs and disrupt trade.” GAO also noted that “the number of U.S. trade and regulatory agencies with biotech-related roles . . . creates a challenge for effective coordination.”¹⁴

The concerns expressed in the OSTP and GAO reports were echoed in the 2002 Farm Bill, where Congress established five provisions relating to trade and biotechnology.

- Section 3206 required that the Department develop and implement a global market strategy that identifies opportunities for the growth of agricultural exports to overseas markets; ensures that the resources, programs, and policies of the Department are coordinated with those of other agencies; and removes barriers to agricultural trade in overseas markets.
- Section 3204 established a biotechnology and trade program whose purpose is to remove, resolve, or mitigate significant regulatory nontariff barriers to the export of U.S. agricultural commodities into foreign markets.
- Section 7210 authorized biotechnology risk assessment research that would help identify and analyze the environmental effect of biotechnology, and help regulators develop long-term policies concerning the introduction of such technology.
- Section 7505 required that FAS establish and administer a program to make competitive grants to eligible entities to develop agricultural biotechnology for developing countries.
- Section 10802 required that the Secretary of Agriculture develop and implement a program to communicate with the public regarding the use of biotechnology in producing food for human consumption.

In Finding 2, we discuss the actions USDA has taken to address these provisions of the 2002 Farm Bill, as well as how the 2008 Farm Bill has altered these requirements.

In June 2003, the Congressional Research Service (CRS) issued a report describing the “widely divergent approaches to regulating biotechnology” being adopted around the globe. This report discussed U.S. concerns including the EU’s moratorium on new GE approvals, labeling and traceability regulations, biosafety protocols, the effect of GE commodities on food aid, and the role biotechnology can play in developing countries.¹⁵ CRS

¹⁴ GAO, “International Trade: Concerns Over Biotechnology Challenge U.S. Agricultural Exports,” pp. 8 and 13, June 2001.

¹⁵ CRS, “U.S. Agricultural Biotechnology in Global Markets: An Introduction,” p. ii, June 19, 2003.

also described the numerous Federal agencies and departments that deal with issues affecting trade in GE commodities and concluded that coordinating these agencies' contributions was a significant challenge. According to CRS, "critics [have] assert[ed] that the U.S. response to biotechnology remains largely reactive, ad hoc, and not well coordinated." These critics contend that "*a more comprehensive long-term strategy is needed*" (OIG's emphasis).¹⁶

The utility of developing a trade strategy was demonstrated when the National Security Council prepared the U.S. position for its successful suit in WTO. In collaboration with FAS, the National Security Council developed, in 2002, a predecisional, deliberative, draft strategy for U.S. agricultural exports, including GE commodities. Although this strategy was revised in 2006, it remained in draft and was not implemented by FAS or USDA.

Industry representatives we interviewed from the North American Export Grain Association, Biotechnology Industry Organization, and North American Millers' Association stated that they believed USDA has done good work dealing with particular trade problems as they arise. However, they also argued that the Department could use a comprehensive, clearly articulated strategy—one that coordinates the many agencies concerned with GE crops and biotech issues. In addition to coordinating USDA groups, offices, and positions concerned with biotechnology, that strategy should also consider other departments and agencies with biotechnology-related interests, including the Departments of State and Commerce, FDA, and EPA.

OIG concluded that the Department can improve how it responds to market volatility by developing a coordinated, comprehensive strategy for promoting the export of U.S. agricultural commodities, including GE crops. That strategy should coordinate all the various biotechnology-related activities discussed in Finding 3, and it should include plans for improving the competitiveness of American agriculture during economic downturns, as well as profiting from its advantages during periods of prosperity.

Recommendation 1

Develop and implement a coordinated, comprehensive strategy for promoting the export of U.S. GE crops.

Agency Response.

In a response, dated January 27, 2009, the current Secretary of Agriculture stated that he had reviewed this report and determined it had merit. The Secretary stated that he had asked the Acting Under Secretary for Research, Education, and Economics to lead the Department's effort to develop a comprehensive strategy relating to the export of GE agricultural commodities

¹⁶ CRS, "U.S. Agricultural Biotechnology in Global Markets: An Introduction," p. 16, June 19, 2003.

and directed that the framework for such a strategy be completed within 6 months of the issuance of this report.

OIG Position.

We acknowledge the Secretary's plan for corrective action. To reach management decision, additional information is needed as to the framework of the comprehensive strategy.

Finding 2**USDA Has Made Limited Progress in Completing Goals Related to Trade and Biotechnology**

When it passed the 2002 Farm Bill, Congress established five provisions that, together, mandated a vision of where the United States should be headed in terms of biotechnology and international trade. We found limited evidence that USDA has made measurable progress in fulfilling the various biotechnology goals of the 2002 Farm Bill, nor could we determine what progress USDA has made towards completing its strategic goals relating to trade and agricultural biotechnology. This occurred because USDA has not requested funds for three of the five provisions of the 2002 Farm Bill relating to biotechnology and had not developed performance measures tied to any specific goal or objective.¹⁷ Since, as reported in Finding 1, the Department lacked a coordinated, comprehensive strategy for biotechnology-related activities, USDA did not accomplish Congress' goals for biotechnology and international trade.

On June 18, 2008, Congress enacted the Food, Conservation, and Energy Act of 2008 (referred to as the 2008 Farm Bill), which changed several of the provisions relating to biotechnology and trade. Below, we discuss the current status of each of these sections according to the 2002 and 2008 Farm Bills, as well as the current relevance of the programs they involve.¹⁸

Section 3206—Global Market Strategy

The 2002 Farm Bill required USDA to develop and implement a global marketing strategy that would identify opportunities for the growth of agricultural exports to overseas markets; ensure that the resources, programs, and policies of the Department were coordinated with those of other agencies; and remove barriers to agricultural trade in overseas markets.

In a prior audit, we reported that, although FAS had implemented various measures to encourage strategic planning by its market development participants and to evaluate their export strategies, they needed to develop comprehensive strategies that can be implemented on a worldwide basis if U.S. trade goals are to be reached.¹⁹ Over the last decade, U.S. producers have adopted GE versions of several U.S. commodities—73 percent of corn and 91 percent of soybeans planted in the United

¹⁷ The Government Performance and Results Act (GPRA) emphasizes a results-oriented process by requiring the development of a strategic plan, as well as annual reporting, and by seeking specific measurable targets of performance and a data-based assessment of success.

¹⁸ P.L. 110-246, "The Food Conservation and Energy Act of 2008," enacted on June 18, 2008.

¹⁹ OIG Audit Report No. 50601-12-At, "FAS Implementation of the Trade Title of the 2002 Farm Bill and the 2002 President's Management Agenda," March 2007.

States are, as of 2007, planted with GE seeds. Given these facts, OIG maintains that a global marketing strategy should include strategies for expanding exports of GE commodities as part of its overarching strategies for U.S. agriculture.

The 2008 Farm Bill did not repeal this requirement, and OIG believes that USDA continues to need a global marketing strategy.

Section 3204—Biotechnology and Agricultural Trade Program

The 2002 Farm Bill required USDA to establish a biotechnology and agricultural trade program intended to remove, resolve, or mitigate significant regulatory nontariff barriers to the export of U.S. agricultural commodities to foreign markets through public and private grants that address (1) quick response intervention regarding nontariff barriers to U.S. exports involving (a) U.S. agricultural commodities produced through biotechnology, (b) food safety, (c) disease, or (d) other sanitary or phytosanitary concerns; or (2) developing protocols as part of bilateral negotiations with other countries on issues such as animal health, grain quality, and genetically modified commodities.

Congress authorized up to \$6 million yearly for this section, but the Department did not seek apportionment of any funds until 2004.²⁰ In that year, USDA requested and received \$1.6 million and continued to receive \$1.6 million in both fiscal years 2005 and 2006. Of the approximately \$4.9 million received under this section, the Department used funds for several different activities:

- \$557,000 was used to maintain the Office of the Special Assistant to the Secretary for Biotechnology (SASB), which is responsible for coordinating departmental activities related to biotechnology;
- FAS received \$3 million for bilateral and multilateral trade negotiations such as the U.S.-China Biotechnology Working Group, U.S.-Japan negotiations, and international efforts such as biosafety protocol negotiations and the U.S. WTO case against the EU;
- APHIS received \$1.1 million to initiate a transgenic animal unit, perform scientific and environmental impact assessments, and strengthen Federal-State partnerships;
- The Cooperative State Research, Education, and Extension Service (CSREES), the Agricultural Marketing Service, and the Grain Inspection, Packers and Stockyards Administration (GIPSA) together

²⁰ The apportionment process is used by the Office of Management and Budget to monitor and disburse funds to agencies.

received \$242,000 to fund various special projects related to trade in biotechnology, including GIPSA's laboratory certification program, CSREES' program to implement a GE specialty crop initiative, and the Agricultural Marketing Services' efforts to standardize methodologies for testing GE seed.

