2011 Report on Sanitary and Phytosanitary Measures

Ambassador Ronald Kirk

Office of the United States Trade Representative

ACKNOWLEDGEMENTS

The Office of the United States Trade Representative (USTR) is responsible for the preparation of this report. U.S. Trade Representative Ron Kirk gratefully acknowledges in particular the contributions of Deputy U.S. Trade Representatives Demetrios Marantis, Michael Punke, and Miriam Sapiro; USTR General Counsel Timothy Reif; Chief Agricultural Negotiator Isi A. Siddiqui; Chief of Staff Lisa Garcia; Assistant USTR for Public/Media Affairs Carol Guthrie, Senior Policy Advisor Janis Lazda, Special Assistant Stephen Ostrowski, Director of Speechwriting Jeremy Sturchio, and all USTR staff who contributed to the drafting and review of this report. Thanks are extended to partner Executive Branch agencies, including the Environmental Protection Agency, the Food and Drug Administration, and the Departments of Agriculture, Commerce, and State. Ambassador Kirk would also like to thank Elizabeth Teague for her contributions.

In preparing the report, substantial information was solicited from U.S. embassies around the world and from interested stakeholders. The draft of this report was circulated through the interagency Trade Policy Staff Committee.

March 2011

LIST OF FREQUENTLY USED ACRONYMS AND ABBREVIATIONS

AI	Avian Influenza
APEC	Asia Pacific Economic Cooperation
APHIS	USDA's Animal and Plant Health Inspection Service
BSE	Bovine Spongiform Encephalopathy
CACM	Central American Common Market
CAFTA-DR	Dominican Republic-Central America-United States Free Trade Agreement
CAN	Andean Community
Codex	Codex Alimentarius Commission
EPA	U.S. Environmental Protection Agency
EU	European Union
FAO	United Nations Food and Agriculture Organization
FAS	USDA's Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FSIS	USDA's Food Safety and Inspection Service
FTA	Free Trade Agreement
HACCP	Hazard Analysis and Critical Control Points
HPAI	Highly Pathogenic Avian Influenza
IPPC	International Plant Protection Convention
LPAI	Low Pathogenic Avian Influenza
MOU	Memorandum of Understanding
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
NTE	National Trade Estimate
OIE	World Organization for Animal Health
PMWS	Post-Weaning Multisystemic Wasting Syndrome
PRA	Pest Risk Assessment
PRRS	Porcine Reproductive and Respiratory Syndrome
PRT	Pathogen Reduction Treatment
SPS	Sanitary and Phytosanitary
SRM	Specified Risk Material
TBT	Technical Barriers to Trade
TIFA	Trade and Investment Framework Agreement
TPSC	Trade Policy Staff Committee
TWG	Trade Working Group
USDA	U.S. Department of Agriculture
USTR	Office of the U.S. Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

FOREWORD

This year the Office of the United States Trade Representative (USTR) publishes its second annual *Report on Sanitary and Phytosanitary Measures* (*SPS Report*). This report was created to respond to the concerns of U.S. farmers, ranchers, producers, and workers who are running into SPS trade barriers as they seek to export high-quality American agricultural products around the world. SPS measures are rules and procedures that governments use to ensure that foods and beverages are safe to consume and to protect animals and plants from pests and diseases.

Many SPS measures are fully justified, but too often governments cloak discriminatory and protectionist trade measures in the guise of ensuring human, animal, or plant safety. These SPS barriers not only harm U.S. farmers, ranchers, producers, workers, and their families, they also deprive consumers around the world of access to high-quality American agricultural goods. USTR is committed to identifying and combating unjustifiable SPS barriers to U.S. agricultural exports, many of which are detailed in this report. USTR's efforts to remove foreign SPS barriers serve the President's goal of doubling U.S. exports by the end of 2014 through the National Export Initiative.

As discussed in this report, the United States achieved some important successes since the publication of last year's report in dismantling SPS barriers that blocked U.S. agricultural exports. For example, U.S. negotiators removed SPS barriers in Chile and Egypt for U.S. beef and beef products as well as barriers in Colombia, Ecuador, and Russia to U.S. exports of poultry and poultry products. The United States also persuaded China to lift its unnecessary swine flu-related import restrictions that kept U.S. producers from selling live swine to China.

In 2011, USTR will continue to work with colleagues from across the U.S. Government, as well as interested stakeholders, to encourage governments around the world to remove their unwarranted SPS rules. As always, we will engage in all available bilateral, regional, and multilateral fora in our efforts to dismantle these barriers to U.S. agricultural exports and strengthen the rules-based trading system to ensure a level playing field abroad for U.S. ranch and farm products. We look forward to making further progress on behalf of America's farmers, ranchers, producers, and workers, as well as families who depend on export-supported American jobs.

Ambassador Ron Kirk
U.S. Trade Representative
March 2011

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I. EXECUTIVE SUMMARY

The *2011 Report on Sanitary and Phytosanitary Measures* (*SPS Report*) is a specialized report dedicated to describing significant barriers to U.S. food and farm exports arising from measures that foreign governments apply on the ground that they are necessary to protect human, animal, or plant life or health from risks arising from the entry or spread of pests, from plant- or animal-borne pests or diseases, or from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs. These measures, known in World Trade Organization (WTO) parlance as "sanitary and phytosanitary (SPS) measures," play an increasingly critical role in shaping the flow of global trade. The United States strongly supports the right of governments to protect their people, animals, and plants from health risks of this kind. This report is focused on SPS measures that appear to be unscientific, unduly burdensome, discriminatory, or otherwise unwarranted and create significant barriers to U.S. exports. Many of these measures can present particular challenges for small and medium sized enterprises (SMEs) that typically lack the resources to identify and address such barriers. This report is intended to describe and advance U.S. efforts to identify and eliminate these measures.

Section II of this report presents an overview of SPS measures, describes the relevant international agreements governing these measures, and discusses the U.S. and international mechanisms for addressing them. In particular, Section II covers the following topics: (1) the genesis of this report; (2) the growing importance of SPS measures in global trade; (3) rules governing SPS measures under the WTO's *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement); (4) rules and mechanisms regarding SPS measures in U.S. free trade agreements; (5) international standard setting in the SPS area; (6) the role of various U.S. Government agencies in addressing SPS-related trade issues; (7) sources of information about SPS trade barriers; and (8) U.S. trade policy mechanisms for considering and addressing SPS measures, including bilateral engagement and WTO dispute settlement.

Section III discusses important SPS issues that affect U.S. exports in multiple foreign markets. Among the most significant of these cross-cutting barriers are restrictions related to avian influenza (AI), biotechnology, bovine spongiform encephalopathy (BSE), maximum residue limits (MRLs) on pesticides, and ractopamine.

The focal point of this report is Section IV, which identifies and describes significant unwarranted SPS-related trade barriers currently facing U.S. exporters, along with U.S. Government initiatives to eliminate or reduce the impact of these barriers. The report identifies SPS measures in the following countries and groups of countries: Argentina, Australia, Bolivia, Brazil, Chile, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, the European Union, Guatemala, the Gulf Cooperation Council, Honduras, Hong Kong, India, Indonesia, Israel, Jamaica, Japan, Kazakhstan, Kuwait, Mexico, Morocco, New Zealand, Nicaragua, Norway, Peru, Philippines, Russia, Saudi Arabia, Singapore, South Africa, the South African Development Community, South Korea, Sri

Lanka, Switzerland, Taiwan (Chinese Taipei), Thailand, Turkey, Ukraine, United Arab Emirates, Uruguay, Venezuela, and Vietnam.

Section V discusses the U.S. Government's efforts to provide technical assistance to developing countries on SPS issues. Such assistance is instrumental to U.S. efforts to ensure that countries adopt and maintain science-based SPS measures.

II. INTRODUCTION

A. Genesis of this Report

Shortly after taking office in 2009, President Obama reaffirmed America's commitment to ensuring the effective implementation and enforcement of the World Trade Organization's (WTO) system of multilateral trading rules. The President's 2009 Trade Policy Agenda vowed an aggressive and transparent program of defending U.S. rights and benefits under the rules-based trading system as a key element in his vision to restore the role of trade in leading economic growth and promoting higher living standards. The President's Agenda also recognized that "behind the border" measures and other non-tariff barriers have grown in significance for U.S. exporters seeking access to foreign markets.

In a major policy speech delivered at the Edgar Thomson Plant of the Mon Valley Works in Pittsburgh, Pennsylvania in July 2009, the U.S. Trade Representative, Ambassador Ron Kirk, pledged more aggressive action to break down barriers to U.S. exports. Ambassador Kirk highlighted two kinds of non-tariff measures that pose increasing challenges to U.S. producers and businesses seeking to export products abroad: sanitary and phytosanitary (SPS) measures, which are measures that governments apply to protect human, animal, or plant life or health from risks arising from the entry or spread of pests, from plant- or animal-borne pests or diseases, or from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs; and standards-related measures, such as mandatory product standards and testing requirements.

In his speech, Ambassador Kirk pledged stepped up monitoring of trading partners' SPS and standards-related practices that act as obstacles to U.S. trade. He also vowed increased engagement to resolve trade issues and to help ensure that U.S. trading partners are complying with trade rules – particularly those relating to obligations under two WTO agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). The goal of this intensified monitoring and engagement is to help to facilitate and expand trade in safe, high quality U.S. products.

Ambassador Kirk also relayed his determination to make USTR's annual reports to Congress "more than paperwork." To this end, he directed that the annual reports be used to bring new energy to the process of identifying non-tariff measures that act as significant barriers to U.S. exports; to provide a central focus for intensified engagement by U.S. agencies in resolving trade concerns related to non-tariff barriers; and to document ongoing efforts to give greater transparency and confidence to American workers, producers, businesses, consumers and other stakeholders with regard to the actions this Administration is taking on their behalf.

The *SPS Report on Sanitary and Phytosanitary Measures* (*SPS Report*) serves these goals. This specialized report was first published in 2010. It is dedicated to describing significant and unwarranted SPS foreign barriers. Many of these measures were previously addressed

in the *National Trade Estimate Report on Foreign Trade Barriers* (*NTE Report*).[1] By addressing significant foreign trade barriers in the form of SPS measures, the *SPS Report* meets the requirements under Section 181 of the Trade Act of 1974, as amended, to report on significant foreign trade barriers with respect to SPS measures. Accordingly, the *2011 NTE Report* itself does not contain information on these measures. A separate report addressing significant foreign trade barriers stemming from technical regulations, standards, and conformity assessment procedures (*2011 Report on Technical Barriers to Trade*, or *TBT Report)* is being released in parallel with this report.

The *SPS Report* begins with an overview of SPS measures and the international trade rules that govern them. It then summarizes the manner in which the U.S. Government addresses foreign SPS trade barriers. Next, the *SPS Report* discusses certain SPS trade barriers that U.S. producers face in a number of different markets. The following section, comprising the focal point of the *SPS Report*, identifies and describes SPS trade barriers on a country-by-country basis, along with a description of U.S. Government engagement on these issues. The *SPS Report* concludes with a discussion of the U.S. Government's efforts to provide technical assistance to developing countries on SPS issues.

Like the *NTE Report*, the source of the information for the *SPS Report* includes stakeholder comments that USTR solicited through a *Federal Register* notice, reports from U.S. embassies abroad and from other federal agencies, and USTR's ongoing consultations with domestic stakeholders and trading partners. An appendix provides a list of entities that submitted comments in response to the *Federal Register* notice.

B. SPS Measures – What They Are, Why They Are Needed, and When They Become Trade Barriers

SPS measures are measures that governments apply to protect human, animal, or plant life or health from risks arising from the entry or spread of pests, from plant- or animal-borne pests or diseases, or from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs. For example, the United States and other governments routinely apply measures at the border to protect domestic crops or livestock from imported farm products or animals that may introduce a plant pest or animal disease into the country. As an illustration, many countries have established maximum residue limits (MRLs) for pesticide residues in food to promote food safety, as well as requirements that imported vegetables be treated to eliminate a particular pest to protect plant health. In

[1] In accordance with section 181 of the Trade Act of 1974 (the 1974 Trade Act), as amended by section 303 of the Trade and Tariff Act of 1984 (the 1984 Trade Act), section 1304 of the Omnibus Trade and Competitiveness Act of 1988 (the 1988 Trade Act), section 311 of the Uruguay Round Trade Agreements Act (the 1994 Trade Act), and section 1202 of the Internet Tax Freedom Act, the Office of the U.S. Trade Representative is required to submit to the President, the Senate Finance Committee, and appropriate committees in the House of Representatives, an annual report on significant foreign trade barriers. The statute requires an inventory of the most important foreign barriers affecting U.S. exports of goods and services, foreign direct investment by U.S. persons, and protection of intellectual property rights.

addition, governments often require live animals to be subject to veterinary health examinations, disease testing, and possibly pre- or post-entry quarantine.

At times, however, some governments impose SPS measures that are really disguised barriers to trade, not grounded in science, or that are otherwise unwarranted, and which create substantial barriers to U.S. exports. For example, many countries have used the threat of avian influenza (AI) or bovine spongiform encephalopathy (otherwise known as BSE or "mad cow disease") as a reason to block U.S. poultry and beef exports, respectively, ignoring international science-based standards that establish appropriate measures for addressing those diseases.

Maintaining dependable export markets for U.S. agricultural producers is critical to this nation's economic health. Overall, U.S. farm exports totaled $108.7 billion in FY 2010. According to Economic Research Service estimates, each $1 billion in agricultural exports supports approximately 8,400 jobs on and off the farm. At the same time, however, SPS trade barriers prevent U.S. producers from shipping hundreds of millions of dollars worth of goods, hurting farms and small businesses. The elimination of unwarranted SPS foreign trade barriers is a high priority of the U.S. Government.

The U.S. Government's pursuit of both goals – safeguarding the United States from risks to human, animal, or plant life or health as discussed above, and aggressively defending the interests of U.S. producers in exporting safe, wholesome products to foreign markets – are fully consistent. The United States and other governments have a legitimate right to adopt and enforce measures to protect their people, animals, and plants from SPS-related risks. At the same time, it is appropriate to question SPS measures that appear to be discriminatory, unscientific, or otherwise unwarranted and that, accordingly, do not serve to guard against legitimate heath risks but rather act to protect domestic or favored foreign producers.

C. The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

The SPS Agreement, to which all WTO Members are parties, explicitly recognizes that countries have the right to adopt regulations to protect human, animal, or plant life or health – including food safety regulations and measures to protect domestic crops, livestock, and poultry – and to establish the levels of protection from risk they deem appropriate. Starting from that premise, the SPS Agreement establishes a number of general requirements and procedures to ensure that governments adopt and apply SPS measures to protect against real risks rather than to protect local producers from import competition. The SPS Agreement also encourages harmonization of SPS measures among WTO Members, where appropriate.

Some of the more important elements of the SPS Agreement are described in this section.

The Scope of the SPS Agreement

The SPS Agreement applies only to those governmental measures that may directly or indirectly affect international trade. If a measure has no trade effect or is imposed by a private company or trade association, the SPS Agreement does not apply to it. The Agreement defines SPS measures as any measure that a WTO Member applies:

- to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

- to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages or feedstuffs;

- to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

- to prevent or limit other damage in the territory of the Member from the entry, establishment or spread of pests.

SPS measures include all relevant laws, decrees, regulations, requirements, and procedures including, among others: end product criteria; processes and production methods; testing, inspection, certification, and approval procedures; quarantine treatments, including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures, and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

Appropriate Level of Protection

As noted above, the SPS Agreement explicitly recognizes the right of WTO Members to take SPS measures necessary to protect human, animal, or plant life or health. An important question is how much protection a Member may seek against a particular risk when it adopts an SPS measure. Under the SPS Agreement, each Member is free to choose its own "appropriate level of sanitary or phytosanitary protection."

Science-Based Measures

Once a WTO Member has established its appropriate level of protection, the SPS Agreement provides that the SPS measures it takes to achieve that level of protection must be based on scientific principles, must not be maintained without sufficient scientific evidence, and may be applied only to the extent necessary to protect human, animal, or plant life or health. In cases where relevant scientific evidence is insufficient, a government may provisionally

adopt SPS measures on the basis of available information. In such circumstances, WTO Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the SPS measure accordingly within a reasonable period of time.

Risk Assessment

The SPS Agreement requires each Member to ensure that its SPS measures are based on an assessment, as appropriate to the circumstances, of the risk that a particular substance or product, including a process or production method, poses to human, animal, or plant life or health.

Unjustifiable Discrimination and Disguised Restrictions on Trade

While each WTO Member is free to choose the level of protection it considers appropriate, the SPS Agreement requires Members to ensure that their SPS measures are not more trade-restrictive than required to achieve that level of protection, taking into account technical and economic feasibility. It also requires governments to avoid arbitrary or unjustifiable distinctions in the levels of protection in different situations if such distinctions result in discrimination against a good from another WTO Member or constitute a disguised restriction on international trade.

Harmonization

The SPS Agreement calls for governments to base their SPS measures on international standards, guidelines, and recommendations developed by international standard setting organizations. The objective in promoting the use of international standards is to facilitate trade by harmonizing different Members' SPS measures on as wide a basis as possible. The three recognized standard-setting bodies in the SPS Agreement are: (1) the Joint Food and Agricultural Organization of the United Nations (FAO)/World Health Organization (WHO) Codex Alimentarius Commission (Codex) for food safety; (2) the FAO International Plant Protection Convention (IPPC) for plant health; and (3) the World Organization for Animal Health, formerly known as the International Office of Epizootics (OIE), for animal health and zoonoses. A Member may depart from an international standard, guideline, or recommendation if the Member's measure is in accordance with the obligations of the SPS Agreement.