Since the 2008 Farm Bill repealed this section, the Department can no longer seek funding for these biotechnology-related activities.

Section 7210—Biotechnology Risk Assessment Research

The purpose of this section was to (1) authorize and support environmental assessment research to help identify and analyze environmental effects of biotechnology; and (2) authorize research to help regulators develop long-term policies concerning the introduction of such technology. It required USDA to establish a grant program supporting environmental assessment to help identify and analyze the environmental effects of biotechnology.

The following types of research were to be given priority for this funding: (1) research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with GE animals, plants, and microorganisms; (2) research designed to develop methods to monitor the dispersal of GE animals, plants, and microorganisms; (3) research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer that may occur between GE animals, plants, and microorganisms, and related wild agricultural organisms; (4) environmental assessment research designed to provide analysis comparing the relative impact of animals, plants, and microorganisms modified through genetic engineering to other types of production; and (5) other areas of research designed to further the purposes of this section.

The 2002 Farm Bill specified that 2 percent of all funds spent on biotechnology research should be allocated for biotechnology risk assessment research. The Secretary assigned responsibility for completing this section of the 2002 Farm Bill to CSREES, which used the 2 percent allocation to fund the Biotechnology Risk Assessment Grant (BRAG) program. These grants were funded for the express purpose of determining what risks are associated with biotechnology. From 2003 to 2006, CSREES funded 47 grants totaling \$14.6 million.

BRAG grants funded a wide variety of projects, including studies titled "The Risk of Western Corn Rootworm Adaptation to Transgenic Corn," "Tracking the Movements of Transgenic Toxins through Complex Food

Webs,” “Industrial Crops: Demonstration of a Practical Seed Sterility System,” and “Biological Containment of GE Fish.”

We found, however, no overall plan or strategy to direct, prioritize, and use the research results to address the challenges U.S. producers face in the market for GE commodities. The fiscal year 2007 request for applications for BRAG grants in fact states that awards will not be made for marketing or trade issues associated with genetically modified organisms.

Environmental assessments may not have a direct bearing on trade, but some consumers’ resistance to these products is based on environmental concerns. Scientific studies that could allay consumers’ concerns about the environmental effects of these products are thus indirectly related to trade. Communicating safety protocols and control measures used when planting and harvesting GE plants should result in better informed consumers and greater willingness to buy these products. OIG thus maintains that BRAG accomplishments should be included in an overall strategy for addressing and mitigating trade challenges and barriers related to GE products.

Since the 2008 Farm Bill did not repeal this section of the 2002 Farm Bill, it remains in effect.

Section 7505—Agricultural Biotechnology Research and Development for Developing Countries

The 2002 Farm Bill required that USDA establish and administer a program to make competitive grants to eligible entities to develop biotechnology for developing countries. These funds were to be used for a variety of purposes, including: (a) enhancing the nutritional content of agricultural products that can be grown in developing countries, (b) increasing the yield and safety of agricultural products that can be grown in developing countries, (c) increasing the yield of agricultural products that are drought- and stress-resistant and that can be grown in developing countries, (d) extending the growing range of crops that can be grown in developing countries, (e) enhancing the shelf-life of fruits and vegetables grown in developing countries, (f) developing environmentally sustainable agricultural products that can be grown in developing countries, and (g) developing vaccines to immunize against life-threatening illnesses and other medications that can be administered by consuming GE agricultural products.

FAS was assigned responsibility for completing this requirement. The Office of Budget and Program Analysis stated that funds were not available for some projects, and that FAS would try to comply with these

sections of the 2002 Farm Bill through other funded sections. However, FAS officials could not provide evidence of what was done.

With the passage of the 2008 Farm Bill, Congress extended this program through 2012 under Section 7310 of the new legislation. The Secretary of Agriculture recently emphasized its importance when speaking before the United Nations' Food and Agriculture Organization in June 2008. He remarked that by embracing new technologies and basic infrastructures, nations can help make agriculture more resilient to climate variability and climate change. He also commented that nations must therefore invest in scientists and research institutions, and that they should work together to identify and introduce existing and new technologies with the potential to significantly boost crop yields. The Secretary also stressed that in countries vulnerable to climatic or weather-related challenges, new biotechnology-based solutions are imperative to growing viable yields.

We concluded that the Department needs to make greater efforts to fully implement this section of the 2002 Farm Bill.

Section 10802—Program of Public Education Regarding the Use of Biotechnology in Producing Food for Human Consumption

The 2002 Farm Bill required USDA to develop and implement a program to communicate with the public regarding the use of biotechnology in producing food for human consumption. This program would provide information concerning: (a) science-based evidence on the safety of foods produced with biotechnology, and (b) scientific data on the human outcomes of the use of biotechnology to produce food for human consumption.

CSREES was responsible for this part of the 2002 Farm Bill. Instead of establishing a program to specifically address the intended goals of this provision, a CSREES official stated that he had been directed to review preexisting programs to determine if any grants had been funded that satisfied the legislative requirement. We determined that seven of these grants CSREES identified were approved and funded prior to 2002; the remaining six grants totaling \$1.2 million were funded in 2002 or later.

Since the 2008 Farm Bill repealed this requirement, it is no longer in effect.

In May 2000, OSTP published a position paper identifying the challenges American producers face when planting GE crops. As OSTP argued, “one of the most difficult choices a farmer faces each year is what to plant—what types of crops and what specific varieties . . . [T]he current uncertainty in

overseas markets concerning biotech crops has made their selections even more difficult.”²¹ OSTP identified a number of specific challenges USDA must overcome to help U.S. producers. Many of these suggestions relate to improving the available science on GE crops. OSTP suggested that USDA, FDA, and EPA “support an expanded program of competitively awarded, peer-reviewed research focusing on current and future safety issues” and “coordinate their research programs related to risk assessment of agricultural biotechnology and expand these programs . . . in a way that maintains a strong science-based regulatory program.”²² OSTP suggested that USDA facilitate “the creation of reliable testing procedures and quality assurance programs for differentiating non-bioengineered commodities to better meet the needs of the market;” “enhance domestic and foreign public education and outreach activities to improve understanding of the nature and strength of our regulatory process;” and “provide farmers with reliable information on markets to inform their planting decisions and with best farming practices for new crop varieties.”²³ OSTP concluded that by disseminating information more effectively, USDA could help reluctant consumers learn more about the benefits of biotechnology and help producers determine which varieties of GE plants consumers were ready to accept.

The GPRA requires agencies to develop strategic plans, set performance goals, and report annually on actual performance compared to goals.²⁴ Efforts to meet goals must be measurable and reportable. However, we could not determine what measurable progress USDA has made towards accomplishing its strategic goals relating to trade and agricultural biotechnology. We also could not determine the effectiveness of the Department’s implementation of the 2002 Farm Bill provisions in disseminating information (and other outreach efforts) to mitigate the public’s concerns, both domestically and abroad, on biotechnology and its products.

OIG believes that the three requirements of the 2002 Farm Bill not repealed by the 2008 Farm Bill continue to be relevant to the contemporary global trade situation, and that USDA should take steps to fully implement them. Department officials have argued that “several of these Farm Bill provisions, although authorized, were not funded.” However, we found that the Department requested funds for only two of these five sections, and in those cases, it received funding. In line with the Department’s strategic plans and strategic plans for FAS and CSREES, program agency officials, in consultation with the SASB, should develop plans and request funds to implement these Farm Bill provisions.

²¹ OSTP, “Food and Agricultural Biotechnology Initiatives: Strengthening Science-Based Regulation,” p. 5, May 3, 2000.

²² *ibid.*

²³ *ibid.*

²⁴ OMB *Circular A-123*, “Management’s Responsibility for Internal Control,” sec. 3, December 21, 2004.

Since 2001, the Department has received an average of \$288 million for biotechnology-related programs, but it cannot state how much of these funds were used to promote U.S. producers' export interests. OIG maintains that by developing a coordinated, comprehensive strategy designed to address and mitigate GE trade challenges and barriers, USDA could make better informed decisions about how future funds should be distributed.

Recommendation 2

Integrate each of the three remaining biotechnology-related requirements from the 2002 Farm Bill into the strategy developed in response to Recommendation 1.

Agency Response.

The January 27, 2009 response to the audit did not specifically address Recommendations 2 through 5; it did, however, state that USDA will develop the framework for a comprehensive strategy relating to the export of GE agricultural commodities within 6 months of the issuance of this report.

OIG Position.

To reach management decision, specific information is needed describing how the comprehensive strategy will address corrective actions to implement the three still-relevant provisions of the 2002 Farm Bill. The importance of the three cited provisions was recently emphasized by Congress when the 2008 Farm Bill was enacted and these three provisions remained.

Recommendation 3

Assist appropriate program agency officials in developing plans to implement the Farm Bill provisions in line with the Department's and program agencies' strategic plans and priorities and in requesting funds to implement each of these provisions. If USDA decides that funding is not necessary, then the Department should document why funding is not being requested.

Agency Response.

The January 27, 2009 response did not specifically address Recommendation 3; it did, however, state that USDA will develop the framework for a comprehensive strategy relating to the export of GE agricultural commodities within 6 months of the issuance of this report.

OIG Position.

To reach management decision, information will be needed as to how the strategy will address actions to be taken in response to this recommendation.

Recommendation 4

Develop performance measures to evaluate the effectiveness of the Department's biotech trade-related activities.

Agency Response.

The January 27, 2009 response did not specifically address actions to be taken in response to this recommendation.

OIG Position.

To reach management decision, plans for the development and implementation of performance measures need to be provided.

Finding 3**USDA's GE Commodities Trade Efforts Need Better Coordination and Oversight by Senior Departmental Officials**

One of USDA's long-term strategies is to "conduct research to support the development and marketing of bio-based products . . . [and] to expand the range of agricultural products in the marketplace."²⁵ As GE plants have become more important to the U.S. agricultural sector, USDA has established several groups, offices, and positions with responsibilities for various aspects of biotechnology. Viewed collectively, the Department employs hundreds of scientists, trade specialists, and administrators concerned, in their different ways, with promoting and exploring the potential of biotechnology. However, without a comprehensive strategy (see Finding 1), we found that the Department's efforts to promote and market biotechnological products have been ad hoc, uncoordinated, and inadequately documented. Although the position of the SASB was created to coordinate and direct biotechnology activities, this official functioned more as an advisor and facilitator than as a coordinator. As a result, a coordinated approach to addressing the Department's first strategic goal, particularly as it applies to biotechnology trade issues, cannot be demonstrated.

Since 2001, USDA has spent an average of about \$288 million on biotechnology-related programs. USDA assigned several agencies and has established many groups with responsibilities relating to different facets of trade in biotech agricultural commodities. We found, however, that their activities were not coordinated or integrated into an overall strategy for resolving or mitigating trade issues. A description of each of these activities follows.

Special Assistant to the Secretary for Biotechnology (SASB)

In 2003, the Secretary of Agriculture established the position of SASB to offer advice and guidance to the Department and provide "senior[-]level leadership in the planning, initiation, and execution of biotechnology policy and operations for the Department." As the direct advisor to the Secretary, SASB's major responsibilities and duties include "develop[ing] and implement[ing] strategies to fulfill U.S. strategic interests with respect to biotechnology activities; coordinat[ing] USDA biotechnology activities within USDA and with other [F]ederal agencies; [and] provid[ing] coordination among and advice to officials in APHIS, FAS, and other USDA agencies involved with biotechnology activities."

²⁵ The "USDA Strategic Plan 2000-2005" identifies this as a long-term strategy for addressing strategic goal 1: "Enhance economic and trade opportunities for U.S. agricultural producers," pp. 21 and 28, September 2000.

When we spoke with the official who served as SASB from April 2004 to March 2006, however, we learned that the former SASB was reluctant to develop written strategies and did not see a need for planning. The SASB informed us that USDA did not have a formally structured biotech policy, and explained that the Department had not addressed and analyzed what sort of plan it should have. The SASB stated that she would “hate to see the Department writing strategy rather than doing strategy,” and questioned whether developing such a strategy would be an effective or efficient use of resources. The SASB did not, however, provide an alternate method for determining what would be an efficient or effective use of resources in the absence of a written strategy. SASB further stated that trade barriers to GE commodities should be treated like other nontariff trade barriers, and cautioned against taking GE commodities out of context and developing separate strategies for them.

Given the growing importance of agricultural trade to the U.S. economy and the growing prevalence of GE commodities as part of U.S. agricultural exports, we question this position. The U.S. Government has a major role to play in negotiating to remove, resolve, or mitigate these barriers, especially since many of these trade barriers have been established by other governments.

OIG maintains that, since there are a number of stakeholders that deal with biotechnology—often from different perspectives—a written strategy is crucial for coordinating their contributions and ensuring that they are working towards common goals.

Biotechnology Policy Group (BPG)

USDA convenes two different policy groups to discuss and comment on biotechnology—the first of these groups is BPG. Although there was no formal directive to establish BPG, it was started on an ad hoc basis around the time of the StarLink corn event (2000-2001).²⁶ No written directives govern the group’s activities, authorities, and responsibilities. A member of BPG stated that the group was always “irregular and entirely informal”—he could not state exactly when it was formed or when it acquired its name.

Senior departmental staff—such as the SASB, Under Secretaries, or Deputy Under Secretaries of USDA’s mission areas—usually attend BPG meetings, although others might be asked to participate if their expertise were required. Generally, one BPG member stated that these meetings are convened as needed if there is a significant update

²⁶ Aventis CropScience genetically engineered StarLink corn for resistance to caterpillar pests and tolerance to herbicides. EPA approved StarLink corn for animal feed, but not for human consumption. An independent testing lab found StarLink corn in taco shells in September 2000. The unauthorized release of StarLink corn into the human food supply resulted in product recalls, buyback programs for the corn, and reduced corn exports.

involving a new technology, a regulatory development, or a policy decision to be made.

BPG meetings were held infrequently, conducted informally, and its proceedings were not documented. According to a BPG member, meetings were held only once or twice a year, on an ad hoc basis, and typically no written agendas were developed. No record was maintained of who attended these meetings, what issues were discussed, or what decisions were made. One of the participants in BPG meetings stated that the group is, “if anything, . . . losing an official title, and is just a meeting called with relevant individuals on an as needed basis.” This official stated that BPG has largely been superseded by weekly meetings with the chief of staff.

Biotechnology Coordinating Group (BCG)

The second of these departmental groups is BCG. Like BPG, BCG is informal; no departmental directive established the group. Currently, the biotechnology coordinator—an assistant to the SASB—convenes meetings of BCG; he also develops the agenda for BCG, but no minutes are kept.

BCG is attended by representatives chosen by administrators of the various USDA agencies. Agencies and offices that are represented in BCG have included APHIS, Agricultural Marketing Service, GIPSA, Economic Research Service, Agricultural Research Service (ARS), Forest Service, Food Safety and Inspection Service, FAS, Office of the Chief Economist, Office of Budget and Program Analysis, Natural Resources Conservation Service, and CSREES. As schedules permit, BCG meets every two weeks to review positions for international negotiations on biotechnology, share information about departmental efforts involving biotechnology, and help frame or identify issues for 21st Century Agriculture’s (AC21) or BPG’s consideration. We reviewed BCG agendas provided by the biotechnology coordinator, and they indicated that meetings were called to discuss issues such as APHIS’ policy on low-level intermittent presence, bilateral negotiations with Japan, and a CODEX committee meeting on methods analysis and biotech testing guidelines.²⁷ Because no minutes were kept, we could not determine what actions were taken to address these issues.

²⁷ CODEX Alimentarius is an international working group that develops international standards relating to food safety. USDA actively participates and presents policy statements to CODEX for review and discussions.

Advisory Committee on Biotechnology and AC21

Recognizing the importance of biotechnology for the future of American agriculture, USDA established in 2002 an advisory panel comprised of biotechnology experts from a range of fields.²⁸ Unlike BPG and BCG, AC21's structure was formally established. The committee is made up of 20-25 members, as well as 7 *ex officio* members from Federal and State agencies outside USDA. AC21 members are drawn from a variety of fields, including the academic community, consumer rights advocates, and corporate interests. They are appointed by the Secretary for a term of up to 2 years. AC21 is chaired by a member selected by the Secretary.

AC21 was tasked with "provid[ing] information and advice to the Secretary of Agriculture related to the use of biotechnology in agriculture. The committee is charged with examining the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and providing guidance to USDA on pressing individual issues." AC21 is only an advisory committee. It serves the Department as an external think-tank, and it issues reports to the Secretary, who is then responsible for determining what, if any, action should be taken.