Transparency

The SPS Agreement requires WTO Members promptly to publish all adopted SPS measures in a manner that enables other interested WTO Members to become acquainted with them. The SPS Agreement also requires each Member to maintain an enquiry point that is responsible for providing relevant documents and answers to all reasonable questions from interested Members concerning SPS regulations adopted or proposed in the Member's territory. In addition, the SPS Agreement requires each WTO Member to publish

any proposed SPS measure that is not based on an international standard, guideline, or recommendation and that may have a significant effect on trade in order to provide other Members with prior notice and an opportunity to comment on the proposal, except where "urgent problems of health protection" are involved.

The United States takes its transparency obligations very seriously and encourages other WTO Members to do the same. Since the WTO was established in 1995, the United States has submitted an average of 162 SPS notifications per year.

SPS Committee

The SPS Agreement establishes a Committee on Sanitary and Phytosanitary Measures (SPS Committee) to provide a regular forum at the WTO for consultations about SPS measures that affect trade and to oversee the implementation of the SPS Agreement.

The SPS Committee is open to all WTO Members as well as governments that have observer status in higher level WTO bodies. The U.S. delegation to the SPS Committee is led by USTR, and includes representatives from the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Departments of Commerce and State. The United States is an active participant at SPS Committee meetings, where it regularly raises issues for Members to consider. In addition to participating WTO Members, the SPS Committee has invited representatives of several international intergovernmental organizations to attend as observers. Among the observers have been representatives from Codex, the OIE, the IPPC, and the WHO.

The agenda for SPS Committee meetings varies, but several items appear regularly. Committee members routinely discuss matters related to how the SPS Agreement is being applied and implemented and specific trade concerns, such as pesticide residue level restrictions. Members also discuss and develop procedures and guidelines that help governments implement their obligations under the SPS Agreement. All procedures and guidelines that the SPS Committee establishes must be adopted by consensus.

Technical Assistance

The SPS Agreement encourages all Members to facilitate technical assistance to developing country Members either bilaterally or through relevant international organizations, such as the Standards and Trade Development Facility (STDF) and the Inter-American Institute for Cooperation on Agriculture (IICA). The STDF is a joint initiative of the WTO, FAO, OIE, and WHO aimed at raising awareness on the importance of SPS issues, increasing coordination in the provision of SPS-related assistance, and mobilizing resources to assist developing countries enhance their capacity to meet SPS standards. The IICA is a specialized agency of the Inter-American System, whose purpose is to encourage and support the efforts of its Member States to achieve agricultural development and well-being for rural populations.

D. Other SPS-Related International Agreements

The North American Free Trade Agreement

Because the North American Free Trade Agreement (NAFTA) entered into force before the WTO was established, and thus before there were multilateral disciplines on SPS measures, the NAFTA contains a much more detailed SPS chapter than later U.S. Free Trade Agreements (FTAs). For example, the NAFTA imposes specific disciplines on the development, adoption, and enforcement of SPS measures. As is the case with the SPS Agreement, the NAFTA SPS disciplines are designed to prevent the use of SPS measures as disguised restrictions on trade, while still safeguarding each country's right to protect consumers from unsafe products, or to protect domestic crops and livestock from the introduction of imported pests and diseases.

The NAFTA encourages the three NAFTA Parties (the United States, Canada, and Mexico) to adopt international and regional standards, while at the same time explicitly recognizing each country's right to determine its appropriate level of protection. Such flexibility permits each country to set standards that are more stringent than international guidelines, as long as those standards are scientifically based.

The NAFTA Committee on SPS Measures promotes the harmonization and equivalence of SPS measures between the three governments and facilitates technical cooperation, including consultations regarding disputes involving SPS measures. The Committee meets periodically to review and resolve SPS issues.

The NAFTA SPS Committee also hosts a number of technical working groups (TWGs) that have served to enhance regulatory cooperation and facilitate trade between the three NAFTA countries. TWGs address trade issues and national regulatory and scientific review capacity. They also coordinate regulatory decision-making to reduce the burden on industry. For example, the NAFTA TWG on pesticides has created a venue for collaboration between U.S. EPA's Office of Pesticides Programs and its counterparts in Canada and Mexico. The primary objective of this working group is to enhance cooperation and harmonize pesticide standards while maintaining and enhancing standards of food safety, public health, and environmental protection.

Other U.S. Free Trade Agreements

Most FTAs that the United States has concluded since the WTO was inaugurated in 1995 include an SPS chapter.[2] While those chapters do not impose new or additional substantive rules or obligations, many of these agreements establish SPS committees that provide a

[2] Among the U.S. Free Trade Agreements that include an SPS chapter are the U.S. – Australia FTA, the U.S. – Bahrain FTA, the U.S. – Chile FTA, the Dominican Republic – Central America – United States FTA (CAFTA – DR), the U.S. – Oman FTA, and the U.S. – Peru Trade Promotion Agreement (TPA). The U.S. – Morocco FTA does not have a stand-alone SPS chapter, but does include various SPS provisions in its agriculture chapter.

forum for the parties' trade and regulatory authorities to resolve contentious bilateral or regional SPS issues, consult on SPS matters that are pending before relevant international organizations, and coordinate technical cooperation programs.

E. International Standard Setting Bodies

The WTO officially recognizes three standard setting bodies to deal with SPS matters: the Codex Commission for food safety, the OIE for animal health and zoonoses, and the IPPC for plant health. U.S. Government experts participate actively in these organizations, which meet periodically to discuss current and anticipated threats to human and agricultural health, evaluate scientific issues surrounding SPS-related issues, and develop internationally recognized SPS standards based on science. These standards are voluntary and are intended to provide guidance for countries in formulating their own national SPS measures and, ultimately, to help avoid and resolve disputes over appropriate SPS measures. As discussed below, various USDA agencies lead the U.S. delegations to these three international bodies. The United States strongly encourages its trading partners to adopt the standards set by Codex, IPPC, and the OIE**.**

In recent years, the United States has supported a number of important standards developed by these international bodies. For example, the OIE has worked to promulgate science-based guidelines to be followed in the event that a potentially dangerous strain of AI is detected. According to these guidelines, unprocessed poultry products from countries that report detections of low pathogenic avian influenza (LPAI) may be traded with minimal restrictions, and countries reporting highly pathogenic avian influenza (HPAI) may trade safely in poultry and poultry products under specified conditions. The guidelines do not, however, recommend any type of import bans on poultry commodities from countries with non-notifiable subtypes of AI.

F. U.S. Government Agencies

The Executive Branch has robust policies and procedures in place for addressing and resolving foreign SPS trade barriers. The following discussion describes the roles that the relevant federal agencies play in that effort.

Office of the United States Trade Representative

USTR, a component of the Executive Office of the President, is responsible for developing and coordinating U.S. international trade policy, and overseeing negotiations with other countries, including with respect to foreign SPS measures. USTR meets with governments, business groups, legislators, public interest groups, and other interested parties to gather input on SPS issues and to discuss trade policy and negotiating positions. USTR then coordinates U.S. trade policy through an interagency structure (as discussed below). USTR plays a variety of roles with regard to trade barriers generally, including SPS barriers, such as by serving as the lead U.S. agency in negotiating bilateral, regional, and multilateral trade agreements and lead U.S. counsel in all WTO disputes.

The head of USTR is the U.S. Trade Representative, a Cabinet member who serves as the President's principal trade advisor, negotiator, and spokesperson on SPS and other trade issues. Created in 1962, USTR has offices in Washington and Geneva, and posts representatives in Beijing and Brussels.

U.S. Department of Agriculture

USDA plays a key role in addressing foreign SPS trade barriers as the vast majority of these barriers are restrictions on U.S. agricultural exports. In particular, three USDA components, the Foreign Agricultural Service (FAS), the Animal and Plant Health Inspection Service (APHIS), and the Food Safety and Inspection Service (FSIS), are actively engaged in interagency deliberations and coordination as well as in the direct engagement with U.S. trading partners on SPS matters.

Foreign Agricultural Service

FAS coordinates and executes USDA's strategy to address foreign market access for U.S. products (including addressing SPS barriers to U.S. exports), build new markets, improve the competitive position of U.S. agriculture in the global marketplace, and provide food aid and technical assistance to foreign countries. FAS has primary responsibility for USDA's international activities – market development, trade agreements and negotiations, and the collection and analysis of statistics and market information. To perform these tasks, FAS relies on its global network of overseas offices with staff in over 90 foreign countries that monitor policies and other developments that could affect U.S. agricultural exports. FAS collects and analyzes information that a number of U.S. agencies use to develop strategies to increase market access, monitor trade agreements, and improve programs and policies to make U.S. farm products more competitive. FAS also provides significant funding to address SPS trade barriers under the Technical Assistance for Specialty Crops (TASC) program. The pest research, field surveys, and pre-clearance programs funded by TASC play an important role in supporting efforts to remove such trade barriers. FAS is a member of the U.S. delegation to the WTO SPS Committee and is an active member of all other SPS interagency teams.

Animal and Plant Health Inspection Service

APHIS works to prevent the spread of agricultural pests and diseases affecting animals and plants in the United States and to foster safe agricultural trade, thus serving to ensure an abundant, high-quality, and varied food supply worldwide. As a result of its expertise, APHIS plays a key role in addressing foreign agricultural trade barriers by developing and advancing science-based standards with U.S. trading partners to ensure that U.S. agricultural exports are protected from unwarranted SPS restrictions. APHIS leads the U.S. Government delegation to the OIE and IPPC and actively participates in helping shape the draft animal and plant health standards proposed by these international organizations.

APHIS also serves as a member of the U.S. delegation to the WTO SPS Committee and is an active member of all other SPS interagency teams.

Food Safety and Inspection Service

FSIS is USDA's public health agency, responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS has significant expertise in addressing SPS barriers that foreign governments apply to U.S. exports of these products. FSIS is the U.S. Government coordinator for Codex meetings, as well as an active member of the U.S. delegation to the WTO SPS Committee and other SPS interagency teams.

U.S. Environmental Protection Agency

EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) regulates pesticides use in the United States to protect human health and the environment; establishes MRLs to ensure safety of both domestically produced and imported foods; promotes the use of safe means of pest control; and establishes standards and requirements regarding sound pesticide and chemical management practices based on science. OCSPP has the lead role in coordinating EPA activities with respect to foreign SPS measures, particularly pesticide MRLs and biotechnology. EPA is a member of the U.S. delegation to the WTO SPS Committee and is an active member of all other SPS interagency teams.

U.S. Food and Drug Administration

The FDA is the regulatory agency responsible for the safety of most of the nation's domestically produced and imported foods, as well as food additives and dietary supplements. In addition, FDA's regulatory authority also covers the manufacture and distribution of food additives and drugs intended for use in animals. To work more effectively with foreign regulators, industry, and other stakeholders to promote product safety, FDA has recently established posts in strategic locations around the globe, including China, India, the United Kingdom, Belgium, Italy, Mexico, Costa Rica and Chile. FDA takes an active role in assessing foreign SPS measures and practices as part of the interagency process and is a member of the U.S. delegation for the WTO SPS Committee. FDA is also an active member of other SPS interagency teams.

U.S. Department of Commerce

The Monitoring and Compliance (MAC) unit at the U.S. Department of Commerce leads the Trade Agreements Compliance (TAC) Program, which supports the enforcement side of the National Export Initiative (NEI). Under the TAC Program, MAC coordinates U.S. Government efforts and resources to systematically monitor, investigate, and ensure that foreign governments comply with the over 270 international trade agreements to which the United States is party. The TAC Program represents the U.S. Government's focal point for reducing or eliminating the foreign trade barriers that obstruct U.S. exporter market

access. Commerce works closely with its interagency colleagues to address SPS-related trade barriers, as well as all matters pending before the SPS Committee. In addition, to advance the NEI's advocacy efforts, the Department's U.S. Commercial Service works with U.S. companies to help them expand market access opportunities abroad. The Commercial Service operates in more than 100 U.S. cities and nearly 80 countries around the world. The Department of Commerce is a member of the U.S. delegation to the WTO SPS Committee and is an active member of all other SPS interagency teams.

U.S. Department of State

The U.S. Department of State is responsible for carrying out the foreign policy of the United States. With a diplomatic presence in 190 countries, the Department of State provides on-the-ground context for foreign government actions on SPS measures. Department of State officers advocate for fair consideration of U.S. products which may be targets of unjustified barriers to trade. The Department of State is an active participant in interagency deliberations and policy formulation concerning SPS measures, as well as part of the U.S. delegation to the WTO SPS Committee.

G. Sources of Information about SPS Trade Barriers

The United States maintains a vigorous process for identifying SPS measures that create barriers to U.S. exports. USTR and other agencies learn of issues directly from concerned U.S. businesses and industries, consumer organizations, and other stakeholders. U.S. agencies also rely on an extensive network of U.S. Government officials stationed around the globe, particularly in embassies that house both State Department and FAS representatives.

In addition, the United States receives formal notifications under WTO procedures when WTO Members are considering making changes in their SPS measures. FAS leads an interagency team that reviews these notifications on a weekly basis and consults with stakeholders including industry and consumer organization advisers. Where warranted, the United States submits comments to the relevant WTO Members on the potential trade effects or scientific concerns that may arise from the changes they are considering. In 2010 alone, the interagency group reviewed 1,044 notifications by 50 WTO Members and provided comments to these trading partners on 173 proposed or in force SPS measures.

Nearly one-half of the comments were measures regarding processed products; one-third of the comments addressed requirements for live animals and fish (and their products, including dairy products); and almost one-quarter of the comments were for measures that introduced new standards or entry requirements for plants, bulk commodities (including those made with biotechnology), and horticultural products. The leading recipients of U.S. Government comments included China with 19 comments, South Korea (17), Brazil (12), Taiwan (11), and Thailand (11).

As part of these submissions, the United States requested its trading partners to take a number of actions, including the following: change or reduce product certification requirements; modify requirements of a measure; repeal an import ban; rescind entry requirements; delay implementation of a measure; and reduce testing fees. The United States also requested its trading partners to adopt the international standards of Codex, the OIE, and the IPPC where appropriate.

H. U.S. Government Engagement on Foreign SPS Trade Barriers

The United States maintains a broad and active agenda of engagement both to prevent the adoption of SPS measures that would create unnecessary barriers to U.S. exports and to resolve specific SPS trade concerns.

Interagency Consultation

Before formally engaging a foreign government with respect to a proposed or existing SPS measure, USTR generally consults with those federal agencies that participate in addressing SPS trade policy matters. USTR coordinates SPS policy through a multi-tiered interagency process. The Trade Policy Staff Committee (TPSC), with representation at the senior civil service level, serves as the primary operating body for this interagency process. A TPSC subcommittee specifically devoted to addressing SPS matters supports the TPSC's deliberations.

Levels of Engagement

The U.S. Government addresses SPS trade issues and unwarranted barriers in a variety of ways. As discussed above, the United States provides comments to foreign governments when appropriate on SPS measures that those governments have notified to the WTO. In addition, FAS and State Department officials stationed at U.S. embassies frequently identify proposed foreign SPS measures and transmit U.S. Government comments on proposed foreign SPS measures to the relevant foreign government officials. In parallel with these comments, FAS and State Department representatives typically ask the government concerned to provide a formal written response and to arrange meetings between their relevant regulatory authorities and FAS representatives so that they can describe U.S. concerns in detail. FAS and State Department officials submit reports on these meetings to the relevant U.S. agencies for their collective consideration. Depending on the nature of the specific measure, the interagency team may request technical experts of the pertinent U.S. regulatory agency to meet with their counterparts in the relevant country to discuss U.S. concerns and, where appropriate, to propose reasonable alternatives that are less trade restrictive.

If the United States is unable to resolve an SPS concern through these methods, USTR, following coordination with the TPSC, may elect to request a meeting with the country's senior regulatory and trade agency representatives, or may decide to raise the matter during a regularly scheduled bilateral meeting with the trading partner at the WTO SPS

Committee meeting in Geneva. USTR leads these discussions and works closely with the relevant regulatory agencies to address the relevant concern.

If the issue cannot be resolved through bilateral consultations, USTR may ask the U.S. Ambassador in the country concerned to raise the matter with the appropriate senior foreign government officials. In addition, USTR may opt to add the issue to the agenda of a meeting convened under the appropriate bilateral or regional U.S. FTA or decide to pursue the issue during the course of a formal WTO SPS Committee meeting where all WTO Members will have the opportunity to listen and comment on the issue at hand.

WTO Dispute Settlement

If none of these methods of engagement is successful in resolving a particular concern, USTR may conclude that a negotiated settlement is not possible on a bilateral basis. At that point, if the trading partner is a WTO Member, and if the United States considers that measure is inconsistent with WTO rules, the United States may decide to assert its rights under the SPS Agreement through the WTO's dispute settlement system. Since the WTO was established in 1995, the United States has successfully challenged foreign SPS measures in four separate proceedings, with a fifth proceeding currently underway. These proceedings are described below.

European Communities – Hormones[3]

In 1996, the United States challenged the European Union's (EU) ban on beef derived from U.S. cattle that have been treated with certain growth-promoting hormones. In 1998, the WTO found that the EU's ban was not supported by science and was thus inconsistent with the EU's obligations under the SPS Agreement. Accordingly, in 1999, following authorization from the WTO's Dispute Settlement Body, the United States raised its duties on a list of EU products.

In May 2009, the United States and the EU concluded a Memorandum of Understanding (MOU) that has enabled U.S. producers to gain additional duty-free access to the EU market for high-quality beef produced from U.S. cattle that have not received growth-promoting hormones. The MOU, which took effect in August 2009, is currently providing additional duty-free access to the EU market for high-quality beef produced from cattle that have not been raised with growth-promoting hormones – 20,000 tons in each of the first three years, with the possibility of increasing to 45,000 tons beginning in the fourth year. Under the MOU, the United States may maintain the additional duties it had in place on EU products in March 2009 and will not impose new duties on EU products during the initial three-year period, and may eliminate all sanctions during the fourth year. In February 2011, the United States and EU held consultations under the MOU to discuss the possibility of moving into the next phase, which would provide up to 45,000 tons of duty-free access for U.S.

[3] Before 2010 the European Union was referred to for purposes of the WTO as the European Communities.

high-quality beef. Before the four-year period ends, the United States and the EU will seek to conclude a longer-term agreement.

Japan – Varietal Testing

In 1997, the United States challenged Japan's varietal testing requirement, which prohibited the importation of certain fruits and nuts on the basis that they could become potential hosts for codling moths. In 1999, the WTO found that Japan's restrictions were maintained without sufficient scientific evidence and that they were not based on a risk assessment. In 2001, the United States and Japan reached a mutually agreed solution to end the dispute, allowing U.S. exporters to regain market access in Japan.

Japan – Apples

In 2002, the United States challenged Japan's restrictions on imports of U.S. apples, which were based on concerns over the introduction of fire blight. The WTO ruled in 2003 that Japan's restrictions were inconsistent with its obligations under the SPS Agreement. In particular, the WTO found that Japan's measures were maintained without sufficient scientific evidence and were not based on a risk assessment. A WTO compliance panel found in 2005 that Japan had not complied with the WTO's recommendations and rulings. Later that year, Japan and the United States reached a mutually agreed solution to ensure access for U.S. apples to Japan's market.

European Communities – Biotech

In 2003, the United States challenged the EU's *de facto* moratorium on approvals of U.S. biotechnology agricultural products, such as certain corn and soybeans varieties, and marketing prohibitions that individual EU Member States had imposed on biotechnology products that the EU had previously approved. In 2006, a WTO panel found that EU and Member State measures were inconsistent with WTO rules. This dispute remains unresolved. A large backlog of applications remains pending in the EU approval system, which has the effect of blocking U.S. exports of certain agricultural products. The EU approved several products early last year, but there have been no approvals issued since July 2010. The United States continues to press the EU for fundamental improvements in its regulatory system with the goal of normalizing biotech trade.

European Union – Poultry

At the request of the United States, the WTO established a dispute settlement panel in November 2009 to examine whether the EU's restrictions on imports of U.S. poultry are consistent with its obligations under the SPS Agreement. The dispute is focused on the EU's ban on the import and marketing of poultry meat and poultry meat products processed with certain pathogen reduction treatments (PRTs) used in the United States that both U.S. and European scientists have judged to be safe.

Technical Assistance

In addition to these efforts, the U.S. Government has put in place a number of programs that provide technical assistance to developing countries to help these countries meet their international obligations with respect to SPS measures and thereby facilitate trade in agricultural products. In 2010, the U.S. Government obligated to provide SPS trade capacity building in excess of $10.4 million. This assistance takes various forms, including training seminars, laboratory training, advice on drafting rules and regulations, staff internships, and data sharing. U.S. technical assistance is discussed in greater detail in Section V.

III. MAJOR CROSS-CUTTING SPS ISSUES

This section of the report discusses certain important SPS issues that restrict U.S. agricultural exports in multiple markets and describes the efforts the U.S. Government has made to address these issues. These cross-cutting issues are as follows: AI, biotechnology, BSE, MRLs for pesticides, and ractopamine. Individual country reports in section IV provide further details on barriers imposed by countries regarding these issues.

A. Avian Influenza

AI is a poultry disease that can infect chickens, turkeys, pheasants, quail, ducks, geese, and guinea fowl, as well as a wide variety of other birds. AI virus strains are divided into two groups based on their ability to produce disease and on the severity of the illness they cause: low pathogenic avian influenza (LPAI) and highly pathogenic avian influenza (HPAI). LPAI naturally occurs in wild birds and can spread to domestic birds. In most cases it causes no signs of infection or only minor symptoms in birds. These strains of the AI virus pose a negligible threat to human health. Certain subtypes of LPAI are notifiable to the OIE due to the propensity of these subtypes to mutate into HPAI. Since mutation requires live cells, there is no risk of mutation in poultry products. LPAI also is not present in the muscles (meat) or eggs of birds, and therefore these products do not present an AI-related risk.

HPAI is an extremely infectious and fatal form of the disease that, once established, can spread rapidly from flock to flock. HPAI is often fatal in chickens and turkeys. It spreads more rapidly than LPAI and has a higher death rate in birds. HPAI H5N1 is the type of HPAI that has spread rapidly in some regions of the world in recent years. Because of the potential health effects of HPAI H5N1, the OIE requires governments to report outbreaks of the disease as soon as possible.

U.S. AI-Related Controls

While there have been two minor outbreaks of HPAI in U.S. poultry since the Second World War, there is no evidence that HPAI currently exists in the United States. Further, the United States has taken numerous actions to prevent the spread of AI consistent with the science-based standards, guidelines, and recommendations issued by the OIE, the international authority on AI issues.

U.S. regulatory authorities have put in place numerous safeguards to ensure that HPAI is not established in the U.S. poultry population. For example, federal agencies have worked with states and the poultry industry to monitor U.S. bird populations. These programs monitor four key areas: live bird markets, commercial flocks, backyard flocks, and migratory bird populations. Extensive testing is carried out in live bird markets and commercial flocks. In addition, any birds that show signs of illness are tested for AI, and if these birds are found to be infected with AI, the USDA works to identify the subtype of AI. Finally, federal officials and their state and industry partners have also worked to establish

an effective and coordinated emergency response plan that would mitigate the impact of any outbreak of HPAI in the United States.

Foreign Trade Barriers to U.S. Exports of Poultry and Poultry Products

Despite these measures, many countries have imposed AI-related import bans on U.S. poultry. China, for example, currently has bans on poultry and poultry products from four U.S. states. Although China recently lifted bans on two U.S. states, the remaining bans, already in effect from one to four years, are not consistent with OIE guidelines. India prohibits imports of U.S. poultry and poultry products, as well as pork products, based on AI-related concerns. Other countries, including Japan, have also banned U.S. poultry and poultry products citing concerns over AI.

The United States is concerned with these restrictions and the impact that they have had on U.S. poultry exports. Many of the import bans appear to be inconsistent with science and the relevant OIE guidelines. Those guidelines recognize that unprocessed poultry products from countries that report detections of LPAI may be traded with minimal restrictions, and countries reporting HPAI may trade safely in poultry and poultry products under specified conditions. The guidelines do not, however, recommend any type of import bans on poultry commodities from countries with non-notifiable subtypes of AI.

Accordingly, the United States has raised concerns over the various AI-related imports bans around world in numerous bilateral and multilateral fora with the pertinent trading partners. The United States has succeeded in having 57 AI-related bans lifted since 2008. It remains a high priority for the United States to remove the remaining AI-related import bans on U.S. poultry and poultry products that China, India, and other countries have imposed.

B. Biotechnology

In recent years, farmers around the world have increasingly planted crops developed through biotechnology. Agricultural biotechnology encompasses a range of tools, including traditional breeding techniques that alter living organisms, or parts of organisms, to make new products or modify existing ones; improve plants or animals; or develop micro-organisms for specific agricultural uses. Modern biotechnology includes the tools of genetic engineering (GE).

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) the number of countries growing biotechnology crops has grown considerably, from six in 1996 to 29 countries in 2010. Crops produced using agricultural biotechnology that are consumed in the United States for food, fiber, or feed include corn, soybeans, cotton, canola, alfalfa, and squash. USDA's National Agricultural Statistics Service estimates that in 2010, of the farm acreage in the United States devoted to soybeans, corn, and cotton, 93 percent, 86 percent, and 93 percent, respectively, were planted with biotech varieties. New GE crops and products, such as those intended for pharmaceuticals, phyto-

remediation, and biofuel production, are likely to appear in the market in the next few years, and create acceptance and trade challenges for the United States and its trading partners.

U.S. exports of biotech corn and soybeans, as well as other agricultural products that contain – or may contain – biotech-derived ingredients, face a multitude of trade barriers. Some U.S. trading partners have continued to impose import bans on these products even though repeated science-based dietary risk assessments continue to show that these foods are as safe as non-biotech varieties. These unwarranted import bans and other trade restrictions on U.S. biotech products are enumerated in the country-specific sections of this report. In addition, some trading partners impose mandatory labeling requirements on foods derived from biotech products. Those requirements serve as a trade barrier by wrongly implying that these foods are unsafe. The labeling restrictions are treated in the *TBT Report*.

The United States is actively engaged with the relevant trading partners to remove these unwarranted trade barriers, and, more broadly, with a wide spectrum of trading partners in efforts to share experiences related to biotechnology development, regulation, and trade. As part of these efforts, U.S. officials have helped shape the development of international standards related to safety assessment of, and trade in, agricultural biotechnology products. Specifically, the United States contributed to the establishment of Codex plant guidelines for assessing the food safety of biotech crops. The United States has also supported the development of Codex food safety assessment guidelines for nutritionally enhanced biotech crops and for cases of low-level presence of unapproved biotech events. Although the United States is not a party to the Cartagena Protocol on Biosafety, which guides the transboundary movement of living modified organisms, the U.S. Government has consistently participated in meetings of the protocol parties and related capacity-building efforts. The United States is also actively involved in regulatory and policy dialogues in the Asia Pacific Economic Cooperation forum (APEC) addressing agricultural biotechnology.

C. Bovine Spongiform Encephalopathy

History

BSE, commonly known as mad-cow disease, is a transmissible, fatal neuro-degenerative brain disease of cattle. BSE was first diagnosed in the United Kingdom (UK) in 1986. At its peak in 1992, there were 37,316 reported cases of BSE, 99.9 percent of which were in the UK. By 2010, the number of cases had decreased to 37 cases globally, only 1 of which was outside of Europe. The United States has had only three animals test positive for BSE – an animal imported from Canada in 2003, a U.S.-born animal in 2005, and another U.S.-born animal in 2006.

The World Organization for Animal Health (OIE)

The OIE is the intergovernmental organization responsible for improving animal health worldwide. OIE classifies the BSE risk status of cattle populations in particular countries on the basis of a risk assessment and other criteria. The OIE has established three risk categories: negligible risk, controlled risk, and undetermined risk, with different recommendations for the safe trade in beef and beef products from countries in each category. In May 2007, based on a review of the interlocking BSE-related controls in place in the United States, the OIE classified the United States as having a "controlled risk" status.

OIE guidelines specify that beef and beef products from a controlled risk country can be safely traded provided that certain slaughter and processing conditions are met, and appropriate "specified risk materials" (SRMs) are removed from the carcass before shipment. SRMs are tissues where the BSE agent is known to accumulate and can therefore pose a human health risk.

From a human health perspective, the removal of these tissues from cattle over the designated age is the single most significant measure in ensuring the production of safe beef and beef products. With respect to BSE, all cattle parts that the OIE has not designated as SRMs are considered safe for human consumption.

U.S. BSE-Related Controls

The United States implemented an OIE-consistent feed ban in 1997, which prohibits feeding most mammalian protein to ruminants. The U.S. feed ban was further strengthened in 2009 by prohibiting the use of the highest risk cattle tissues in all animal feed. Both of the indigenous BSE cases in U.S. cattle were in animals born before the 1997 feed ban. A ban of this type is the most important step a country can take to protect its cattle population from BSE via feed. In 2004, the United States implemented BSE-related measures in U.S. slaughterhouses and meat production establishments, the most important of which requires SRM removal. As a result of these interlocking measures, beef and beef products produced in the United States are safe for consumption.

Foreign Trade Barriers to U.S. Exports of Beef and Beef Products

In December 2003, as a result of the first case of BSE detected in the United States, at least 100 countries closed their markets to all U.S. beef and beef products, causing substantial harm to the U.S. beef industry, which at the time exported approximately ten percent of its total production. In 2003, U.S. producers exported $3.86 billion of beef and beef products. The following year, as a result of the widespread import ban, U.S. exports fell by 79 percent, to $808 million. By 2010, U.S. beef and beef product exports had rebounded, totaling nearly $ 4.08 billion. However, much of the recovery was due to higher prices, and trade volumes are only at 84 percent of 2003 levels.

U.S. beef producers currently export their products to a wide variety of markets around the world. Section IV of the *SPS Report* identifies several countries that continue either to ban U.S. beef entirely or impose other OIE-inconsistent restrictions on U.S. beef products. Such measures represent unwarranted foreign SPS trade barriers and greatly burden U.S. beef producers. Moreover, the discrepancy in BSE-related measures in different markets represents a separate burden and undercuts the comparative advantage of U.S. exporters. USDA currently maintains 11 country-specific export verification programs for U.S. beef exports, plus three additional programs covering beef for human consumption, and one program for SRM-free inedible material.

Countries also maintain bans on other bovine and/or ruminant commodities (e.g., bovine gelatin; pet foods with bovine ingredients; bovine blood), as well as a large number of non-ruminant commodities (e.g., rendered meals such as poultry or porcine meals and fishmeal; non-ruminant blood products; and hydrolyzed proteins), based on BSE-related concerns. The United States continues to engage with its trading partners to secure the removal of these bans.

Restoring full access for U.S. beef and beef products based on science, the OIE guidelines, and the status of the United States as a controlled BSE risk country is a priority of the U.S. Government. The United States is continuing its efforts to negotiate bilateral protocols with trading partners to open their markets to U.S. beef. It has proven difficult in some instances to initiate and conclude these negotiations given the political sensitivity of the issue in some countries.

D. Maximum Residue Limits

MRLs, known as tolerances in the United States, represent the maximum concentration of residues (generally expressed as parts per million or mg/kg of residue on food/animal feedstuff) permitted in or on food and animal feedstuffs after the application of approved pesticides. Governments around the world, including the United States, set MRLs to ensure food safety.

EPA establishes MRLs for pesticides in the United States. Under U.S. law, EPA must ensure a "reasonable certainty of no harm" to consumers of the food, including special consideration of infants and young children and other potentially vulnerable populations.

All agricultural products produced in the United States or intended for consumption in the United States must comply with the tolerances that EPA establishes. Inspectors from the FDA and USDA monitor both domestic and imported food and feedstuffs to ensure that MRLs are enforced. Codex develops and maintains international standards for MRLs. In principle, governments should base their tolerances on Codex MRLs. Nevertheless, it is not uncommon for countries – including the United States – to set their own, stricter standards. When a government sets an MRL that is more stringent than the relevant Codex standard, however, the SPS Agreement requires the MRL be based on scientific principles and a risk assessment.

Given the technical complexity of establishing MRLs, the United States works closely with key trading partners to share data and assist them in establishing their own science-based tolerance levels. For example, the United States, Canada, and Mexico initiated a new level of trilateral regional regulatory cooperation on pesticides under the NAFTA framework by establishing a TWG. Since its creation, the NAFTA TWG has focused on facilitating cost effective pesticide regulations in the three countries through collaboration and sharing, while achieving a high level of environmental and human health protection. This collaboration has been instrumental in reducing trade barriers and increasing access to safer means of pest control in all three markets.

As discussed more specifically in the country reports that follow, a variety of countries have either set pesticide MRLs at unreasonably low thresholds or have failed to establish a MRL for certain pesticides that are safe to use as evidenced by tolerances set by Codex or the United States. This has created significant trade barriers for U.S. horticultural exports. For example, MRL enforcement policies in Japan and Taiwan are of particular concern.

Increasingly, countries are working to establish their own positive lists of approved pesticides. The United States believes that the creation of approved pesticide MRL lists or systems that are based on Codex standards are best suited to facilitate trade. Unfortunately, positive list systems require a great deal of data, staff training, and financial resources. It takes countries years to establish credible and transparent MRL regimes and enforcement programs. The United States works closely with its trading partners to jointly establish pesticide tolerances where appropriate. To ensure against trade disruptions while a pesticide is under evaluation, U.S. authorities often ask countries to adopt Codex MRLs on an interim basis until their permanent MRLs are established. If countries are unwilling to adopt the Codex MRLs or to defer to the U.S. MRL in the interim, U.S. growers could be subject to onerous penalties and serious trade barriers for using pesticides that EPA has approved.

E. Ractopamine

Ractopamine is a veterinary drug used to promote lean meat growth in pigs, cattle, and turkeys. It is commonly used in the swine industry in the United States. The FDA approved ractopamine for use in U.S. pork production in 1999, after an extensive review of the scientific evidence related to its health implications. The FDA approved the drug for use in cattle in 2003 and for use in turkeys in 2008. Ractopamine is also approved for use in swine in 26 other countries and for use in beef in four countries.

In 2004, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), a body of experts which provides scientific advice to Codex on food additives, contaminants, and residues of veterinary drugs, issued a report recommending the establishment of a MRL for ractopamine in the edible tissue of animals treated with the drug. This report provides further scientific evidence that this product is safe. The Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) subsequently adopted the draft MRLs for ractopamine and forwarded them to the Codex Commission. The Codex Commission requested that the JECFA evaluate additional residue data for ractopamine in swine provided by China and

report any impact this might have on the recommended MRLs. The JECFA provided a 2010 report reaffirming the previously recommended MRLs. During its July 2010 meeting, the Codex Commission, in the final stages of an eight-step process to establish food standards, did not adopt the MRL recommended by JECFA and the CCRVDF due to opposition from the EU and China.