AC21 has published four reports on the emerging 21st century global agricultural market, each of which has dealt with trade in biotech agricultural commodities:

- "Preparing for the Future," published on May 9, 2005, imagined and described several different scenarios for how agricultural biotechnology might progress in the 21st century.
- "Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States," published on May 9, 2005, describes the current status of varying labeling and traceability requirements in the global agricultural marketplace. AC21 noted that the "complexity of complying with multiple labeling and traceability requirements . . . differ[ing] by market and country imposes additional costs and inefficiencies on the supply chain."²⁹ AC21 suggested that there was a need for international standards on food safety issues relating to GE crops.
- "Opportunities and Challenges in Agricultural Biotechnology in the Decade Ahead," published on July 13, 2006, discussed many controversial issues in the field of biotechnology and stated minority

²⁸ AC21 was established by Departmental Regulation 1043-049, March 20, 2006.

²⁹ USDA Advisory Committee on Biotechnology and AC21, "Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States," p. 32, May 9, 2005.

and majority positions within the group, as different positions were often represented. For instance, AC21 members expressed widely differing opinions on labeling foods from GE plants. Some members believed that consumers have a fundamental right to know what is contained in their food; others believed that such labels would confuse consumers since a food derived from GE plants is fundamentally indistinguishable from its nonmodified equivalent.

- “What issues should USDA consider regarding coexistence among diverse agricultural systems in a dynamic, evolving, and complex marketplace?” published March 5, 2008. This report discusses the need for continued existence of and support for those factors enabling coexistence among identity-preserved conventional, organic, and GE production.

According to a member of BPG, all four of these reports have been widely read by officials concerned with biotechnology. These reports were intended to describe complex issues surrounding the use of biotechnology in agriculture; they have not included specific recommendations. As one BPG member remarked, it would be very difficult to obtain consensus from a committee as diverse as AC21 on any specific recommendation. Since AC21 reports present issues and concerns related to biotechnology, OIG believes these reports should be a useful tool in developing an overall strategy for coordinating biotechnology-related activities and promoting the export of U.S. GE agricultural products.

Because USDA does not have an overall strategy for coordinating biotechnology-related activities or promoting the export of U.S. GE products, there is no indication that specific actions were coordinated by USDA to address issues raised in these reports.

Capacity Building and Outreach Activities

The Department has stated that it has initiated a number of actions in terms of capacity building and outreach activities. These efforts include working with the economies of Asia Pacific Economic Cooperation (APEC); negotiating bilaterally with China; working with the Inter-American Institute for Cooperation on Agriculture (IICA); and negotiating under the auspices of the North American Biotechnology Initiative (NABI).

Asia Pacific Economic Cooperation (APEC)

APEC is a public sector forum established in 1989 to promote greater economic and trade cooperation along the Pacific Rim. APEC is governed by an annual ministerial meeting of foreign ministers and the trade ministers of member economies that delegate responsibilities to APEC senior officials. Senior official meetings are held about four times a year.

Since its inception, APEC has worked to reduce tariffs and other trade barriers across the Asia-Pacific region to create efficient domestic economies, increase exports, and enhance free and open trade and investment. APEC also works to create an environment for the safe and efficient movement of goods and services across borders in the region through policy alignment and economic and technical cooperation.

In 2001, APEC called for the establishment of High Level Policy Dialogue on Agricultural Biotechnology to be chaired by the United States. The Department advised OIG that the intended purpose of the policy dialogue is for APEC's member economies to exchange information and achieve consensus on the importance of biotechnology to agricultural productivity, the environment, and food security.

North American Biotechnology Initiative (NABI)

Since its inception in 2002, the NABI has been intended to foster closer, more positive working relations between the three member countries—Mexico, Canada, and the United States. The Department advised OIG that NABI serves as a forum for exchanging ideas and information, and for addressing issues related to the regulation of, and trade in, bioengineered products. NABI sessions focus on broad themes such as biodiversity, coordination on biotech-related policy issues, training and capacity building, biotechnology intellectual property, harmonization of regulatory approaches for agricultural biotechnology products, and collaboration with international organizations.

According to USDA officials, activities under NABI were instrumental in initiating the “trilateral arrangement” between the United States, Canada, and Mexico on documentation requirements for the Cartagena Protocol on Biosafety. USDA has also stated that NABI activities helped facilitate Mexico's passage in early 2005 of comprehensive biosafety legislation

which will continue to enable bilateral trade with the United States and help preserve U.S. coarse grain and soybean exports to Mexico, valued at close to \$2.3 billion annually.

Inter-American Institute for Cooperation on Agriculture (IICA)

IICA is a specialized agency of the Inter-American System, and its purpose is to encourage and support the efforts of its member states to achieve agricultural development and well-being for rural populations. IICA provides innovative technical cooperation to the member states, with a view to achieving their sustainable development.

According to departmental officials, FAS has taken the lead in establishing and providing guidance to IICA's Hemispheric Biotechnology and Biosafety Program. The Department advised OIG that the hemispheric program was approved by IICA's executive board in September 2006, following a mandate from the Inter-American Board on Agriculture. One purpose of the hemispheric program is to facilitate mechanisms for the development, management, and responsible use of biotechnology in order to promote competitive and sustainable agriculture in the Americas.

Bilateral Negotiations with China

Currently the largest market for U.S. agricultural biotechnology products, China is also the fifth largest producer of biotechnologically enhanced plants based on total number of acres, and is developing a strong biotech research program. China is set to become an even larger player in agricultural biotechnology as it has just ratified the Biosafety Protocol.

According to departmental officials, significant barriers still exist for U.S. biotech products entering the Chinese market. These barriers include requirements that products be fully approved first in the originating country before they can be approved in China, duplicative testing for products already approved in the United States, lack of a regulatory framework for GE events with multiple traits, and holding only two windows a year for acceptance of applications for new products.

However, USDA officials have stated that the United States and China are working closely on several fronts to assist China in its capacity to effectively and fairly handle its biotechnology sector.

Foreign Agricultural Service (FAS)

FAS supports USDA's strategic goal of enhancing the competitiveness of U.S. agriculture. Among its many responsibilities, FAS serves U.S. agriculture's interests by expanding and maintaining international export opportunities for U.S. products. It also supports international economic development and trade capacity building, and improving the global sanitary and phytosanitary regulatory system to facilitate international trade. FAS' core objective is to expand overseas market opportunities. Its duties include serving as first responders in cases of market disruption, providing critical market and policy intelligence to support our strategic goals, and representing U.S. agriculture in consultations with foreign governments.³⁰

On November 13, 2006, FAS implemented a far-reaching reorganization designed to focus its efforts on inherently governmental activities. Prior to this date, FAS had established a biotechnology group that was charged with promoting the export of U.S. GE agricultural commodities. During the 4 years of its existence, the biotechnology group dealt with trade problems on an ad hoc, reactive basis.

As part of its reorganization, FAS implemented a new plan for receiving information from its liaison officers stationed in foreign countries. These liaisons will now be submitting country strategy statements for their country that technicians in FAS' new Office of Country and Regional Affairs will evaluate and use to develop specific strategies relevant to that country. These strategies will address trade practices and restrictions for all imports, including GE-derived commodities. USDA officials advised us that individual country strategy statements for the 2008 cycle have incorporated GE marketing goals as appropriate.

FAS representatives serving in foreign countries actively report on market conditions in their countries. They submit Global Agriculture Information Network (GAIN) reports, which detail trade obstacles U.S. agricultural commodities—including GE crops—may face in that country's market. We found that these reports contained valuable and relevant information, including a list of biotechnology products approved in the relevant market, a description of marketing issues, and instructions for labeling products for those markets. These reports are published on the Internet and are made available to the public. We noted, however, that the GAIN reports are not being summarized or analyzed on a global level. We conclude that this is a missed opportunity, as these reports might prove useful for the Department's senior-level policy meetings involving the BCG and BPG.

³⁰ USDA's 2008 Budget, vol. 2, p. 21-1.

Animal and Plant Health Inspection Service (APHIS)

Within USDA's APHIS, the agency's Biotechnology Regulatory Services (BRS) regulates new GE plants while they are under field testing development. BRS deregulates a new GE plant when it is determined that the GE species does not pose a risk as a plant pest or a risk to the environment, and is safe to grow. In the United States, deregulated GE grains may be freely sold and commingled with non-GE grains, subject to any contractual arrangements between buyer and seller.