Despite the scientific evidence attesting to the safety of ractopamine, a number of important trading partners, including China, the EU, Taiwan, and Thailand, continue to ban imports of pork and pork products containing ractopamine residues. Taiwan also has begun to inspect for traces of ractopamine in U.S. beef and beef products, creating commercial uncertainty for U.S. producers. There measures create significant barriers to U.S. exports of meat and meat products.

IV. COUNTRY REPORTS

This section sets out specific SPS concerns in individual country reports. The issues discussed in this section are the subject of U.S. Government engagement at home and abroad with U.S. stakeholders concerning unwarranted SPS foreign trade barriers that U.S. exporters have encountered. The selection of barriers for discussion in this report reflects a considered process that is based on the U.S. Government's understanding of those barriers. They raise significant trade concerns and, in some instances, give rise to questions concerning whether a trading partner is complying with its obligations under a trade agreement to which the United States is a party.[4]

The U.S. Government's goal is to work as vigorously and expeditiously as possible to resolve the concern identified in this section. The tools the U.S. Government uses vary depending on the particular facts and circumstances. In many instances the U.S. Government seeks to resolve specific concerns through dialogue with the pertinent trading partner – either bilaterally or through multilateral fora – and by working collaboratively to obtain changes that result in improved market access for U.S. exporters. In appropriate instances, dispute settlement under the WTO or in another relevant forum can be a tool to address specific concerns.

In response to USTR's outreach in compiling this report, U.S. stakeholders raised a number of new SPS concerns. Stakeholders should not view the absence of an issue in the report as an indication that USTR does not believe the matter raises significant concerns; it may simply reflect the fact that USTR requires additional time or information to consider it. For those issues, USTR will seek to compile additional information, including by following up with stakeholders, U.S. embassies, and other Federal agencies.

The *SPS Report* provides more focused and structured reporting on country-specific issues than appeared in past years' *NTE Report*, which may have included SPS issues that USTR has not included in the report. Where possible, each listing sets out the United States' current understanding of the measure or practice, why it raises concerns, and how the United States is seeking to address it. The report is not simply a recounting of all outstanding issues that stakeholders have brought to USTR's attention this year or in the past. For purposes of this report, USTR included measures that represent significant and unwarranted SPS foreign trade barriers to U.S. exports and that the U.S. Government has devoted substantial resources to resolving. Regardless, the U.S. Government continues to gather information, and follow all concerns affecting U.S. stakeholders and pursue those issues as appropriate.

Finally, much of the U.S. Government's engagement in international and regional fora focuses on those trade-restrictive SPS measures that recur in a number of markets. Five of these measures are described in Section III of this report. The U.S. Government adopts a

[4] Nothing in this report should be construed as a legal determination that a measure included in the report falls within the scope of any particular WTO Agreement (e.g., whether the measure is subject to the SPS as opposed to the TBT Agreement).

strategic approach to measures of this kind, deploying resources where they can be most effective. In some instances, the U.S. Government elects to focus its efforts on a few countries where the concern is the greatest. In other instances, the U.S. Government seeks to work with those countries with which the matter can be resolved most expeditiously or where engagement on the issue would produce maximum benefit for the United States and U.S. stakeholders.

ARGENTINA

Food Safety

Live Cattle, Beef, and Beef Products

Argentina bans all U.S. live cattle, beef, and beef products due to BSE-related concerns following the detection of a BSE positive animal in the United States in 2003. In November 2010, Argentina issued a final regulation on the importation of bovine products related to BSE, but it failed to resolve many of the issues of concern to the United States. The United States continues to engage with the relevant Argentine government agencies to open its market for imports of all live cattle, beef, and beef products from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Poultry

While U.S. exporters currently have access to Argentina's market for certain miscellaneous poultry products, including day-old chicks and hatching eggs, Argentina does not allow imports of fresh, frozen, and chilled poultry from the United States. Argentina recently promulgated new rules that will require the imposition of import restrictions on findings of AI or Newcastle's disease in the exporting country, which may impact future U.S. exports. Argentina has indicated that it would accept cooked poultry products from the United States, but there is no agreement yet on what the U.S. sanitary certificate will say, as Argentina has determined that the U.S. poultry inspection system is not "equivalent" to the Argentine system. The United States has expressed concerns regarding both Argentina's equivalency determination and its proposed rule on AI and Newcastle's disease and will continue to press this issue.

See section III.A for an explanation of the AI trade issue.

Plant Health

Apples and Pears

Argentina currently blocks imports of U.S. apples and pears due to concerns about the transmission of *Erwinia amylovora* (the bacteria that cause fire blight). The United States has submitted technical information to Argentine plant health officials documenting that there is no evidence that mature, symptomless apple and pear fruit transmit fire blight and will continue to work with Argentine officials to address the issue.

AUSTRALIA

Food Safety

Beef and Beef Products

Australia currently prohibits the importation of bovine products from countries that have reported one or more indigenous cases of BSE. On March 1, 2010, Australia modified its food safety import policies to allow imports of beef and beef products from countries that have been affected by BSE. Under these new requirements, a country interested in exporting beef and beef products to Australia must apply for an individual country risk assessment, addressing human health and food safety issues from Food Standards Australia New Zealand, a regional food safety agency. On March 18, 2010, the Australian Minister for Agriculture, Fisheries and Forestry announced that Biosecurity Australia must conduct a separate import risk analysis for each exporting country to address animal quarantine issues. The United States submitted a completed BSE-related questionnaire in June 2010 and hosted a visit by an Australian official in July 2010 to discuss Australia's BSE evaluation process. Australia has not yet concluded its risk assessment. The United States continues to engage on the technical aspects of BSE and BSE-related trade issues with the relevant Australian government agencies in order to open the Australian market for imports of beef and beef products from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Poultry

Australia bars imports of fresh, frozen, or cooked turkey from the United States. In 2009, the United States asked Australia to prioritize granting market access for U.S. cooked turkey meat. Despite this request, to date, Australia has not done so, and the United States continues to press Australia to prioritize this request and begin its evaluation of U.S. cooked turkey meat.

The United States also considers that Australia's risk assessment for U.S. chicken meat overestimates the risk presented by imports of this product in a number of ways, resulting in mitigation requirements that are overly restrictive. For example, variant strains of infectious bursal disease are present in both countries, yet Australia's assessment concluded that the U.S. strains are exotic to Australia, citing a research study that did not follow standard procedures to detect differences in immunogenicity (the effect of the virus on the bird). Moreover, Australia's cooking requirements for killing the AI virus are more stringent than those recommended by the OIE.

Pork

In 2008, citing concerns about the introduction of porcine reproductive and respiratory syndrome (PRRS) and post-weaning multisystemic wasting syndrome (PMWS), Australia implemented new disposal requirements for imported pork. Based on these requirements, all solid waste from pork imports, regardless of whether the pork is cooked or uncooked, must be treated as a quarantine waste product. The new requirements have raised the costs of handling imported pork, and have the potential to impact negatively U.S. pork trade with Australia.

Plant Health

Stone fruit

Australia has banned imports of U.S. stone fruit (peaches, nectarines, plums, and apricots) due to concerns about four plant pests (the peach twig borer, apple maggot, cherry fruit worm, and lesser apple worm). Following a risk assessment and appeals, it was anticipated that the ban would be lifted. However, in 2010, Australia expressed concern about the presence of the spotted wing drosophila (*Drosophila suzukii*, or SWD) in the United States. As a result, the United States will not gain market access for U.S. stone fruit until a mutually acceptable mitigation for SWD for stone fruit has been established. The two countries continue an active dialogue on mitigation measures for SWD and are seeking to develop a preclearance program. This issue remains a top priority of the United States in its SPS engagement with Australia and is regularly addressed in bilateral discussions.

Apples

Australia currently prohibits the importation of apples from the United States and New Zealand based on concerns about fire blight, a contagious, bacterial disease affecting apples, pears, and other rosaceous plants. For the past 15 years, the U.S. Government and the U.S. apple industry have been working closely with Australian officials to demonstrate that U.S. mature apples pose no risk of transmission of fire blight. In October 2009, Australia published a pest risk assessment (PRA) for apples from the United States. This PRA includes overly restrictive fire blight mitigation measures. If the PRA is approved as currently drafted, it will continue to prevent the commercial export of U.S. apples to Australia.

New Zealand requested a WTO panel in 2007 claiming that Australia's measures regarding the importation of New Zealand apples, including Australia's mitigation measures for fire blight, were not based on a risk assessment in compliance with the WTO SPS Agreement. In August 2010, a WTO panel ruled in favor of New Zealand. In December 2010, the WTO Appellate Body largely upheld the panel's findings. The United States was an active third party in the case and is monitoring this matter closely.

Table grapes

The United States has been working with Australia for over 20 years to achieve access to the Australian market for California table grapes. Australia first opened its market under limited conditions in 2002. The United States has worked through the U.S.-Australia FTA SPS Committee to remove the majority of the remaining restrictions. However, one Australian state, Western Australia, continues to deny market access for U.S. table grapes. This prohibition has been maintained despite the absence of significant pests during the first seven years of California table grape exports to the rest of Australia. Australia has recently indicated that it would complete a risk assessment to initiate the process allowing California table grapes to gain access to Western Australia. The United States will continue discussions with Australia as it moves forward with this process.

BOLIVIA

Food Safety and Animal Health

Live Cattle, Beef, and Beef Products

Bolivia continues to ban imports of all U.S. live cattle, beef, and beef products due to BSE-related concerns following the detection of a BSE positive animal in the United States in 2003. Until April 2010, Bolivia and the other three Andean Community (CAN) member countries (Colombia, Ecuador, and Peru) maintained that CAN rules prevented them from lifting their BSE-related restrictions.

In 2009, the United States submitted comments on a proposed CAN risk assessment, which stipulated that only live animals under 24 months of age could be imported. A CAN resolution, published on April 13, 2010, stipulated that CAN member countries could establish their own requirements for imports of U.S. live cattle in accordance with the CAN risk assessment.

The U.S. Government continues to engage Bolivia to re-open its market for U.S. live cattle, as well as U.S. beef and beef products, based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

BRAZIL

Food Safety

Live Cattle, Beef, and Beef Products

Brazil bans imports of U.S. live cattle, beef, and beef products due to the detection of a BSE positive animal in the United States in 2003. In late 2008, Brazil promulgated a draft regulation that establishes sanitary requirements for the importation of ruminants and ruminant products from countries affected by BSE. Brazil continues to state that it has not completed its review of technical information provided by the United States. During high-level discussions, Brazil indicated it was not willing to conform its import restriction to the OIE guidelines. The United States will continue to engage Brazil to open its market for all live cattle, beef, and beef products from the United States on based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Pork

Brazil only allows imports of U.S. pork from plants that its inspectors have individually inspected and approved. This approach is burdensome on the industry and significantly limits the market access of companies that are willing and able to export to Brazil. Brazil has been unable to explain why a plant-by-plant inspection system is required rather than a systems-based approach that analyzes the level of food safety protection afforded by the U.S. Government's pork plant inspection and approval system. The United States continues to discuss this issue with Brazil.

Brazil also restricts imports of pork and pork products from the United States citing the risk of trichinosis. Currently fresh, chilled U.S. pork can be imported into Brazil only if the product is tested to be free of trichinae or cold treated. The United States does not consider that such testing is necessary as U.S. producers maintain high biosecurity protocols that serve to limit the incidence of trichinosis in the United States to extremely low levels.

In May 2009, the United States proposed a voluntary certification process, which Brazil rejected in October 2009. In August 2010, the United States held technical discussions with Brazil on U.S. risk management techniques for trichinosis. In October 2010, Brazil indicated that it was prepared to work with the United States on this issue. U.S. officials plan to travel to Brazil in 2011 to continue discussions and encourage Brazil to lift is current restrictions.

CHILE

Food Safety

Pork

Chile requires U.S. pork to be frozen or tested as a mitigation measure for trichinosis. Chile's testing requirement is costly, and is a significant impediment to U.S. fresh/chilled pork exports to Chile. The United States does not consider that such testing is necessary as U.S. producers maintain high biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. As an alternative, the United States has proposed less trade restrictive risk mitigation measures to assure Chile that U.S. pork exports do not contain trichinae. The United States will continue to work with regulatory authorities in Chile to resolve this trade concern.

Beef and Beef Products

In 2003, Chile banned imports of all U.S. beef and beef products, live cattle, and beef-containing pet food due to the detection of a BSE positive animal in the United States. In July 2005, Chile agreed to partially re-open its market to U.S. deboned beef from animals under 30 months of age.

In April 2009, Chile revised its beef and beef products import statute to align with the recommendations set forth by the OIE. As part of the SPS Committee agenda under the United States-Chile FTA, the United States and Chile began a series of negotiations to open the Chilean market to exports of U.S. beef and beef products. In March 2011, these negotiations concluded with an agreement that allows for imports of U.S. beef and beef products that are accompanied by an appropriate health certificate. Chile is now importing a full range of U.S. beef and beef products, consistent with the OIE guidelines on the safe trade in these products.

However, Chile continues to maintain unjustified restrictions on imports of U.S. live cattle, despite a commitment to fully adhere to OIE guidelines. The United States will continue to engage Chile to achieve full market access for live cattle from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Poultry

Chilean authorities impose a trade-restrictive zero tolerance limit for the presence of *Salmonella* in imports of mechanically deboned U.S. fresh poultry. Such a zero tolerance standard for pathogens is unwarranted because it is generally accepted by food safety experts and scientists that such pathogens cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of

a number of food-borne diseases caused by these microbes. The United States continues to engage with Chile on this issue.

CHINA

Food Safety

H1N1 Restrictions

China was among the countries that banned U.S. pork products in 2009 due to H1N1 influenza concerns. In October 2009, Ambassador Kirk, Agriculture Secretary Tom Vilsack, and Commerce Secretary Gary Locke participated in a meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT) in Hangzhou, China, where China announced its intent to remove its H1N1 ban on pork products. Following that meeting, the United States pressed China to implement that commitment.

On March 19, 2010, USTR and USDA announced that the United States and China had reached agreement to re-open the Chinese market to U.S. pork and pork products. In May 2010, China and the United States concluded an agreement on export certificate language referencing the H1N1 influenza A virus. Such a certificate accompanies an export shipment and attests to the fulfillment of various SPS requirements. Nevertheless, the United States will continue to request that China remove references to the H1N1 influenza A virus from the export certificate for pork and pork products given the international consensus that the H1N1 influenza A virus is not transmitted by food products.

In March 2011, China informed the United States that it was lifting its H1N1-related import suspension on U.S.-origin live swine as a result of an agreement with USDA to conduct H1N1 testing and certification. Under the new arrangement, USDA will temporarily test and certify that live swine exported from the United States are free from the H1N1 virus. In return, China agreed immediately to resume imports of U.S. live swine.

Ractopamine

China bans imports of pork containing any residue of the veterinary drug ractopamine. China has enforced this ban by barring imports from several U.S. producers that have previously shipped pork to China that contained trace amounts of ractopamine at concentrations below the U.S. tolerance and the proposed Codex MRL. Although China maintains that there are serious concerns about the safety of ractopamine, China has not responded to repeated U.S. Government requests for risk assessments that support such concerns. In any event, the United States strongly disagrees with China's assertions.

During meetings of the JCCT Agricultural Working Group in 2010, U.S. officials asked China to adopt an interim MRL while awaiting the Codex Commission's final adoption of an MRL. China's Ministry of Agriculture denied the U.S. request, claiming that China needs to await a

final decision by Codex. The United States will continue to press China on this issue in bilateral discussions and at Codex.

See section III.E for an explanation of the ractopamine trade issue.

Meat and Poultry

China has imposed a zero tolerance limit for the presence of *Salmonella*, *Listeria spp.*, and other pathogens in imported meat and poultry. Such a zero tolerance standard for pathogens is unwarranted because it is generally accepted by food safety experts and scientists that pathogens cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by these microbes. In 2009, China's regulatory authorities assured the United States that they were in the process of revising China's standards for *Salmonella* in poultry, but China has yet to do so. The United States continues to engage China on this issue.

Live Cattle, Beef, and Beef Products

In December 2003, China imposed a ban on U.S. live cattle, beef, and beef products due to the detection of a BSE positive animal in the United States in 2003. Since that time, the United States has repeatedly provided China with extensive technical information on all aspects of U.S. BSE-related surveillance and mitigation measures, which the OIE has recognized as effective and appropriate, for both food safety and animal health.

At the end of June 2006, after three inconclusive rounds of negotiations, China's food safety regulators unilaterally announced a limited market opening, restricted to the entry of U.S. deboned beef from animals 30 months of age or less. One month later, China followed that announcement with a more detailed measure setting out 22 conditions for entry, many of which were unrelated to BSE mitigation. The cumulative effect of these restrictions is that the market remains closed to U.S. beef and beef products.

In March 2010, USTR and USDA senior officials met with their Chinese counterparts in Beijing to restart beef market access negotiations based on full consistency with the OIE guidelines on BSE. Bilateral discussions on U.S. beef exports continued throughout the remainder of 2010, including high-level meetings between USDA and USTR officials and their Chinese counterparts. During the JCCT meeting in December 2010, the United States and China agreed to resume beef market access talks at the start of 2011.

During the first two weeks of January 2011, senior officials from USTR and USDA led a team of experts from both agencies and FDA for a meeting with their counterparts in Beijing. The talks were beneficial both in assisting the two sides in understanding each other's positions on the key issues as well as in narrowing differences in a number of areas. The participants agreed to continue the discussions in an effort to reach an agreement that

would allow trade to resume based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Dairy Products

On April 21, 2010, China informed the United States that it would suspend imports of U.S.-origin dairy products beginning on May 1, 2010 if the two governments could not reach agreement on a new export certificate. China's attestation requirements for the certificate related to animal health and contaminants do not appear to be consistent with OIE and Codex guidelines.

Responding to requests by the U.S. Government, China moved the implementation deadline to June 1, 2010, and allowed the United States to continue to ship products to China after the new rules went into effect so long as technical talks to resolve the issue were continuing. The United States has proposed that the two sides conclude a memorandum of understanding that would keep China's market open to U.S. dairy products. The United States will continue to work in 2011 to ensure that any changes to China's dairy certification rules are based on science and do not unduly restrict imports of U.S. dairy products.

Animal Health

Bovine Products

In 2003, China banned imports of low-risk U.S. bovine products (i.e., bovine semen and embryos, protein-free tallow, and non-ruminant feeds and fats) even though they are deemed safe to trade by the OIE regardless of a country's BSE status. By 2006, U.S. producers were exporting these products pursuant to protocols signed in 2004, with the exception of protein-free tallow.

U.S. exports of protein-free tallow have still not resumed. China's protein-free requirement is difficult to comply with and appears inconsistent with the OIE guidelines, which allow for trade in tallow with maximum level of insoluble impurities of 0.15 percent in weight, regardless of the BSE status of the exporting country. In August 2010, Chinese officials announced that China was prepared to open its market to U.S.-origin tallow intended for industrial use. However, since that time the United States and China have not yet reached agreement on what the export certificate that accompanies U.S. exports must state.

Poultry

China currently bans poultry and poultry products from Arkansas, Pennsylvania, Texas, and Virginia due to detections of LPAI in those states. In addition, China bans imports of U.S.-origin poultry and poultry products that are transshipped through these four states.

China's current AI-related import bans do not appear to be science-based or consistent with OIE guidelines.

During bilateral meetings during 2010, including JCCT working group meetings, the United States pressed China to remove its state-level bans and to adopt OIE-consistent policies governing imports of U.S. poultry and poultry products. During the course of the December 2010 JCCT meeting, China announced that it would lift its AI-related bans then in effect on U.S. poultry products from Idaho and Kentucky. The two sides agreed to hold further technical talks to address China's remaining bans on imports from the four remaining states. The United States will continue to press China in 2011 to remove those bans.

See section III.A for an explanation of the AI trade issue.

Animal Feed

In 2004, U.S. and Chinese officials signed a veterinary health protocol that authorized the shipment of U.S.-origin non-ruminant derived animal fats and feed (including pet food) to China. As of June 2010, 149 U.S. facilities (including those that export fish meal) have been approved by the United States to export these products to China. However, China's Ministry of Agriculture (MOA) maintains a duplicative and cumbersome product-based registration process for U.S. companies that produce animal feed (including pet food) that has prevented or inhibited products from entering the Chinese market. U.S. companies that desire to export pet food to China must first have U.S. authorities certify that the exporting facilities meet the Chinese requirements in accordance with the veterinary health protocol (this is a separate facility registration procedure under the purview of China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)). After completing this process, U.S. companies must register their products with China's MOA.

The MOA's requirements still present a significant barrier to U.S. pet food, animal feed, and feed additive exports. China has thus far not been receptive to USDA requests either to eliminate the MOA registration requirement or justify its duplicative requirements. However, the United States continues to engage China on the issue, both at WTO SPS Committee meetings and bilaterally.

Plant Health

Apples

Since 1995, China has only allowed imports of two varieties of U.S.-origin apples from Idaho, Oregon, and Washington. In March 2000, U.S. officials requested AQSIQ to allow imports of additional apple varieties from those states, and to permit imports of apples from California.

U.S. authorities have provided their Chinese counterparts with a substantial amount of peer-reviewed scientific information indicating that there is no evidence that mature

symptomless commercial apples can transmit fire blight. However, China continues to cite concerns about this disease as the reason for not approving additional apple varieties from the three approved states.

In the course of bilateral technical meetings in November 2010, the United States and China continued to discuss developing an agreed list of apple pests that would be the appropriate focus of China's PRA for U.S apples. Chinese officials have indicated that once the two sides agree on the pest list, China will undertake a risk assessment based on that list.

Pears

China does not permit imports of U.S. pears, in particular, pears from California, Oregon, and Washington, due to concerns over fire blight. In May 2007, U.S. officials provided AQSIQ with research confirming that mature, symptomless pear fruit is not a pathway for fire blight and supplemented this with additional information in December 2009. As part of its ongoing evaluation of the important U.S. request to open China's market to these products, AQSIQ has initiated a risk assessment and is reviewing additional pest management information that U.S. regulatory authorities have provided. In 2010, the United States asked China to add pears from Idaho to the list of pears from other states that China is evaluating for risk assessment purposes. During bilateral technical meetings in November 2010, the United States and China agreed to continue technical discussions regarding imports of U.S. pears with the goal of having China provide the United States with a set of proposed pest mitigation measures for it to review in the first half of 2011.

Potatoes

China has not permitted imports of U.S.-origin table stock potatoes based on concerns over plant pests and diseases. In 2000, the United States officially requested China to allow imports of fresh potatoes from Idaho, Oregon, and Washington. The United States has been waiting for AQSIQ to share the results of its risk assessment for these potatoes. The United States continues to engage China on this issue in a variety of bilateral and multilateral fora, including in the WTO SPS Committee.

Strawberries

China granted special permission for importations of fresh strawberry fruit from California for the Shanghai World Expo and the 2008 Beijing Olympics. U.S. growers shipped approximately 2,168 pounds of strawberries to China for the Olympics, and the shipments raised no apparent concerns. (The U.S. industry elected not to ship strawberries to the Shanghai World Expo due to quantity restrictions that the Chinese authorities imposed.) During bilateral technical meetings in 2010, China indicated that it had not completed its final PRA for U.S. strawberries. The United States will continue to press Chinese authorities to complete their review of the U.S. Government's request for permanent market access.

Biotechnology

Pursuant to China's regulatory system for products of agricultural biotechnology, a biotechnology product developed in a country other than China must first be approved in the country of export before it can be the subject of an application for use in China. The United States has concerns that this requirement creates an automatic delay in China's biotech approval process that may lead to significant disruption in exports of U.S. biotechnology products that are approved for marketing in the United States but not yet eligible for use in China. Chinese government restrictions on investment, such as joint venture requirements and limits on ownership, also constrain foreign companies' ability to engage in biotechnology product development in China and maintain control over important genetic resources. The United States held bilateral consultations with China on these issues in 2010, and will continue to engage with China on this subject in 2011.

See section III.B for an explanation of the biotechnology trade issue.

COLOMBIA

Food Safety

Poultry

In August 2007, the Colombian Ministry of Health began implementing a zero tolerance standard for *Salmonella* on imported raw poultry products, which restricted imports of U.S. those products. A zero tolerance standard for this pathogen appears to lack a scientific basis because it is generally accepted by food safety experts and scientists that this pathogen cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by *Salmonella*. In response to growing complaints, Colombian authorities implemented an agreement with Colombian food processors to eliminate the zero tolerance requirement for mechanically deboned poultry meat imports for further processing. The agreement, however, does not cover imports of raw poultry products intended for retail sale, creating uncertainty for U.S. producers and Colombian importers. The United States will continue to work with Colombia to address continuing U.S. concerns about these requirements.

Rice

In March 2009, Colombia rejected a shipment of U.S. paddy rice, claiming that it contained fungus rice smut (*Tilletia*). The U.S. Government, with assistance from U.S. industry, undertook a lengthy negotiation with the Colombian Agricultural Institute (ICA), Colombia's SPS regulatory agency, as a result of which ICA eventually issued phytosanitary import certificates for other shipments of paddy rice. These certificates required a costly methyl bromide treatment for each shipment. In 2010, Colombian importers were unable to obtain phytosanitary import certificates as ICA indicated that U.S. exports would be

denied entry due to concerns with fungus rice smut. In April 2010, ICA sent a request to the CAN SPS regulatory agency for help in developing a PRA for *Tilletia*. It could take up to five years for Colombia to complete the PRA. The United States has expressed concern regarding Colombia's handling of U.S. paddy rice exports, both to the ICA and Colombia's Ministry of Trade as recently as March 2011.

Animal Health

Live Cattle

Colombia continues to ban U.S. live cattle due to BSE-related concerns following the detection of a BSE positive animal in the United States in 2003. Until April 2010, Colombia and the other three CAN member countries (Bolivia, Ecuador, and Peru) had maintained that CAN rules prevented them from lifting their BSE-related restrictions on live cattle.

In 2009, the United States submitted comments to CAN on a proposed risk assessment, which stipulated that only live animals under 24 months of age could be imported. A CAN resolution, published April 13, 2010, stipulated that CAN member countries could establish their own requirements for imports of U.S. live cattle in accordance with the CAN risk assessment.

In June 2010, Colombia temporarily allowed live cattle imports from the United States under requirements that are not commercially viable. Colombia is in the process of reviewing those requirements. The United States continues to engage with Colombia to re-open its market for U.S. live cattle based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Poultry

In 2006, Colombia formally recognized that the U.S. poultry inspection system is equivalent to Colombia's. The two countries also reached agreement on a U.S. sanitary certificate to accompany U.S. poultry and poultry products from Arkansas, Idaho, Kentucky, and Oregon. Such a certificate accompanies an export shipment and attests to the fulfillment of various SPS requirements. However, Colombia's Ministry of Agriculture continued to impose separate, AI-related import requirements on U.S. poultry and poultry products that were not consistent with the relevant OIE recommendations, and which resulted in a ban on imports of poultry and poultry products from a number of U.S. states. After several years of bilateral negotiations, Colombia agreed to lift its AI-related restrictions on U.S. poultry and poultry products in August 2010. The Ministry of Agriculture continues to ban U.S. poultry genetics, including hatching eggs and day old chicks from Arkansas, Idaho, and Oregon, based on separate AI-related import requirements that are not consistent with the relevant OIE recommendations.

See section III.A for an explanation of the AI trade issue.

COSTA RICA

Food Safety

Poultry

In 2008, the Central American Common Market (CACM) member countries, including Costa Rica, notified the WTO of their intent to establish microbiological criteria for a number of foods, including zero tolerance for *Salmonella* on poultry meat. The United States shared with the CACM members, both in writing and in meetings and workshops, concerns that the proposed zero tolerance for *Salmonella* on poultry meat appeared to lack a scientific basis because it is generally accepted by food safety experts and scientists that this pathogen cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by *Salmonella*. After reviewing the U.S. comments on the zero tolerance proposal, the CACM members decided that each country would establish its own country-specific standard for *Salmonella* on raw poultry. In September 2010, U.S. officials met with Central American government authorities to discuss this issue further. Costa Rican officials explained that Costa Rica was contemplating legislation on *Salmonella* tolerances and looking specifically at moving to allowable levels above zero. The United States will continue to work with government officials in Costa Rica and the other CACM member countries to address U.S. concerns regarding the zero tolerance policy.

DOMINICAN REPUBLIC

Food Safety

Beef and Beef Products

The Dominican Republic bans imports of U.S. beef and beef products from cattle over 30 months of age due to concerns about BSE. The United States continues to engage the Dominican Republic to provide full market access for all beef and beef products from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

ECUADOR

Food Safety

Live Cattle, Beef, and Beef Products

Ecuador continues to ban imports of all U.S. live cattle, beef, and beef products due to BSE-related concerns following the detection of a BSE positive animal in the United States in 2003. Until April 2010, Ecuador and the other three CAN member countries (Bolivia, Colombia, and Peru) maintained that CAN rules prevented them from lifting their BSE-related restrictions.

In 2009, the United States submitted comments on a proposed CAN risk assessment, which stipulated that only live animals under 24 months of age could be imported. A CAN Resolution, published on April 13, 2010, stipulated that CAN member countries would establish their own requirements for imports of U.S. live cattle in accordance with the CAN risk assessment.

The United States continues to engage with Ecuador to re-open its market for U.S. live cattle, as well as U.S. beef and beef products, based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Poultry

Until recently, Ecuador banned imports of poultry products and live animals from Arkansas and West Virginia due to LPAI. U.S. officials expressed concerns about these restrictions, which were not consistent with OIE guidelines. Ecuador removed its import ban in December 2010.

See section III.A for an explanation of the AI trade issue.

EGYPT

Food Safety

Beef and Beef Products

At the start of 2010, Egypt only allowed imports of boneless beef, including livers, hearts and kidneys, from cattle less than 30 months of age that originated in Mexico, Canada, or the United States, based on BSE concerns. During 2010, the United States urged Egypt to re-open its market for all U.S. beef and beef products. On January 28, 2011, Egypt fully

opened its market to all U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Poultry

Egypt currently bans certain U.S. poultry products due to concerns about AI. While Egypt currently allows imports of whole frozen U.S. poultry, U.S. poultry parts and offal products remain prohibited. The United States had been negotiating with Egypt to allow imports of U.S. turkey parts and offals, but Egypt has postponed the completion of these negotiations.

See section III.A for an explanation of the AI trade issue.

Plant Health

Wheat

In April 2010, Egypt's Central Administration for Plant Quarantine (CAPQ) imposed a zero tolerance policy for the presence of Ambrosia (ragweed) in wheat imports. One or more varieties of Ambrosia are present in all major wheat exporting countries, including in Egypt. CAPQ and the General Authority for Supply of Commodities, Egypt's state wheat buyer, later modified the restriction to provide that all wheat imports must be "free of Ambrosia seeds." No other country that imports U.S. wheat imposes a restriction of this kind. If Ambrosia seeds are detected in a shipment, CAPQ permits the wheat cargos to be discharged and cleaned. However, exporters and importers face a high degree of risk that shipments could be rejected because of this restriction. The U.S. Government and industry are working together to convince Egypt to remove this unnecessary restriction.

Seed Potatoes

Egypt remains one of the world's last large importers of seed potatoes that bans imports of U.S. seed potatoes. Egypt requires a mandatory field trial for three seasons, as well as a mutually agreed work plan for all varieties for which U.S. seed potato exporters seek marketing approval. After the two sides held a first round of technical meetings on the subject in 2010, Egypt agreed to conduct field trials for U.S. varieties. The trials began at the start of 2011. Egyptian authorities granted an import permit for the U.S. seed potatoes needed to carry out the field trial. The United States is urging Egypt to develop a mutually agreeable work plan that will allow for commercial shipments of U.S. seed potatoes to Egypt.

EL SALVADOR

Food Safety

Poultry

In 2008, CACM member countries, including El Salvador, notified the WTO of their intent to establish microbiological criteria for a number of foods, including zero tolerance for *Salmonella* on poultry meat. The United States shared with CACM members, both in writing and in meetings and workshops, its concerns that the proposed zero tolerance for *Salmonella* on poultry meat appeared to lack a scientific basis because it is generally accepted by food safety experts and scientists that this pathogen cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by *Salmonella*. After reviewing the U.S. comments on this proposal, CACM members decided that each country would establish its own standard for *Salmonella* on raw poultry. In September 2010, U.S. officials met with Central American government authorities to discuss this issue further. El Salvador is updating its regulations, and is aware of the need to avoid creating an unnecessary trade barrier for U.S. poultry exports. The United States will continue to work with government officials in El Salvador and the other CACM member countries to address U.S. concerns regarding the zero tolerance policy.

Live Cattle, Beef, and Beef Products

Due to concerns about BSE, El Salvador prohibits imports of U.S. beef and beef products from cattle over 30 months of age, as well imports of non-breeding cattle. The United States continues to engage with El Salvador to open fully its beef and beef products market based on science, the OIE guidelines and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

ETHIOPIA

Biotechnology

In September 2009, Ethiopia established a biosafety law which has the potential to become an unnecessary barrier to trade in biotech products by imposing what appear to be unduly burdensome documentation and testing requirements. Ethiopia has since issued implementing regulations. U.S. officials continue to engage Ethiopian officials to express concerns about the restrictive biosafety legislation and to seek clarification regarding implementation procedures.

See section III.B for an explanation of the biotechnology trade issue.

EUROPEAN UNION

Biotechnology

EU measures governing the importation and use of agricultural goods produced through the use of modern bioengineering (often known as "agricultural biotechnology"or "biotech") have resulted in substantial barriers to trade. Several U.S. commodity crops – including corn and soybeans – are produced predominately from biotech varieties. Restrictions on biotech products can result in import prohibitions on U.S-produced commodities, as well as prohibitions on the cultivation of biotech seeds.

Under EU law, each biotech trait, as well as each combination of traits, must be approved for a specific use before an agricultural product containing or produced from that trait or traits is allowed to be imported or used in the EU. The EU approval system has two basic steps: an initial scientific assessment, followed by a "comitology" process, which involves interactions between the European Commission and the EU Member States. Even when the EU approves a particular biotechnology product, EU biotechnology legislation provides that individual Member States may invoke their own bans under a so-called "safeguard clause."

The European Food Safety Authority (EFSA) undertakes the scientific assessment. EFSA assessments of biotech products generally take longer than comparable scientific assessments in the United States and other countries. However, EFSA generally reaches the same scientific conclusion as scientific authorities in the United States and other countries. EFSA has never concluded that a biotech variety in U.S. commercial production is unsafe.

If EFSA concludes that the biotech trait is as safe as its conventional counterpart, the application will proceed to the "comitology" process. The European Commission first prepares an approval measure based on the scientific assessment. The Commission then submits the measure to a regulatory committee comprising representatives of each of the 27 EU Member States. Not once in over 12 years has an EU regulatory committee accepted a proposed measure to approve a new biotech product. Instead, EU regulatory committees have always issued a "no-decision." This non-result leads to further, time-consuming procedures in the comitology process. The failure of EU regulatory committees to make decisions in accordance with the EU's own scientific opinions has resulted in substantial delays in the approval of biotech products.