When determining if a new GE plant should be deregulated, BRS uses a science-based process along with the results of field tests to determine whether or not GE commodities are safe to grow. According to senior departmental officials, APHIS' BRS approaches this decision from a purely scientific point of view in that it determines if the plant is a plant pest; issues and risks that are not science-based, such as consumer acceptance and marketability of GE products, are not part of APHIS' analysis. Once the GE plant is deregulated, the new variety may be developed further through traditional breeding and produced, marketed, distributed, and grown without any other special oversight on APHIS' part. There is no requirement in Federal regulations to include market or public acceptance in this determination, nor is BRS required to consider U.S. trade implications before it deregulates a GE plant.

In one recent instance, BRS received a petition to deregulate a new GE plant that some U.S. producers feared could compromise their trade with countries where the new plant was not approved. U.S. wheat producers rejected the new GE variety of wheat BRS was requested to deregulate. The petition for deregulation was later withdrawn. However, FDA did issue a Biotechnology Consultation Agency Response Letter, which allowed the life science company to commercialize the product as safe to eat. According to news reports, producers feared that GE wheat would rapidly spread throughout the country, and that the U.S. supply of wheat could become commingled with GE grains. If the EU did not approve this variety of wheat and EU members did not import it, American producers would stand to lose a percentage of this market—worth \$3.6 billion in 2000-2002, or 7 percent of all American agricultural exports.³¹

In other instances, GE plants that received permits for field testing and were still regulated were released into the environment and commingled with non-GE crops. This caused substantial short term losses to U.S. exporters of the affected agricultural crops. According to USDA officials, following the August 2006 announcement of trace amounts of

³¹ CRS, "U.S. Agricultural Biotechnology in Global Markets: An Introduction," pp. 2-3, June 19, 2003.

GE rice detected in the U.S. commercial long-grain rice supply, the EU, which normally imports about 250,000-300,000 metric tons of U.S. long-grain rice, issued sampling and testing requirements that constituted a *de facto* prohibition on U.S. rice. Russia, however, was the only country that officially closed its market to U.S. rice but since has reopened that market. Furthermore, USDA asserted that other markets showed no discernable disruptions.

One industry representative stated “we are increasingly frustrated by the apparent lack of ability on the part of private companies and Federal regulators to control research and maintain accountability of the resulting products. The current approach to research, development, and management in the biotechnology industry must be replaced with more conservative methodologies.” This industry representative stated that he believes there must be market acceptance and approval prior to regulatory approval of GE plants in the United States. This statement was precipitated by failure of a life science company to follow prescribed directives for regulated GE commodities, leading to commingling of a regulated GE commodity with domestic non-regulated commodities.

Grain Inspection, Packers and Stockyards Administration (GIPSA)

GIPSA facilitates the marketing of grains and oilseeds through various services, including verifying the accuracy of tests used to detect GE plants. GE commodities present a special testing challenge because these commodities are superficially identical to their unmodified equivalents. Ensuring that accurate and reliable tests are available to test the presence and quantity of biotech material in a given sample is thus crucial to commerce.

In 2002, GIPSA began offering a voluntary proficiency program to provide standardization of testing in the commercial market. Rather than providing tests, GIPSA evaluates and reports on the proficiency of private, academic, and public sector laboratories to detect GE events in grain and oil seeds. GIPSA also evaluates the performance of commercially available rapid protein based test kits upon request of the manufacturer. To verify the accuracy of these tests, GIPSA must have access to reference samples of genetic material, specific information on genetic sequences, and analytical techniques. Because this proprietary information belongs to the company that developed the GE plant, biotech companies are not required to provide this information to GIPSA, but do so on a voluntary basis.

GIPSA also works to establish international standards relating to testing—a critical issue for commerce. To this end, GIPSA works with

CODEX Alimentarius, the National Institute for Standards and Technology, and other organizations to develop official methods and references that will be recognized on a global basis.

GIPSA is a member of BCG, but its participation is mostly a matter of offering its technical expertise regarding testing. As the Department develops a coordinated, integrated strategy for promoting the export of U.S. GE agricultural commodities in the global market, it should better integrate GIPSA's laboratory certification program within those efforts.

Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES)

ARS and CSREES each support research into biotechnology-related projects, some of which may affect U.S. trade. As the principal research agency of the USDA, ARS conducts research directed at developing and transferring technological solutions to the agricultural sector. From 2005-2007, ARS spent on average approximately \$178 million on research in the biological sciences, including biotechnology; during the same period, CSREES funded an additional \$106 million in grants for similar research.

We found no evidence that research was planned or targeted to address specific priorities in biotechnology trade challenges, such as reducing the risk or disseminating information to mitigate the risk of biotechnology agricultural products. Moreover, ARS officials we spoke to described their participation on BCG as purely advisory, relating mainly to technical matters—CSREES officials also attend these meetings.

As the Department develops a strategic plan for promoting the export of U.S. GE crops, it should work to better integrate research into the overall strategy for addressing and mitigating GE trade challenges and barriers.

We conclude that the Department needs to better coordinate its various biotechnology-related activities to meet the Department's strategic goal of expanding economic and trade opportunities for U.S. producers. Once it establishes a comprehensive, integrated strategy for promoting the export of U.S. GE commodities, it should develop processes that measure USDA's progress towards the goals articulated in that strategy and the overall goals of the Department.

Recommendation 5

Formalize and better document existing processes to effectively coordinate and utilize USDA's various biotechnology-related activities in developing its strategies for resolving or mitigating GE trade barriers.

Agency Response.

The January 27, 2009, response did not specifically address actions to be taken in response to this recommendation.

OIG Position.

To reach management decision, specific information is needed as to how and when USDA will formalize and better document existing processes to more effectively coordinate biotechnology-related activities, including any activities and initiatives resulting from the planned comprehensive strategy.

Scope and Methodology

Our audit work focused primarily on identifying the role of USDA agencies in the export of GE commodities, including policies and procedures used to enhance the international competitiveness of U.S. agriculture. We evaluated the Department's role in the export of GE commodities, and reviewed its efforts to develop a proactive trade strategy and establish a coordinated, integrated strategy for promoting the export of U.S. GE agricultural commodities.

Our fieldwork was conducted at the USDA Headquarters in Washington, D.C., from November 2005 to March 2006 and covered calendar years 2002 through 2006. We solicited additional documents and conducted followup interviews through August 2008.

To accomplish our audit objective, we:

- interviewed representatives from USDA, the SASB's office, and individual agencies to determine how they contribute to the Department's role in the export of GE commodities;
- submitted written questionnaires, requested documents, reviewed documentation, and conducted interviews at applicable USDA agencies;
- analyzed the Department's efforts to create a global market strategy addressing agricultural trade issues;
- interviewed trade industry sources and private commodity associations to obtain observations and opinions on how USDA can better facilitate the export of GE agricultural commodities;
- reviewed FAS' realignment of assigned responsibilities for international trade resulting from the agency's reorganization; and
- reviewed applicable legislative history, laws, regulations, GAO and CRS reports, prior OIG reports, and agencies' internal reviews, including Federal Managers' Financial Integrity Act reports.

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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on audit objective.

Exhibit A – World Agricultural Biotechnology Regulations

Country	Biotech Legislation		Thresholds for Traces of GE Material		Mandatory Labeling Laws		Traceability Requirements	
	Yes	No	Yes	No	Yes	No	Yes	No
Total	58		54		50		31	
Albania				1		1		1
Algeria		1		1		1		1
Argentina		1	1			1		1
Armenia		1		1		1		1
Australia	1		1		1			1
Austria	1		1		1		1	
Azerbaijan		1		1		1		1
Bahamas		1		1		1		1
Bahrain		1		1		1		1
Bangladesh		1		1		1		1
Barbados		1		1		1		1
Belgium	1		1		1		1	
Belize		1		1		1		1
Benin		1	1			1		1
Bermuda		1		1		1		1
Bolivia		1		1		1		1
Bosnia/Herzegovina		1		1		1		1
Botswana		1		1		1		1
Brazil	1				1			1
Bulgaria	1			1	1		1	
Burkina Faso		1	1			1		1
Burma		1		1		1		1
Cameroon	1		1		1			
Canada	1			1	1			1
Chad		1		1		1		1
Chile			1			1	1	
China	1			1	1			1
Colombia	1		1			1		1
Costa Rica	1		1		1			
Ivory coast		1		1		1		
Croatia	1		1		1		1	
Cyprus	1		1		1		1	
Czech Republic	1		1		1		1	