In response to these types of problems, in May 2003 the United States – joined by Canada and Argentina – initiated a WTO challenge to the EU's operation of its biotech approval system. In September 2006, the WTO dispute settlement panel upheld the U.S. claims. The panel found: (1) that the EU had adopted a *de facto*, across-the-board moratorium on the final approval of biotech products, and that the moratorium resulted in undue delays in violation of the EU's obligations under the SPS Agreement; (2) that the EU had violated its SPS obligations to consider biotech applications without undue delay with respect to 24 specific biotech product applications; and (3) that EU Member State bans on products

approved in the EU prior to the moratorium were not supported by scientific evidence and were thus inconsistent with the EU's SPS obligations.

The WTO Dispute Settlement Body adopted the report in November 2006, and the EU's "reasonable period of time" for compliance expired in January 2008. At that time, the United States submitted a request to the WTO for authority to suspend trade concessions. Under an agreement with the EU, however, proceedings on the U.S. request were suspended to provide the EU an opportunity to demonstrate meaningful progress on the approval of biotechnology products. The United States continues to engage the European Commission in an effort to normalize trade in biotech products.

Dozens of biotech product applications are backed up in the EU approval system. In the first few months following the publication of the *2010 SPS Report*, the EU approved several biotech products for use as food and animal feed. However, no additional biotech products have been approved since July 2010. In addition, with respect to approvals for cultivation use, the EU has not approved in over 12 years a single biotech product of commercial significance to the United States.

EU delays in biotech product approvals can result in prohibitions not only on the products subject to the delays, but can also result in prohibitions on shipments of approved varieties. Under the EU's implementation of its biotechnology legislation, the presence in U.S. crop shipments of traces of biotechnology crops that are legally grown in the United States, but not yet approved in the EU, can make U.S. crops unmarketable in the EU. In late February 2011, Member States approved a Commission proposal to address the presence of trace amounts of EU-unapproved biotech products in shipments. The proposal only covers shipments of imported animal feed (thus excluding food for human consumption), and provides what appears to be an impractically low threshold level.

With respect to the Member State bans that the WTO panel found to be inconsistent with the EU's SPS obligations, the EU has taken steps to address some but not all of these bans. However, EU Member States have continued to adopt new bans on products approved at the EU-level. In most cases, the European Commission requests that EFSA issue an opinion on whether the Member State ban can be justified on a scientific basis. EFSA consistently has determined that the Member State bans lack a scientific justification. In several instances, the Commission has proceeded to draft a measure, in accordance with the EFSA scientific opinion, that would require a Member State to lift an unjustified ban. However, the EU regulatory committees have blocked each such measure, just as the regulatory committees have failed to approve new biotech varieties.

In July 2010, the Commission presented a package of proposals that would expand the reasons that a Member State could use to justify bans on cultivating biotech crops in its territory. The package includes a new recommendation on the co-existence of biotech crops with conventional and organic crops, and a proposal amending the governing legislation. The recommendation on co-existence took immediate effect. It provides Member States greater flexibility when developing national co-existence measures, and

allows them to define biotech-crop-free areas. The legislative proposal is still under consideration, and is subject to "co-decision" by both the Member States and the European Parliament. It would allow Member States to restrict or prohibit the cultivation of biotech crops in all or part of their territory. Any such restrictions or prohibitions must not be based on safety, and instead must be based on other societal concerns.

See section III.B for an explanation of the biotechnology trade issue.

Food Safety

Food Additives

On July 2, 2009, the EU notified the WTO of adoption of its final regulations on food additives. The final regulations contain a provision, not present in the draft regulations, that mandates the inclusion of warning statements regarding hyperactivity on products containing six synthetic colors (Sunset Yellow, Quinoline Yellow, Carmoisine, Allura Red, Tartrazine, and Ponceau 4R). Manufacturers are now required to apply a label to products containing any of these six colors stating that that the color "may have an adverse effect on activity and attention in children." Moreover, discussions are now underway in the EU to expand the list of additives for which warning labels will be required. The United States has asked the EU to provide more information the alleged risks posed by these synthetic colors.

The certified equivalents of three of the six colors (Sunset Yellow, Allura Red, and Tartrazine) are approved for use in food by FDA and are widely used by the global food industry. FDA also has approved the use of Quinoline Yellow's certified equivalent for use in drugs, cosmetics, and medical devices. The warning labels that the EU mandates are neither required in the United States nor justified by Codex guidelines (either adopted or currently proposed).

The EU's list of colors and the subject of hyperactivity was addressed in a much-criticized research piece known as the Southampton Study. This study concluded that these six color additives presented a risk of hyperactivity. In November 2009, EFSA released scientific opinions that contradicted the results of the Southampton Study, concluding that the currently available data did not substantiate a link between the individual color additives and possible behavioral effects.

The United States disagrees that FDA-certified color additives have negative health impacts for children when these colors are included in food products in amounts prescribed under U.S. law, and therefore does not consider that warning labels are necessary. Despite requests by senior U.S. Government officials for a delay in implementing its labeling requirement until it undertook further scientific review, the EU implemented this requirement on July 20, 2010. The United States continues to urge the EU to delay implementation of this measure to minimize negative effects on trade while technical discussions are underway.

Beef and Beef Products

In May 2009, the United States signed a MOU with the EU to resolve on a provisional basis their WTO dispute over beef raised with growth-promoting hormones. The MOU, which took effect in August 2009, provides additional duty-free access to the EU market for high-quality beef produced from cattle that have not been raised with growth-promoting hormones – 20,000 metric tons (MT) in each of the first three years, increasing to 45,000 MT beginning in the fourth year. Under the MOU, the United States may maintain the additional duties it had in place on EU products in March 2009, will not impose new duties on EU products during the initial three-year period, and will eliminate all retaliatory import duties during the fourth year. Before the end of the four-year period, the United States and the EU will seek to conclude a longer-term agreement.

Seafood

Under the provisions of the United States-European Community Veterinary Equivalence Agreement, U.S.-origin molluscan shellfish had been permitted for export to the EU. In 2008, the European Commission's Directorate General Health and Consumers (SANCO) notified FDA that the import approval for U.S.-origin molluscan shellfish would expire at the end of 2009. Despite high-level U.S. Government engagement on the issue, the EU began barring imports of U.S.-origin molluscan shellfish, except scallops, in July 2010.

The U.S. Government has actively engaged with the European Commission on this issue and has provided the EU sufficient evidence that U.S.-origin molluscan shellfish are safe to consume. The United States believes that the EU has the information it needs to make an equivalence determination.

Poultry

In 1997, the EU began blocking imports of U.S. poultry products that have been processed with PRTs. The EU has further prohibited the marketing of poultry as "poultry meat" if it has been processed with PRTs. In late 2002, the United States requested the EU to approve the use in processing poultry intended for the EU market of four PRTs that are approved for use in the United States: chlorine dioxide, acidified sodium chlorite, trisodium phosphate, and peroxyacids.

Between 1998 and 2008, various EU agencies issued scientific reports concerning poultry processed with these PRTs. Taken together, the reports conclude that residues of these PRTs do not pose a health risk to consumers.

In May 2008, the European Commission, after years of delay, prepared a proposal that approved the use of the four PRTs for processing of poultry, but imposed highly trade-restrictive conditions that did not appear to be based on science. EU Member States

rejected the Commission's flawed proposal, first at the regulatory committee level and then, in December 2008, at the ministerial level.

In January 2009, the United States requested consultations with the EU on whether the EU's failure to approve the four PRTs was consistent with the EU's commitments under various WTO agreements, including the SPS Agreement. The United States and the EU held those consultations in February 2009 but failed to resolve the matter. In November 2009, the WTO Dispute Settlement Body established a panel to address the matter. That litigation is pending.

Ractopamine

The EU currently maintains a ban on pork produced with ractopamine, a veterinary drug that promotes lean meat growth in pigs and certain other farm animals, despite scientific evidence indicating that ractopamine is safe. As a consequence of this ban, U.S. pork exporters must participate in the burdensome *Pork for the EU Program* to verify that the pork has not been produced using ractopamine. In addition, U.S. pork shipments to the EU must undergo expensive laboratory testing to verify the absence of ractopamine residue. These requirements, which appear to lack scientific justification, act as a major impediment to U.S. pork exports to the EU, confining U.S. exports to a small group of U.S. suppliers.

See section III.E for an explanation of the ractopamine trade issue.

Animal Health

Animal By-Products

In 2002, the EU published Regulation (EC) 1774/2002, which established problematic new requirements for marketing animal by-products that are not intended for human consumption, including by-products used in materials intended for animal consumption. Some of the previously high volume U.S. exports that this regulation barred included pet food, tallow, and other animal protein products. In most cases, the requirements appeared to be unwarranted.

Starting in 2002, APHIS met with EU representatives repeatedly in an attempt to shape revisions to Regulation (EC) 1774/2002. In 2009, the EU published Regulation (EU) 1069/2009 to begin the replacement of Regulation (EC) 1774/2002. The new regulation does appear to address many major U.S. concerns, but also imposes some new requirements about which the United States remains concerned. It did not change the requirements for import into the EU, but laid the groundwork for Regulation (EU) 142/2011, which does replace the requirements for import. APHIS is currently reviewing Regulation (EU) 142/2011 to determine the extent of U.S. concerns which will be remedied by the revisions. While review is ongoing, the initial indication is that the new regulation will allow significantly more U.S. product to be eligible for export to the EU.

EU Country-Specific Issues

Austria

Biotechnology

Since 1997, Austria has maintained a series of cultivation and import bans on products of agricultural biotechnology. The United States challenged several of these bans at the WTO, which found them inconsistent with Austrian and EU obligations under the SPS Agreement. In May 2008, Austria lifted its import bans on the MON 810 and T25 biotech corn varieties, but left in place its cultivation ban on these varieties. Moreover, in July 2008, Austria issued new import bans on MON 863 corn as well as on three rapeseed (canola) lines.

See section III.B for an explanation of the biotechnology trade issue.

Bulgaria

Biotechnology

In March 2010, Bulgaria issued a new biotechnology law, which prohibits the cultivation of biotech crops in all protected regions, as well as surrounding areas. The combined restrictions cover the entire country and, in effect, ban all biotech field trials and production. In addition, the law requires the Minister of Agriculture to invoke a "safeguard clause" for a particular biotech crop in Bulgaria whenever another Member State applies a safeguard clause for that same crop in its own territory. Separately, in July 2010, Bulgaria enacted a prohibition on the use of biotechnology products and ingredients in the production of foods for children and in baby food. The new regulation also banned distribution and sale of biotech foods and food products in nurseries, kindergartens, and schools, as well as in retail outlets and within 100 meters of such establishments. The United States has raised these measures with the government of Bulgaria and has asked Bulgaria to provide justifications for them.

See section III.B for an explanation of the biotechnology trade issue.

France

Biotechnology

Cultivation in France of MON 810 (a pest-resistant corn variety) grew from 500 hectares in 2005 to 22,000 hectares in 2007. However, in January 2008, following a review by a new "interim" biotechnology authority, France banned the cultivation of MON 810 and invoked the "safeguard" clause under EU regulations. In October 2008, EFSA found that France had presented no scientific basis to justify the safeguard measure. Nonetheless, France has left in place its ban on the cultivation of MON 810.

See section III.B for an explanation of the biotechnology trade issue.

Germany

Biotechnology

In 2009, Germany banned the cultivation of MON 810 corn and invoked the "safeguard" clause under EU regulations. EFSA determined that Germany had not presented any scientific evidence to justify the new ban. Despite the EFSA evaluation, the German Agricultural Ministry has maintained the MON 810 ban.

See section III.B for an explanation of the biotechnology trade issue.

Greece

Biotechnology

Since April 2005, Greece has implemented and extended bans on MON 810. In July 2008, EFSA determined that Greece's ban lacked a scientific basis. In August 2009, Greece extended the ban for another two years and expanded the measure to include both importation and cultivation.

See section III.B for an explanation of the biotechnology trade issue.

Hungary

Biotechnology

Since 2005, Hungary has banned the import and cultivation of MON 810. On several occasions, the European Commission has attempted to require Hungary to lift the ban, but has not received adequate support from EU Member States.

See section III.B for an explanation of the biotechnology trade issue.

Latvia

Biotechnology

On June 18, 2009, Latvia modified its Law on Circulation of Genetically Modified Organisms to grant decision-making authority on biotech cultivation to local municipalities. Since passage of the law, 88 of 109 municipalities in Latvia have banned the cultivation of biotech crops, and eight more are working on similar bans. According to Latvia's Ministry of Environment, the basis for the current regulation is the "EU Environment Ministers agreement - Council Conclusions," which notes that biotech–free zones can be created on the basis of voluntary agreements among the "economic operators" in a particular area.

Prior to June 18, 2009, Latvian law provided that only the Cabinet of Ministers could prohibit biotech plantings, and such a decision had to be based on scientific evidence that a specific biotech crop posed safety concerns for the environment, health, or economy. The United States has engaged the government of Latvia regarding this shift in policy and has requested further information about the basis for the current biotech cultivation bans.

See section III.B for an explanation of the biotechnology trade issue.

Luxembourg

Biotechnology

In March 2009, Luxembourg banned the cultivation of MON 810. EFSA found that Luxembourg's ban lacked a scientific basis, yet the ban remains in place.

See section III.B for an explanation of the biotechnology trade issue.

Poland

Biotechnology

Since 2006, Poland has not only opposed the approval of biotech crops at the EU level, but has taken official steps to become "GM-free." The government banned the sale and registration of biotech seeds in mid-2006 and passed legislation that would have prohibited import, production, and use of animal feed derived from biotech crops by August 12, 2008. On July 27, 2008, Poland's president authorized a delay in implementing the feed ban through January 1, 2013. Separately, the Polish Parliament is in the process of preparing new legislation to regulate biotech crops in Poland. The new law, which will not directly address the feed ban, is expected to be enacted in the first half of 2012.

See section III.B for an explanation of the biotechnology trade issue.

Portugal

Biotechnology

In May 2010, the Autonomous Region of Madeira (a Portuguese archipelago) became the first region of the EU to declare itself free of biotech cultivation after the European Commission failed officially to oppose Madeira's request by the legislated deadline. Madeira's authority for the ban was further codified when, in July 2010, the European Commission announced new "co-existence" measures that authorize Member States to allow, restrict, or ban the cultivation of biotech crops in part or all of their territory. The net effect of the Madeira biotech-free declaration is that no biotech crops can be grown in Madeira. The United States has raised this issue in bilateral meetings with Portugal.

See section III.B for an explanation of the biotechnology trade issue.

GUATEMALA

Food Safety

Poultry

In 2008, CACM member countries, including Guatemala, notified the WTO of their intent to establish microbiological criteria for a number of foods, including zero tolerance for *Salmonella* on poultry meat. The United States shared with CACM members, both in writing and in meetings and workshops, concerns that the proposed zero tolerance for *Salmonella* appeared to lack a scientific basis because it is generally accepted by food safety experts and scientists that this pathogen cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by *Salmonella*. After reviewing the U.S. comments on this proposal, CACM members decided that each country would establish its own standard for *Salmonella* on raw poultry. In September 2010, U.S. officials met with Central American government authorities to further discuss this issue. As a result of U.S. outreach, Guatemala has said that it will not apply a zero tolerance *Salmonella* standard to U.S. poultry exports.

GULF COOPERATION COUNCIL

Food Safety

Food Safety Requirements

In May 2007, Bahrain notified the WTO of proposed procedures meant to harmonize food safety import requirements among Gulf Cooperation Council (GCC) Member States (Bahrain, Kuwait, Oman, Saudi Arabia, Qatar, and the United Arab Emirates). The United States and other WTO Members provided comments outlining significant concerns with the procedures, which did not appear to have a scientific basis and would substantially disrupt food exports to GCC Member States. The United States has established a dialogue with technical experts in the GCC Member States and continues to monitor the situation and suggest alternate procedures that are consistent with international guidelines. The GCC Member States have indicated that they have modified key provisions of the draft import procedures in light of trading partner comments and are continuing to work on a revised set of procedures.

HONDURAS

Food Safety

Poultry

In 2008, CACM member countries, including Honduras, notified the WTO of their intent to establish microbiological criteria for a number of foods, including zero tolerance for *Salmonella* on poultry meat. The United States shared with CACM members, both in writing and in meetings and workshops, concerns that the proposed zero tolerance for *Salmonella* on poultry meat appeared to lack a scientific basis because it is generally accepted by food safety experts and scientists that this pathogen cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by *Salmonella*. After reviewing the U.S. comments on this proposal, CACM members decided that each country would establish its own standard for *Salmonella* on raw poultry. In June 2009, the Government of Honduras established a 20 percent *Salmonella* tolerance for raw poultry products, replacing its previous zero tolerance standard and resolving concerns the United States had expressed regarding a possible trade barrier for U.S. poultry exports.

HONG KONG

Food Safety

Beef and Beef Products

In December 2005, Hong Kong partially re-opened its market to deboned beef from cattle less than 30 months of age, with numerous restrictions and additional measures that appear to be inconsistent with the OIE guidelines. These unwarranted restrictions have discouraged most qualified U.S. beef exporters from shipping to Hong Kong.

In October 2009, Hong Kong authorities conducted a verification visit to beef processing facilities in the United States. In August 2010, Hong Kong provided a report of its findings of the site visits, which the United States is reviewing. The United States will continue to engage with Hong Kong to open fully its market for all U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

INDIA

Food Safety

Dairy Products

Since 2003, India has imposed unwarranted SPS requirements on dairy imports, which have essentially precluded U.S. access to India's dairy market, one of the largest in the world. For example, India requires the U.S. Government to certify that any milk destined for India has been treated to ensure the destruction of paratuberculosis, which according to India, is linked to Crohn's Disease. Despite repeated requests from the United States, India has not provided scientific evidence to substantiate this assertion, and has declined to take into account evidence to the contrary submitted by the United States. The United States maintains that the presence of paratuberculosis in dairy products does not pose a human health risk, and India should not make elimination of this bacterium a condition for issuing a sanitary export certificate for U.S. dairy products.

Pork

The Indian import certificate for pork requires that importers make an attestation that the imported pork does not contain any residues of pesticides, drugs, mycotoxins, or other chemicals above the MRLs prescribed in international standards. However, these certificates fail to identify specific compounds and their corresponding international limits. India also limits pork imports to meat derived from animals that were never fed ruminant-derived protein; requires attestations that are not in accordance with international requirements; and prohibits imports of pork products obtained from animals raised outside the United States even if they were legally imported into the United States before slaughter. Further, certificates are valid for only six months, and a separate import permit must be obtained for each imported lot.

Animal Health

Poultry and Swine

Since 2007, India has banned imports of U.S. poultry, swine, and related products due to the detection of LPAI in the United States. India's ban appears to be inconsistent with OIE guidelines, which do not provide for the imposition of trade restrictions based solely on the limited presence of LPAI in the exporting country. The United States has repeatedly raised concerns about India's measures in the WTO SPS Committee, and has discussed these concerns in a high-level dialogue with India in the U.S.-India Trade Policy Forum. After repeated requests from the United States and other major trading partners for a scientific justification for its ban, India provided supporting material in October 2010. The United States, other trading partners, and the OIE are currently reviewing this material. The United States will continue to raise these concerns bilaterally and multilaterally and to press India to rescind its measures.

Although dry processed pet food is exempt from India's AI ban, Indian officials continue to require AI certification statements, which do not appear to be consistent with OIE guidelines and have effectively stopped imports of U.S. dry processed pet food.

See section III.A for a fuller explanation of the AI trade issue.

Plant Health

Wheat and Barley

India maintains restrictive standards for certain plant quarantine pests, such as for weed seeds and ergot, which have blocked U.S. wheat and barley imports. Bilateral discussions to resolve these issues, including at the senior official level, have achieved little success to date.

The United States has raised concerns about India's plant health requirements, as well as India's other SPS-related restrictions mentioned in this report, in bilateral and multilateral fora, including in the Agriculture Focus Group of the U.S.-India Trade Policy Forum, the WTO SPS Committee, and Codex. Most recently, the United States intensified engagement with India on these issues at senior levels of government in advance of President Obama's November 2010 visit to India. In the course of discussions in these fora, the United States proposed, for example, that India and the United States adopt specific health certificates, including the Codex model certificate, attesting that U.S. milk and milk products are safe for human consumption. In a continued effort to re-open India's market to U.S. products, the United States also developed alternative certification options for India's consideration. Although these discussions have served to narrow the scope of differences in certain areas, India continues to maintain unwarranted SPS-related restrictions. The United States will continue to make use of all available fora with a view to eliminating those differences and securing the entry of U.S. dairy, poultry, pork, and other agricultural products into the Indian market.

INDONESIA

Animal Health

Animal-Derived Products

In October 2009, Indonesia announced Law 18/2009, which will require companies that export animal-derived products to Indonesia to complete a difficult pre-registration process with the Indonesian Trade Ministry based on a recommendation from the Indonesian Ministry of Agriculture. In addition, the law will limit imports of these products to those produced in plants that the Indonesian authorities have individually audited and approved. The law, which could significantly impede U.S. agricultural exports to Indonesia, including dairy and eggs, is due to be implemented in June 2011. To date, Indonesia has

not notified the WTO of Law 18/2009, nor has it published draft implementing regulations. The United States has raised concerns regarding the law with Indonesian officials at various levels during the past year, including during the bilateral Trade and Investment Framework Agreement (TIFA) meeting in September 2010, and will continue to work towards a resolution of this issue.

ISRAEL

Food Safety

Live Cattle, Beef, and Beef Products

Work on an agreement to allow imports of U.S. live cattle into Israel was suspended after the detection of a BSE positive animal in the United States in 2003. Despite regular bilateral consultations since 2003, all U.S. live cattle, beef, and beef products remain banned. In March 2010, the Israeli Veterinary Services published new draft BSE regulations related to all bovine products, including beef meat, feeder cattle, pet food, and blood serums. In July 2010, U.S. officials submitted technical comments on the draft regulations. Israel is currently reviewing the U.S. comments, as well as those submitted by other trading partners. The United States continues to engage Israel to fully open its market for all live cattle, beef, and beef products from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Pet Food

Since 2007, Israeli regulations had prohibited the importation of pet food from the United States containing ruminant materials. These regulations did not appear to be consistent with OIE guidelines. In July 2010, the United States and Israel completed negotiations on new requirements for the export of pet food from the United States to Israel, and the ban on U.S. pet food products was lifted.

See section III.C for an explanation of the BSE trade issue.

Plant Health

Cherries

Israel bans imports of U.S. sweet cherries, citing various plant pests and diseases of concern. U.S. officials are working with Israel to complete Israel's risk assessment on sweet cherries in an attempt to resolve this longstanding issue, which has blocked U.S. exports for

nearly eight years. During technical bilateral meetings in August 2010, Israel agreed to expedite the risk assessment for U.S. sweet cherries.

Table Grapes

Israel bans imports of U.S. table grapes citing various plant pests and diseases of concern. U.S. officials are working with Israel to complete its risk assessment on table grapes in an attempt to resolve this long standing issue, which has blocked U.S. exports for nearly five years. During technical bilateral meetings in August 2010, Israel agreed to expedite the risk assessment for U.S. table grapes.

Apples and Pears

In March 2009, Israel's Plant Protection and Inspection Service in the Ministry of Agriculture and Rural Development informed the United States that U.S. apples and pears would be subject to new cold treatment requirements to mitigate the risks of apple maggot and plum curculio, despite the fact that Israel has not conducted a PRA and these pests have not been found in shipments from the United States. Israel granted the United States a temporary exemption from these requirements until June 1, 2010, and has granted a subsequent exemption until June 1, 2011. The University of Washington and Cornell University recently completed a research project relating to Israel's concerns and U.S. officials are currently preparing a U.S. proposal to present to Israel concerning the removal of the new cold treatment requirements.

JAMAICA

Animal Health

Pork

Jamaica currently bans imports of U.S. pork due to concerns about pseudorabies, a viral disease that can affect swine. The United States has engaged Jamaica on this issue and explained that this disease was eliminated from U.S. commercial production in 2004. In August 2010, officials from USTR and USDA traveled to Kingston to meet with Jamaican government officials to discuss this issue. Jamaican officials visited the United States later that month to learn about the U.S. system for protecting animal health. Jamaica intends to conduct a risk assessment in response to the U.S. request for pork market access. In January 2011, APHIS officials went back to Jamaica for additional consultations. Although efforts to persuade Jamaica to remove its ban have been unsuccessful to date, the United States will continue to press Jamaica to open its market for U.S. pork.

JAPAN

Food Safety

Beef and Beef Products

In December 2003, Japan banned U.S. beef and beef products following the detection of a BSE positive animal in the United States. In July 2006, Japan partially reopened its market to allow imports of some U.S. beef and beef products from animals aged 20 months or younger produced under a special program for Japan. However, the protocol implementing this limited reopening, as well as other border measures taken by Japan, has not proved to be commercially viable and has prevented the United States from regaining a level of trade that approaches historic levels of exports to the Japanese market. Before the ban, Japan was the largest export market for U.S. beef and beef products, totaling nearly $1.4 billion in 2003. The U.S. Government continues to press the Japanese government on this important issue at multiple levels and at every opportunity, and is working vigorously to open the market to U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Frozen French Fries

Japan's standards for microbial content on frozen foods are, in certain instances, overly restrictive, particularly for foods that require cooking before consumption. For example, Japan has occasionally rejected shipments of U.S. frozen French fries, which it classified as a finished product, due to the presence of coliform bacteria. The United States has contended that any coliforms detected are minimal and within industry specified limits. Moreover, the French fries will be cooked in oil, eliminating the presence of coliforms, and thus any risk of negative health effects.

As a result of USTR's requests, Japan has changed the categorization of frozen French fries to recognize that frozen French fries are not a significant source of coliform bacteria. This new categorization protects Japanese consumers, while ensuring that the rejection of imported U.S. frozen French fries would only occur for science-based reasons.

Food Additives

Japan's regulation of food additives has restricted imports of several U.S. food products, especially processed foods. Many additives that are widely-used in the United States and throughout the world are not allowed in Japan. In addition, U.S. manufacturers have complained about the prolonged approval process for indirect food additives (i.e., additives that do not remain on food, such as solvents).

In 2002, as part of Japan's approval process, Japan created a list of 46 food additives that would be subject to an expedited approval process. As of March 2011, six of these substances have yet to be reviewed or approved, notwithstanding the availability of extensive data on the safety of these additives. The U.S. Government has urged Japan to complete its review of the list of food additives and to expedite the review process for food additives generally. U.S. officials may also seek the addition of more globally-used additives to Japan's review process.

In August 2010, Japan removed 80 additives, which Japan's Ministry of Health, Labor and Welfare (MHLW) claims are not used domestically, from the approved list of additives. However, some of these additives are still used by industry in products exported to Japan, and the MHLW has indicated that it is open to adding these additives back to the list of allowed additives after review and confirmation that the particular additives are still in use overseas. The U.S. Government and industry have already submitted comments and supplemental information to Japan on this issue.

Gelatin

Japan bans the importation of U.S.-origin ruminant gelatin for human consumption (along with most other ruminant origin tissues) due to the December 2003 detection of a BSE positive animal in the United States. Although the restrictions on some ruminant-origin products have been amended to allow for their importation, there has been no modification to the prohibition on ruminant-origin gelatin for human consumption. This import ban appears to be inconsistent with OIE guidelines. The United States will continue to press Japan to resolve this issue based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Post Harvest Fungicide

Japan's food safety regulations require a risk assessment for the pre-harvest application of a fungicide. However, Japan classifies fungicides that are applied post-harvest as food additives and requires them to undergo an entirely independent risk assessment. As a result, registrants who use a fungicide pre- and post-harvest must ensure that two risk assessments are performed, which can take as long as five to six years to complete. These requirements deter registrants from pursuing approval for newer products. In addition, Japan often delays initiating the second risk assessment until after the first is complete. Japan's dual risk assessment policy has not impacted domestic producers, as Japanese farmers do not routinely apply fungicide after harvest.

Japan's policy appears to be inconsistent with Codex standards and widely accepted procedures among countries with robust pesticide regulatory systems. Countries assessing the risk posed by a fungicide generally perform a single risk assessment, which takes into

account the manner in which the pesticide is applied, regardless of the time of application to the crop.

Japan has indicated that it would not be feasible in the near future to change the legal statute mandating post-harvest fungicides to be classified as food additives. However, in May 2010, Japan announced a decision to streamline the review process for agricultural chemicals applied as pesticides (pre-harvest application) and as food additives (post-harvest application). As of the date of this report, there has been no indication that this streamlining has occurred and, as such, the length and effectiveness of Japan's new review policies remains unclear. The United States will continue to monitor this process and work with Japan to eliminate these costly and burdensome requirements.

Maximum Residue Limits

Prior to 2009, Japan's enforcement of its MRLs could subject all exports of a commodity from a particular country to increased testing based on MRL violations incurred by other exporters of that commodity from the same exporting country. Under its previous policy, MHLW increased testing after a single violation to 30 percent of the particular agricultural commodity originating from the country in question, even for growers/shippers that had no history of violations. If a second violation occurred within 12 months of the first violation for the same commodity and country, MHLW imposed a 100 percent test and hold requirement on all shipments of the commodity from the exporting country.

In July 2009, the United States and Japan concluded an MOU that addressed certain concerns of the United States. Under the MOU, in the event there is an MRL violation with regard to a U.S. horticultural product where the U.S. MRL is equal to or more stringent than Japan's MRL, Japan will take action only against the producer, exporter, or shipper whose product has violated the MRL. Where there has been an MRL violation with regard to a U.S. horticultural product where the U.S. MRL is less stringent than Japan's MRL, the MOU provides that Japan may take action against the violator, but not the whole U.S. industry, unless there is sufficient evidence of an industry-wide concern. Notwithstanding the MOU, however, there continue to be serious concerns about the amount of time it takes Japan to establish permanent, science-based MRLs, Japan's temporary imposition of unreasonably low default MRLs until permanent MRLs are established, and Japan's enforcement practices where the U.S. MRL is less restrictive than Japan's MRL.

See section III.D for an explanation of the MRL trade issue.

Rice

Japan's rice import regime limits the competitiveness of U.S. rice in the Japanese market through a number of measures, including excessive testing requirements. The MHLW tests imported rice at the port of arrival for hundreds of chemicals. In addition, the Ministry of Agriculture, Forestry and Fisheries (MAFF), as the rice importer of record, also tests 100 percent of the rice it purchases at the pre-loading and loading stages to comply with food

safety regulations. These tests are mandatory and paid for by MAFF. However, as the importer of record, MAFF can, at its option, require an additional test for shipment insurance purposes. Although technically optional, MAFF is the only legal buyer of imported rice and always requires the insurance test, effectively making it mandatory. The requirement that such a large number of chemicals be tested and the number of times these tests must be performed during the import process do not appear to be based on risk. The United States will continue to urge Japan to streamline these apparently excessive testing requirements.

Animal Health

Poultry

U.S. poultry and poultry products, including egg products, are currently exported to Japan in accordance with a 2002 animal health protocol. Japan unilaterally implemented the protocol, which limits market access for these U.S. products in a manner that appears to be inconsistent with the OIE guidelines on AI. The United States continues to press Japan to agree to an OIE-consistent revised protocol.

See section III.A for an explanation of the AI trade issue.

Plant Health

Fresh and Chipping Potatoes

On February 1, 2006, MAFF and USDA reached an agreement to allow limited imports of U.S. fresh potatoes to produce potato chips. Prior to that date, Japan had banned all imports of fresh potatoes from the United States due to phytosanitary concerns. Under this agreement, 14 U.S. states were allowed access to the Japanese market during specific months (February through June of each year). The States of Idaho, Arizona, Wisconsin, Oregon, California, Colorado, Texas, New Mexico, North Dakota, Florida, Michigan, Minnesota, Maine, and Washington were approved to participate in this program. However, in April 2006, after Idaho announced a potato cyst nematode finding, Japan banned imports of all U.S. fresh potatoes. In February 2007, the U.S. regained access for all previously approved states except Idaho. Currently, only one port-area facility is allowed to process U.S. fresh potatoes under MAFF's strict surveillance. Through negotiations with Japan, the United States has continued to seek the reinstatement of Idaho, to secure access to additional port facilities, and, most recently, to extend the shipping period from January to July instead of from February to June.

Requirements on New Cherry Varieties

Japan only approves imports of new fresh cherry varieties based on an individual fumigation trial. This burdensome process, which involves testing the application of pesticides for each separate variety, restricts the entry of new varieties of cherries. The

United States is urging Japan to accept fresh sweet cherries as a single commodity, which would mean that all varieties may be imported without the need for separate testing.

Access for Non-Fumigated Cherries

Since the commonly-used methyl bromide fumigations on fresh cherries cause significant damage to the quality of the fruit and shorten the product's shelf life, the U.S. industry, USDA, and the government of Japan began discussing the possibility of implementing a plant health protocol under which Japan would no longer require methyl-bromide fumigation for U.S. fresh cherries. In 2009, the United States and Japan reached an agreement on a protocol allowing the Pacific Northwest region (Washington and Oregon) to ship fresh cherries to Japan without fumigation. The region's successful implementation of this protocol is now in its second year. In 2010, the United States and Japan finalized a similar protocol for California. U.S. officials are currently working with their Japanese counterparts to incorporate Idaho into the current Pacific Northwest protocol.

KAZAKHSTAN

Systemic Issues

General

The entry into force of the Customs Union of Russia, Kazakhstan, and Belarus (the "Customs Union" or CU) has complicated trade into and among the three countries, as they harmonize and revise their SPS measures. Traders and even customs officials at the border are often unsure about the new requirements and, as a result, customs officials often appear to indiscriminately choose which requirements to apply.

Kazakhstan signed the Agreement of the Customs Union on Sanitary Measures and the Agreement of the Customs Union on Veterinary and Sanitary Measures on December 11, 2009. Since April 2010, Russia, Belarus, and Kazakhstan have concluded a number of additional agreements that harmonize SPS measures. These agreements unify the list of goods subject to veterinary, phytosanitary, and sanitary-epidemiological control at the customs border and within the territory of the CU, unify the veterinary and sanitary-epidemiological and hygienic requirements on those goods, and unify the form of documentation confirming the safety of those goods. On July 1, 2010, the Customs Union implemented harmonized veterinary requirements, which stipulate that imports for all veterinary controlled products are eligible for entry only if they are from facilities on a common list approved by all three Customs Union parties. These various SPS measures have the potential to restrain U.S. exports.