Country	Biotech Legislation		Thresholds for Traces of GE Material		Mandatory Labeling Laws		Traceability Requirements	
	Yes	No	Yes	No	Yes	No	Yes	No
Denmark	1		1		1		1	
Djibouti		1		1		1		1
Dominica		1		1		1		1
Dominican Republic		1		1		1		1
Ecuador				1	1			1
Egypt		1		1		1		1
El Salvador			1			1		1
Eritrea		1		1		1		1
Estonia	1		1		1		1	
Ethiopia		1		1		1		1
Finland	1		1		1		1	
France	1		1		1		1	
Gabon		1		1		1		1
Gambia		1		1		1		1
Germany	1		1		1		1	
Ghana						1		1
Greece	1		1		1		1	
Grenada		1		1		1		1
Guatemala				1	1			1
Guinea		1		1		1		1
Honduras	1			1		1		
Hong Kong				1				1
Hungary	1		1		1		1	
Iceland	1			1				
India	1		1					1
Indonesia	1			1	1			1
Ireland	1		1		1		1	
Israel				1		1		1
Italy	1		1		1		1	
Jamaica				1		1		1
Japan	1		1		1		1	
Jordan		1		1		1		1
Kazakhstan		1		1		1		1
Kenya			1			1		1
Korea	1			1	1			1
Kuwait		1		1		1		1
Latvia	1		1		1		1	
Lebanon		1		1		1		1
Lesotho		1		1		1		1

Country	Biotech Legislation		Thresholds for Traces of GE Material		Mandatory Labeling Laws		Traceability Requirements	
	Yes	No	Yes	No	Yes	No	Yes	No
Lithuania	1		1		1		1	
Luxembourg	1		1		1		1	
Macedonia		1		1		1		1
Madagascar		1		1		1		1
Malawi		1		1		1		1
Malaysia				1				1
Mali		1		1		1		1
Malta	1		1		1		1	
Mauritania		1		1		1		1
Mauritius				1		1		1
Mexico	1		1		1			1
Micronesia		1		1		1		1
Moldova	1			1	1			1
Mongolia		1		1		1		1
Morocco				1		1		1
Namibia				1		1		1
Nepal		1		1		1		1
Netherlands	1		1		1		1	
New Zealand	1		1		1		1	
Nicaragua	1		1			1		1
Niger		1		1		1		1
Nigeria				1				1
Norway	1		1		1		1	
Oman		1		1		1		1
Pakistan				1		1		1
Palau		1		1		1		1
Panama	1			1		1		1
Paraguay			1			1		1
Peru	1			1		1		1
Philippines	1		1					1
Poland	1		1		1		1	
Portugal	1		1		1		1	
Qatar		1		1		1		1
Romania	1		1		1		1	
Russia	1		1		1			1
Rwanda		1		1		1		1
St. Kitts		1		1		1		1
St. Lucia		1		1		1		1
St. Vincent		1		1		1		1

Country	Biotech Legislation		Thresholds for Traces of GE Material		Mandatory Labeling Laws		Traceability Requirements	
	Yes	No	Yes	No	Yes	No	Yes	No
Saudi Arabia	1		1		1			1
Senegal		1		1	1			1
Serbia/Montenegro	1		1					
Singapore	1			1		1		1
Slovakia	1		1		1			1
Slovenia	1		1		1		1	
South Africa	1		1			1		1
Spain	1		1		1		1	
Sri Lanka		1		1				1
Sudan								
Suriname		1		1		1		1
Sweden	1		1		1		1	
Switzerland	1		1		1			1
Syria		1		1		1		1
Taiwan					1			1
Tanzania		1		1		1		1
Thailand			1		1			1
Timor		1		1		1		1
Togo		1		1		1		1
Trinidad/Tobago		1		1		1		1
Tunisia			1			1		1
Turkey				1		1		1
Uganda				1		1		1
Ukraine				1		1		1
United Arab Emirates		1		1		1		1
United Kingdom	1		1		1		1	
Uruguay	1			1		1		1
Uzbekistan				1		1		1
Venezuela	1		1			1		1
Vietnam	1			1	1			1
Yemen			1					
Zambia				1		1		1
Total	58	58	54	85	50	83	31	104

Source: FAS Biotech Group (data through 2004)

Exhibit B – USDA Offices, Groups, and Positions Involved with Biotechnology

Exhibit B – Page 1 of 1

Special Assistant to the Secretary for Biotechnology (SASB)—Acting with the Secretary’s authority, the SASB provides leadership and direction on biotechnology-related activities throughout the Department.

Advisory Committee on Biotechnology and 21st Century Agriculture (AC21)—AC21 is a diverse group of experts in the field of biotechnology that serves as a think-tank providing information and advice to the Secretary of USDA.

Biotechnology Policy Group (BPG)—BPG is a meeting of senior-level departmental officials convened when there is a significant update involving a new technology, a regulatory development, or a policy decision to be made.

Biotechnology Coordinating Group (BCG)—BCG is a meeting of agency representatives to share information about departmental efforts involving biotechnology, to make decisions about technical issues, and to help frame or identify issues for AC21’s or the BPG’s consideration.

Foreign Agricultural Service (FAS)—FAS is the lead USDA agency charged with facilitating international trade. Within FAS, the Biotechnology Working Group served as a quick response team for troubleshooting international trade issues.

CODEX Alimentarius—The *Codex Alimentarius* Commission, or Codex, was created in 1962 by two U.N. organizations, the Food and Agriculture Organization and the World Health Organization, as an international mechanism for promoting the health and economic interests of consumers while encouraging fair international trade in food. CODEX standards are recognized in dispute settlement proceedings of the WTO.

Animal and Plant Health Inspection Service (APHIS)—APHIS is responsible for regulating new varieties of GE plants as they are developed, and deregulating those that are proved to be safe.

Grain Inspection, Packers and Stockyards Administration (GIPSA)—GIPSA certifies the accuracy of tests developed by commercial laboratories. These tests are used to detect the presence of varieties of GE material.

Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES)—ARS and CSREES support research into biotechnology-related projects, some of which may affect U.S. trade, including risk assessment research and projects related to public education.

Exhibit C – Secretary of Agriculture Response

Exhibit C – Page 1 of 1



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

JAN 27 2009

TO: Phyllis K. Fong
Inspector General

FROM: Thomas J. Vilsack *TJV*
Secretary

SUBJECT: Office of Inspector General Report

This letter will acknowledge receipt of an Office of Inspector General Report entitled "USDA's Role in the Export of Genetically Engineered Agricultural Commodities." Attached to the report was a USDA response prepared before I began my service as Secretary of Agriculture.

I have reviewed your report, and it has merit. I have asked the Acting Under Secretary for Research, Education, and Economics to lead our effort to develop a comprehensive strategy relating to the prompt export of genetically engineered agricultural commodities. The Department will deliver the framework for the development of that comprehensive strategy within 6 months of the issuance of your report.

An Equal Opportunity Employer

Exhibit D – Agency Response



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

JAN 15 2009

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: Jeremy Stump *JWS*
Deputy Chief of Staff

SUBJECT: Response to the OIG Audit Report – USDA’s Role in the Export of Genetically Engineered Agricultural Commodities (50601-14-Te)

USDA welcomes the opportunity to comment on the Office of Inspector General (OIG) draft report “USDA’s Role in the Export of Genetically Engineered Agricultural Commodities” (50601-14-Te), and appreciates that OIG has made several corrections to earlier drafts.

The Department continues to take issue with the underlying theme that nontariff trade barriers related to genetic engineering (GE) are widely preventing U.S. producers from exporting agricultural products around the globe. In fact, among major international markets, U.S. exports of these commodities are significantly hampered only into the EU. While U.S. exports of agricultural products derived through biotechnology do face various trade barriers (and USDA continues efforts to reduce these barriers), the effects do not rise above the level typical for non-tariff barriers related to other agricultural products. OIG has not provided any evidence that U.S. exports of biotechnology-derived products are currently impeded on a widespread basis; to the contrary, the OIG report correctly points out that U.S. agricultural exports have been growing. Further, OIG misconstrues the trade situation with the EU, which in 2007 imported over \$1 billion in U.S. soybeans, which are overwhelmingly GE varieties.

Following are USDA’s responses to each of the five recommendations that OIG puts forth in its report. An attachment to these comments contains a listing of corrections and clarifications regarding specific inaccuracies in the report.

Recommendation 1:

Develop and implement a coordinated, comprehensive strategy for promoting the export of U.S. GE crops.

- 1 -

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USDA Response:

Within the USG, USDA does not operate alone in addressing biotechnology-related trade barriers, and we believe USDA should not develop and cannot implement a comprehensive, global strategy by itself. USDA was an active participant in the 2006 interagency process, chaired by the National Security Council, which led to development of a pre-decisional draft strategy. The interagency process did not result in a consensus to finalize that strategy.

Nevertheless, that draft strategy and the conversations required to prepare it have in fact guided and informed USDA activities on an informal and ongoing basis. The OIG's report recognized several active initiatives (APEC, NABI, IICA, China), whereby USDA agencies (FAS, APHIS, GIPSA) work collaboratively with other USG agencies (FDA, EPA, USTR, Department of State, USAID). These are examples of how this strategy, albeit unofficial, has shaped interagency outreach activities. USDA will revisit this issue with our interagency partners during the coming year to determine if there is broad support for formalizing such a national strategy.

Recommendation 2:

Integrate each of the three remaining biotechnology-related requirements from the 2002 Farm Bill into the strategy developed in response to Recommendation 1.

Recommendation 3:

Assist appropriate program agency officials in developing plans to implement the Farm Bill provisions in line with the Department's and program agencies' strategic plans and priorities and in requesting funds to implement each of these provisions. If USDA decides that funding is not necessary, then the Department should document why funding is not being requested.

USDA Response to Recommendations 2 and 3:

USDA notes that the three cited biotechnology requirements were among many unfunded authorizations provided in the Farm Bill. USDA does not believe that, as a general matter, it is at liberty to redirect existing funds to address the many unfunded authorizations for the Department away from programs specifically funded by Congress. Nor, in a quite limited budget environment, can the Department request funding for all authorized but unfunded programs through the President's budget. Instead, each agency must carefully consider Administrative and Congressional priorities, stakeholder input, and programmatic need in formulating its budget request. OIG should, we believe, recognize that this process must occur and should not automatically assume that the particular unfunded authorizations it identified in this audit would necessarily be the highest priorities emerging from such a more broad-based analysis and would therefore

be targets for supplemental funding requests. None of the three requirements cited rose, in previous budget cycles, to the level of other key priorities to become targets for supplemental funding requests. However, USDA has worked in the past and continues to work to address the intent of these three provisions through existing programs and coordination with other agencies.

With respect to Section 3206, as described in our response to Recommendation 1, USDA is operating largely under a draft deliberative strategy that was never finalized by the U.S. Government interagency process. Market access constraints or threats related to biotechnology are counted as a subset of the USDA's Strategic Objective 1.3 related to building a strong, science-based international trading system to minimize restrictive SPS measures and other Technical Barriers to Trade. They are appropriately dealt with within the context of the overall demand on technical and policy resources within the Department.

Recommendation 4:

Develop performance measures to evaluate the effectiveness of the Department's biotech trade-related activities.

USDA Response:

The resolution of biotech-related market access constraints is an integral part of performance measure 1.3.1 in USDA's strategic plan and of some agency-level measures that cascade from that plan. We do not believe, in general, that there is value in establishing separate performance measures for biotechnology apart from those measures.

At a work unit operational level, appropriate performance measures are essential to evaluate properly the effectiveness of certain activities, such as outreach activities. To the extent possible, individual outreach activities do include performance measures. USDA will continue its efforts to develop and improve its measurable standards for such activities.

Recommendation 5:

Formalize and better document existing processes to effectively coordinate and utilize USDA's various biotechnology-related activities in developing its strategies for resolving or mitigating GE trade barriers.

USDA Response:

Because USDA agencies work closely together, often on a daily basis, on many rapidly evolving issues and activities related to biotechnology, meetings are not always documented. However, significant events and outcomes are appropriately documented, as are discussions relating to the mitigation of trade barriers in general.

Attachment

ATTACHMENT TO USDA RESPONSE TO OIG AUDIT REPORT
 USDA's Role in the Export of Genetically Engineered
 Agricultural Commodities (50601-14-Te)

The following additional comments address specific inaccuracies that are contained in the locations specified in the draft report.

Page i, paragraph 1. While it is true that U.S. exports of agricultural products derived through biotechnology do face barriers, U.S. exports of these commodities have been significantly hampered only in the EU and only for corn. U.S. exports of biotechnology-derived commodities, principally corn, cotton, and soybeans, including exports to Japan, have increased steadily over the past three years. OIG has not provided evidence, outside of the EU, where U.S. exports of biotechnology-derived have been severely constrained due to biotechnology-related trade barriers.

Information on the value of U.S. corn, cotton, and soybean exports is provided below. Agricultural biotechnology around the world has grown considerably over the past four years. In the United States, significant gains have been made in the cultivation of biotech varieties of corn, cotton, and soybean. With increasing export values, the statistics below do not appear to support the argument that biotechnology is a significant barrier to U.S. agricultural trade.

Value of Total U.S. Corn, Cotton, and Soybean Exports

Value in 1,000 Dollars

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>
Corn	5,875,414	4,788,825	6,991,702	9,762,572
Cotton	4,251,073	3,929,420	4,514,432	4,588,693
Soybeans	6,667,516	6,273,643	6,935,556	9,992,106

Value of U.S. Corn and Soybean Exports to Japan

Value in 1,000 Dollars

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>
Corn	1,888,744	1,604,371	1,948,254	2,612,051
Soybeans	1,005,217	806,085	854,138	1,096,110

Value of U.S. Corn and Soybean Exports to the EU

Value in 1,000 Dollars

	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>
Corn	9,830	2,256	1,424	7,631
Soybeans	858,577	590,518	722,004	1,020,115

Page i, second paragraph. It should first be noted that the United States does not recognize the "precautionary principle" as an element of international law. That having been noted, we believe that this paragraph does not accurately reflect statements made by

the EU regarding their use of the “precautionary principle.” The stated reason for mandatory labeling of GE food commodities in the EU is “consumer choice”, not the so-called principle. Further, the “precautionary principle,” according to those governments that offer it as a justification for actions, is intended to provide a response to uncertainty, not to justify regulation in the absence of reason for concern.

Page i, third paragraph. The description of the U.S. approach for regulating GE food products is not accurate. APHIS may grant non-regulated status to a GE organism if, based on information provided by the developer, APHIS can determine that the organism is not likely to pose a significant plant pest risk. APHIS’ authority is under the Plant Protection Act. All foods, including GE food products, must also be safe and comply with the provisions of the Federal Food Drug and Cosmetics Act, administered by the Food and Drug Administration. Further, the description omits mention of the role played by the Environmental Protection Agency.

Page ii, last paragraph. Please see the introduction to this memorandum as well as the responses to Recommendations 1 and 4.

Page iii, first full paragraph and last paragraph. OIG offers its policy pronouncements on what a USDA trade strategy should encompass. USDA questions the appropriateness of such policy recommendations. Please also see the response to Recommendation 1.

Page iii, last paragraph. USDA/FAS biotechnology trade efforts do focus proactively to open and maintain markets and also respond appropriately when individual trade issues arise. The capacity building activities undertaken by USDA/FAS that are cited in pages 23-25 of the OIG report are examples of strategic efforts by FAS to “proactively” open and maintain markets for biotechnology-derived exports. Responses are initiated when individual biotechnology-related trade issues arise.

Page 1, last paragraph through Page 2, first paragraph. USDA agrees with the statement that no international consensus has emerged on how GE plant varieties should be regulated. Please see, in addition, the comment relating to page i, second paragraph.

Page 2, end of first paragraph. USDA does not believe that this audit substantiates the assertion that nations other than the EU have used the “precautionary principle” to erect trade barriers to the export of U.S. GE agricultural commodities.

Page 3, last paragraph. USDA believes it is important to note that, in terms of international trade, traceability requirements for GE materials have up until this time proved to be significant trade barriers only with respect to commerce with the EU.

Page 5, first paragraph. USDA does not understand why this audit refers to the existence of nontariff trade barriers with Japan. Japan is the second largest importer of U.S. agricultural commodities containing GE varieties. As noted to OIG previously, U.S. exports of corn and soybeans to Japan, most of which are GE varieties, were valued at

over \$3.7 billion in 2007.

Page 5, second paragraph. USDA disagrees with OIG's contention that biotechnology-related efforts at the departmental level are "ad hoc, uncoordinated, or undocumented." There are established procedures for consultation and coordination among USDA agencies on biotechnology policy issues and other developments, and these mechanisms are robust and effective (as are mechanisms for consultation outside USDA). USDA's trade activities are informed by, and consistent with, the overall Departmental policy priorities elaborated in its strategic plan for 2005-2010, and USDA uses a "pre-decisional draft strategy document" drafted in 2006 by FAS under the auspices of the National Security Council as a general guideline for biotechnology trade-related activities. As indicated in our response to Recommendation 1, the key elements of that strategy have been, and continue to be, executed by USDA officials in our trade activities. With respect to documentation of biotechnology related efforts, USDA believes that individual trade-related activities are well-documented in Departmental records: this record of well-thought-out and successful activities forms an adequate body of documentation.

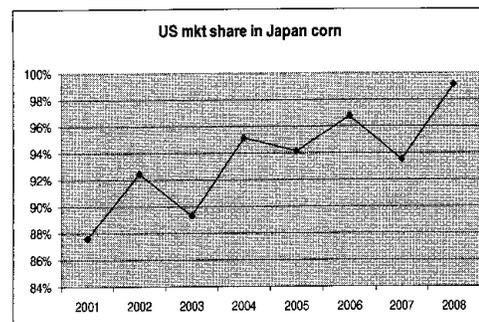
Page 7, last sentence. It is not the U.S. position that there is "no difference" between approved GE crops and their unmodified equivalents. The regulatory standard requires that the GE crops be as safe as their unmodified equivalents, not that they be identical.

Page 8, third full paragraph. USDA does not understand why Japan and South Korea are singled out as having erected trade barriers to U.S. GE agricultural commodities that resemble those of the EU (to which exports of U.S. corn are effectively blocked). Both countries are major markets for U.S. GE exports. Japan is the second largest importer of U.S. GE agricultural commodities, with 2007 imports of U.S. corn and soybeans valued at over \$3.7 billion. South Korea ranks fifth, with 2007 imports of U.S. corn and soybeans valued at just under \$1 billion.

Page 8, last paragraph, first sentence. USDA believes that this statement needs to be put into perspective by recognizing that a substantial contributor to the decline in the U.S. agricultural trade surplus between 1996-2006 was the rise in U.S. agricultural imports from \$33.5 billion to \$65.3 billion over that interval.

Page 9, first full paragraph. Markets are continually changing based on varying supply and demand conditions and thus can never be taken as "final". It is unclear which specific market is referred to that "has experienced a number of especially dramatic shifts in demand". However, this paragraph infers that changes to markets are largely attributable to biotechnology-related issues while in reality other market considerations usually play a far more significant role.

- Contrary to the report's implication that Japan's "negative reaction" (as well as

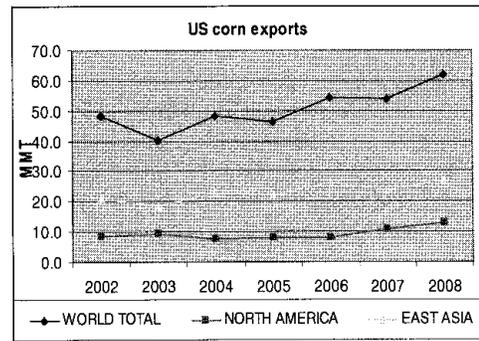


an earlier mention of “precautionary principle”) to GE commodities has “endangered” a \$1.9 billion market, U.S. market share in corn in Japan has actually increased in recent years, to 99 percent.

- U.S. market share in corn in the EU was small prior to the latter enforcing its WTO-inconsistent moratorium on GE products, which led to a further reduction in U.S. exports there.

Other market factors to consider:

- The United States remains a major supplier of corn to the world market. While U.S. corn exports to the EU have declined, total U.S. exports to the world have increased, particularly to East Asia and North America (NAFTA).
- The U.S. stocks-to-use ratio is near historic lows. As a residual corn supplier to the world, over 85 percent of U.S. corn production is consumed domestically for feed, food, and industrial products, including ethanol.



Page 9, third paragraph, third sentence. USDA does not understand why this particular reference is included, given the following two sentences which refute the industry contention. While we acknowledge the industry perspective at the time of the statement, we note that in 2006, U.S. rice exports totaled \$1.271 billion, little changed from the \$1.277 billion recorded for 2005, despite 12 percent less production that year. In 2007, U.S. rice exports jumped to \$1.392 billion.

Page 11, first full paragraph, last sentence. Please see the introductory paragraphs of this memorandum and the response to Recommendation 1.

Page 11, second full paragraph. It remains USDA’s understanding that no consensus exists among the various biotechnology trade associations on the need or desirability of a specific export strategy for biotechnology products. Various private sector stakeholders have different interests which may or may not benefit from a specific USDA export strategy for GE agricultural products. Likewise, the relevant trade associations that promote exports of specific commodities do not as a rule assert that it is in their best interests to have a separate strategy for promoting their crops as genetically engineered.

Page 12, first full paragraph. Please see the response to Recommendations 2 and 3.

Page 15, first and second full paragraphs. USDA stands behind the rigor of APHIS’ scientific reviews for new GE products and the safety of those products that have been deregulated for use in agriculture. To direct scarce additional research funds towards

issues that are adequately addressed would be a waste of resources and would inappropriately enhance the credibility of unfounded concerns. When significant new concerns unexpectedly arise (as in the Bt- monarch butterfly issue raised several years ago) USDA takes action to see that appropriate research is done and those concerns are addressed. As a general matter, USDA does not believe that it was the intent of Congress to allocate these funds to address trade issues and that it would be unwise to flout their intent when the Biotechnology Risk Assessment Grants (BRAG) program was created to address trade concerns as opposed to new or emerging science-based risk concerns. As currently operating, the BRAG program receives regular input from regulatory officials to help identify new or emerging scientific issues and regulatory officials in fact participate in the grant review process.

Page 20, first and second paragraphs. Please see the introductory paragraphs of USDA's response and our response to Recommendation 1. In addition, the second paragraph appears to suggest erroneously that agricultural trade has not been vitally important to the U.S. in the past and is just now becoming so. In fact, however, the U.S. has been negotiating with our trading partners on a variety of agricultural issues for decades.

Page 20, last two paragraphs through first full paragraph on page 21. USDA questions the overemphasis on the BPG in the report. As noted to OIG, the group met very few times and was effectively superseded by weekly meetings led by the USDA Chief of Staff several years ago.

Page 26, second paragraph. Please see USDA comments on page iii, last paragraph.

Page 27, second paragraph. The audit indicates that APHIS is not required to include market or public acceptance, or to consider trade implications, in our decision to deregulate a new GE plants. In fact, APHIS, using existing regulations under the authority of the Plant Protection Act, can only make a determination to deregulate a GE organism if it can be determined that the organism is not likely to pose a significant plant pest risk. APHIS cannot legally consider market or public acceptance or trade implications in its regulatory decisions.

Page 28, first full paragraph. USDA believes that the citation given from one industry representative does not reflect the views from industry as a whole at present and is likely an outdated statement. The paragraph ignores several key developments over the past several years: industry stewardship plans; APHIS' Biotechnology Quality Management System, initiated in 2008, designed to help the regulated community systematically improve compliance with requirements for control of regulated GE materials; provisions in the 2008 Farm Bill designed to help APHIS implement "lessons learned" from instances of low-level presence of regulated GE materials in the marketplace; and the October 2008 publication by APHIS of a proposed rule to modify existing regulations in part to help improve controls over regulated materials. Moreover, as a general matter of policy, the U.S. government does not subscribe to the idea that its science-based regulatory decisions should be conditioned on regulatory decisions made in other

countries.

Page 29, second paragraph. GIPSA is an integral member of the BCG and an active participant in all BCG discussions, not merely a technical resource for information about testing methodologies. Through its discussions and negotiations with other agencies, with industry, and with trading partners as well as its active participation in the BCG, GIPSA has, importantly, taken the lead in drafting and/or developing protocols and international arrangements that have prevented trade disruptions or allowed disrupted markets to reopen. Here are a few examples:

- GIPSA was the original drafter of text that ultimately became a signed arrangement among Canada, Mexico, and the United States to clarify documentation requirements under the Cartagena Protocol on Biosafety, thereby avoiding potential trade disruptions to grain trade that may potentially have arisen upon entry into force of the Protocol in 2003.
- Following the discovery of StarLink corn in the U.S. corn supply, GIPSA was the original drafter of two protocols (one each for food and feed corn) established to sample and test U.S. corn exports for the presence of StarLink, which were subsequently accepted by Japan, allowing the 16 million-ton-per-year market to continue undisrupted.
- Following the announcement in 2006 that regulated LibertyLink rice was detected in trace amounts in the U.S. rice supply, GIPSA developed recommended approaches to sampling and testing to meet requirements of trading partners that are achievable for the U.S. rice industry, and drafted a sampling and testing protocol to meet the regulatory requirements of the European Commission. The protocol was embodied into an official EC Directive which allowed the U.S. rice market to Europe to reopen.

Page 29, fourth full paragraph. Please see comment regarding *Page 15, first and second full paragraphs*, above.