Among the CU's additional SPS measures, Kazakhstan now requires a mandatory "state registration" for the production and importation of certain types of goods. Any importer or producer of these goods must obtain a Certificate of State Registration from the country of origin before the product can be sold. In Kazakhstan, the Committee of State Sanitary and

Epidemiological Supervision under the Ministry of Health will issue such certificates. Goods subject to this certification include:

- mineral water, drinking water in bottles, tonic water, alcoholic beverages;
- specialized food products produced with genetically-modified microorganisms;
- food supplements, complex food supplements, perfumes, plant extracts, microorganisms, and cultures;
- products for disinfection (except of those used in veterinary services); and
- items designated for contact with food products (except dishes, table amenities, and microwaves).

The U.S. Government continues to engage with Kazakhstan as to the basis of these restrictions and to ensure that implementation of these measures are not trade disruptive.

Veterinary Certificates

After over a year of negotiations, USTR and USDA successfully completed negotiations with Kazakhstan of veterinary certificates governing trade in beef, poultry, pork, egg products, sheep and goat meat, and dairy and dairy products. However, the implementation of these certificates has not been completed. These certificates are only valid through 2011; after that point, Kazakhstan will implement a harmonized Customs Union certificate that is currently being developed. The U.S. Government continues to work with Kazakhstan to ensure that trade will not be disrupted during the transition to Customs Union certificates.

Biotechnology

Kazakhstan currently is considering a draft law to regulate the development and testing of biotechnology products in Kazakhstan. While the current draft law provides for the review and registration of biotech events for import and cultivation in Kazakhstan, it also includes rigid timelines for notification and supplementary data submissions. The draft law also lacks clarity with respect to liability and the protection of confidential business information, and establishes a ban on all biotech ingredients in baby food, even in cases where those products have been proven safe. The United States has raised concerns with these issues and has also urged Kazakhstan to consider an interim system for biotech approvals to address the products currently in commerce and to avoid trade disruption as Kazakhstan transitions to implementation of the draft law.

See section III.B for an explanation of the biotechnology trade issue.

KUWAIT

Animal Health

Poultry

Kuwait bans imports of live fowl, hatching eggs, and one-day old chicks from Kentucky and Minnesota due to concerns about the detection of LPAI in those states. This restriction does not appear to be consistent with relevant OIE guidelines, which do not allow for the imposition of trade restrictions for LPAI. U.S. officials have raised this issue with officials in Kuwait and will continue to press them to resolve this matter.

See section III.A for an explanation of the AI trade issue.

MEXICO

Food Safety

Live Cattle, Beef, and Beef Products

In March 2004, Mexico became one of the first major markets previously closed to U.S. beef and beef products to reopen its market when it announced that it would accept imports of U.S. deboned beef from cattle less than 30 months of age. Subsequently, Mexico further opened its market to bone-in beef and beef products from animals less than 30 months of age. In October 2008, the United States and Mexico reached an agreement allowing imports into Mexico of U.S. breeding cattle born after 1999.

Mexico currently allows the importation of U.S. beef (deboned and bone-in) and selected beef products (further processed products, tripe, trimmings, hearts, kidneys, lips, diaphragms, tongue, and cheek meat) derived from animals less than 30 months of age. All other products derived from cattle of all ages, including ground beef, as well as live breeding cattle of all ages, are banned.

In August 2010, the United States hosted a Mexican technical team to perform a verification visit to review the efficacy of U.S. BSE-related safeguard measures. Mexico informed the United States that its risk assessment, including results from this verification visit, would be completed by December 2010. The United States raised concerns regarding Mexico's current restrictions at the October U.S.-Mexico Consultative Committee on Agriculture, as well as during high-level bilateral discussions in December 2010 and January 2011. As of mid-March 2011, the United States has not received the results of the risk assessment from Mexico which would form the basis of the next discussions on access for beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Pork

The United States exports fresh chilled meats for processing to Mexico in "combo bins" or "combos" at the request of the Mexican meat processing sector. Combos are large, plastic-lined, palletized cardboard boxes that contain a single meat product from a single establishment. As a result of U.S. engagement, Mexico has delayed the implementation of an intrusive 100 percent testing system for combos at the border until the publication of new implementing animal health law regulations for combo import inspection. However, due to the legal requirement for 100 percent testing as well as other issues involving combos, Mexico has yet to develop a risk-based inspection system that is not unnecessarily burdensome to trade. Uncertainty surrounding the nature of a new inspection system, as well as its date of implementation, have been causes of concern among U.S. meat exporters.

Plant Health

Stone Fruit

U.S. peach, nectarine, and apricot growers are encountering problems with respect to Mexico's approach to controlling oriental fruit moth and a number of other pests.

California

Under the California Stone Fruit Workplan, Mexico requires a high level of oversight through a large number of inspectors, paid for by the California stone fruit industry, in order to allow market access to Mexico. USDA continues to hold discussions with Mexico to reduce both the oversight in the United States by Mexican inspectors and oversight in Mexico by U.S. inspectors. A draft protocol that would reduce oversight requirements is under discussion.

Georgia and South Carolina

In 2008, USDA requested access to Mexico's market for stone fruit from Georgia and South Carolina. Mexico agreed to complete a PRA in order to review the request. During technical discussions in January 2011, Mexico agreed to let Georgia and South Carolina export stone fruit in the absence of a completed PRA under a modified version of the California Stone Fruit Workplan. Although the work plan is more stringent and expensive than necessary due to the extensive oversight required by Mexico, it will allow Georgia and South Carolina to begin shipping to Mexico, likely in June 2011.

Pacific Northwest

USDA is awaiting a PRA from Mexico to address a request for market access for peaches from the Pacific Northwest. Mexico has noted that in the absence of the PRA, these peaches would require oversight similar to California, although producers are concerned that due to the low risk associated with the region, any export program should require minimal oversight. Mexico has stated that a draft PRA will be completed in June 2011. USDA is continuing technical discussions with Mexico on this issue.

Potatoes

Mexico continues to prohibit the shipment of U.S. fresh potatoes beyond a 26 kilometer zone along the U.S. and Mexico border. Although the two countries reached an agreement in 2003 that provided a road map to allow U.S. potatoes access to the whole of Mexico over a three-year period, Mexico has been slow to implement the agreement. More recently, Mexico has advised that it will modify the existing potato regulation as part of a technical administrative process that could take several years to complete. At the same time, however, Mexico informed the United States that it will convene technical-level bilateral discussions during the pendency of that process.

The United States and Mexico have held several technical meetings on the issue, and U.S. officials also raised the issue at the U.S.-Mexico Consultative Committee on Agriculture in October 2010. USDA sent a risk mitigation proposal to Mexico in early November 2010, and the United States again raised the issue on the margins of the NAFTA Sanitary and Phytosanitary Committee meeting later that month. Technical discussions were again held in early December 2010. On December 10, 2010, U.S. Secretary of Agriculture Tom Vilsack and Mexican Secretary of Agriculture Francisco Mayorga agreed to explore alternative approaches to resolve this issue, including third-party mediation. Since then, Mexico and the United States have agreed to resolve this issue under the auspices of the North American Plant Protection Organization and have initiated the mediation process.

MOROCCO

Food Safety and Animal Health

Morocco restricts imports of U.S. live cattle, beef, and beef products due concerns over BSE and growth hormones, and poultry and poultry products due to AI and *Salmonella*-related issues. Morocco and the United States are working to reach agreement on sanitary certificates that are consistent with international standards to accompany U.S. exports of such products to Morocco.

See section III.C for an explanation of the BSE trade issue and see section III.A for an explanation of the AI trade issue.

NEW ZEALAND

Animal Health

Pork

New Zealand restricts imports of U.S. pork to consumer-ready high value cuts and pork for further processing due to concern about PRRS and PMWS. In April 2009, after several years of consultation and analysis, New Zealand issued four provisional import health standards for pig meat, pig meat products, and by-products from the United States, Canada, the EU, and Mexico. If approved, the provisional standards will allow for the importation of high-value, consumer-ready cuts of uncooked pork from countries not considered free of PRRS. However, these provisional standards are not yet approved.

Later in 2009, New Zealand established an independent panel to review the provisional import health standards. The panel completed its review in April 2010 and submitted recommendations. New Zealand then convened an expert working group in October 2010 to review the risk assessment model in relation to PRRS. New Zealand currently is reviewing the expert working group's findings. The United States continues to engage with New Zealand on this issue.

Plant Health

Stone Fruit

In 2006, the United States requested New Zealand to expand its import health standard for California stone fruit to include fruit from the Pacific Northwest. New Zealand issued a draft PRA in March 2009. The United States and New Zealand have consulted extensively on this draft PRA since then, including in October 2010. The Ministry of Agriculture and Forestry has nearly completed consultations with domestic and U.S. stakeholders and is expected to issue a final risk assessment in 2011. The next stage of the process is the development of an import health standard, which is expected to be completed in 2011.

NICARAGUA

Food Safety

Poultry

In 2008, CACM member countries, including Nicaragua, notified the WTO of their intent to establish microbiological criteria for a number of foods, including a zero tolerance policy for *Salmonella* on poultry meat. The United States has informed CACM members that a zero

tolerance for *Salmonella* on poultry meat is unwarranted because it is generally accepted by food safety experts and scientists that pathogens cannot be entirely eliminated from raw meat, and that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by these microbes.

After reviewing the U.S. comments on this proposal, CACM members decided that each country would determine its own country-specific standard for *Salmonella* in raw poultry. In September 2010, U.S. officials met with Central American government authorities to further discuss this issue. Nicaragua indicated it is reviewing the current regulations and any changes will be notified to the WTO. The United States will continue to work with government officials in Nicaragua and the other CACM member countries to address U.S. concerns regarding the zero tolerance *Salmonella* policy.

NORWAY

Biotechnology

Since 1996, Norway has adopted policies that effectively ban the importation of agricultural biotechnology products. The United States continues to press Norway to open its market to U.S. exports of those products.

See section III.B for an explanation of the biotechnology trade issue.

Food Safety

Beef and Beef Products

Norway implements EU regulations that ban imports of meat from animals treated with growth hormones.

See the discussion of the EU's hormone ban for more detail.

PERU

Animal Health

Live Cattle

Peru continues to ban all U.S. live cattle due to BSE-related concerns following the detection of a BSE positive animal in the United States in 2003. Until April 2010, Peru and the other three CAN member countries (Bolivia, Ecuador, and Colombia) had maintained that CAN rules prevented them from lifting their BSE-related restrictions on live cattle.

In 2009, the United States submitted comments on a proposed risk assessment published by CAN which stipulated that only live animals under 24 months of age could be imported.

CAN Resolution 1314, published April 2010, stipulated that all CAN member countries would be able to elaborate their own requirements regarding the importation of live cattle from the United States in accordance with the CAN risk assessment.

The U.S. Government continues to engage with Peru to re-open its market for U.S. live cattle based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

PHILIPPINES

Plant Health

Quarantine Clearance

The Philippine Department of Agriculture now requires a plant quarantine certificate for processed plant products (e.g., frozen French fries and raisins). This requirement appears to be duplicative because existing Philippine Food and Drug Administration requirements appear to already address the safety issues associated with these products. The United States continues to engage with the Philippines on this issue.

Market Access for U.S. Vegetables

The United States is concerned with the timeliness with which the Philippines is producing PRAs for fresh fruits and vegetables. Since 2006, the United States has been waiting for PRAs for broccoli, cauliflower, lettuce, carrots, cabbage, celery, and, more recently, fresh potatoes. Until these PRAs are completed, the Philippine Department of Agriculture will only allow limited amounts of these vegetables to enter the country on a case-by-case basis for "high-end markets," such as hotels, restaurants, and airline companies. In addition, the Philippines only allows the entry of U.S. fresh potatoes that will be processed into chips and other food products. The Philippines has promised to issue PRAs for the vegetables noted above in the first half of 2011.

Food Safety

Frozen and Chilled Meat and Meat Products

In December 2010, the Philippines implemented Administrative Order (A.O.) 22, which established rules and regulations for the handling of frozen and chilled meat and meat products. A.O. 22 imposes refrigeration requirements on frozen and chilled meat and meat products, as well as burdensome and ambiguous packaging and traceability requirements. Similar regulations do not apply to fresh meat and meat products despite similar food safety-related issues. A.O. 22 disproportionately affects imported products because the vast majority of frozen meat sold in the Philippines is imported. The United States has raised its concerns with A.O. 22 on numerous occasions, including at bilateral meetings and

in high-level correspondence, and will continue to work with Philippine authorities to resolve this issue.

RUSSIA

Systemic Issues

Russia's SPS standards provide extremely prescriptive requirements for facilities and production processes. Russia has attempted to impose these requirements on trading partners by accepting imports only from facilities that are certified as complying with Russian requirements. Russian resolutions directing that international standards, guidelines, and recommendations of the OIE and the IPPC be respected should prove helpful, but in practice it is not clear that Russia always follows international standards or provides justifications for departing from them. Overall, Russia's application of apparently unwarranted SPS measures has had a significant negative effect on U.S. exports.

The entry into force of the Customs Union of Russia, Kazakhstan, and Belarus has further complicated these matters. As the three countries harmonize and revise their SPS measures, traders and border officials are often unsure about the new requirements, and customs officials sometimes indiscriminately choose which requirements to apply. On December 11, 2009, Russia signed both the Agreement of the Customs Union on Sanitary Measures and the Agreement of the Customs Union on Veterinary and Sanitary Measures. In addition, Russia, Belarus, and Kazakhstan have concluded a number of other agreements that also seek to harmonize SPS measures. These agreements unify the list of goods subject to veterinary, phytosanitary, and sanitary-epidemiological control by the CU Parties (whether the goods are imported from outside the CU or from one of the other CU Parties), unify the veterinary and sanitary-epidemiological and hygienic requirements on those goods, and unify the form of documentation confirming the safety of those goods. At the same time, however, Russia's SPS measures also continue to apply to imported goods. On July 1, 2010, the Customs Union implemented harmonized veterinary requirements which stipulate, *inter alia,* that imports subject to veterinary control may be imported only from facilities on a common list approved by all three CU Parties. These various SPS measures have the potential to restrain U.S. exports.

U.S. exporters also face systemic issues in Russia related to the certification of agricultural products. For example, Russia requires phytosanitary certificates for shipments of processed products such as soybean proteins, corn gluten, and distiller's grains, which, due to the nature of the processing process, do not present a pest risk. Consequently, such products do not require a phytosanitary certification from the U.S. Government. Likewise, Russia requests certification that the United States is free from various livestock diseases, even where there is no risk of transmission from the product in question. Several requirements of various certificates are unattainable or involve information that is not available to U.S. officials. For example, with regard to export certificates for milk and milk products, Russia has asked for U.S. Government verification of the Russian port of entry, identification marks, and the absence of *Salmonella* and other bacterial disease agents.

Additionally, to date, the United States has not yet received scientific justification and/or risk assessments for many of these requirements.

In November 2006, the United States and Russia signed bilateral agreements to address SPS issues related to: trade in pork; trade in beef and beef by-products; trade in products of agricultural biotechnology; and the certification of pork and poultry facilities for exporting products to Russia. However, there have been implementation problems with several of these agreements. For example, under the November 2006 U.S.-Russia agreement on plant inspection for meat and poultry facilities, Russia agreed to grant U.S. regulatory officials the authority to certify new U.S. facilities and/or facilities that had remedied a deficiency. In accordance with the agreement, Russia also agreed to specific deadlines for responding to requests to list facilities that U.S. authorities had inspected and determined to be in compliance with the requirements to export to Russia. At present, however, Russia's officials question the reliability of the current inspection and certification system for U.S. meat and poultry facilities that are eligible to export to Russia and have sometimes refused to re-list facilities that U.S. regulatory officials have inspected. The U.S. Government continues to discuss this issue with Russia's veterinary service.

Biotechnology

Although Russia has established a system for the approval of biotechnology food and feed products, the United States continues to have concerns with the implementation of Russia's biosafety system, including its requirements for re-registration of approved products, labeling of genetically engineered products, and the lack of an approval system for the cultivation of biotechnology crops. The United States is pursuing these concerns and greater cooperation on biotechnology with Russia through the U.S.-Russia Biotechnology Consultative Mechanism.

See section III.B for an explanation of the biotechnology trade issue.

Food Safety

Poultry

On January 1, 2010, Russia banned the importation and sale of chlorine-treated chicken, essentially halting all imports of U.S. poultry into Russia. Bilateral negotiations led to the resumption of poultry imports in September 2010, but they did not resolve the chlorine restriction itself. Russian regulations also place an upper limit on the amount of water content in chilled and frozen chicken. In addition, the Russian government has adopted a resolution that bans the importation and sale of poultry that has been frozen for more than three months and is destined for further processing into food intended for use in baby food and special diets. Russia has not yet provided the United States with risk assessments to support these regulations.

Russia also maintains a zero tolerance policy for *Salmonella* and other bacterial disease pathogens, as well as for residues of many veterinary drugs commonly used in U.S. poultry production. Even after imports of U.S. poultry resumed in September 2010, Russia restricted imports of some shipments of U.S. poultry after finding *Salmonella*. These requirements have also led to multiple restrictions of U.S. poultry facilities.

U.S. trade and agricultural officials have discussed these issues extensively with their Russian counterparts, urging them to adopt SPS measures that are consistent with international standards of the OIE and Codex.

Pork and Pork Products

Russia maintains MRLs that are more stringent than the recommended Codex standards, including many that are at or near zero tolerance levels, such as for tetracycline-group antibiotics, but has thus far not provided to the United States risk assessments to support these more stringent standards. Russia continues to restrict imports from U.S. facilities based on findings of tetracycline-group antibiotics. Unless changed, these requirements will continue to constitute major barriers to U.S. exports. The U.S. Government continues to press Russia to adopt standards that are based on science and consistent with international standards.

Beef and Beef Products

Currently, U.S. producers may export boneless and bone-in beef to Russia from cattle under the age of 30 months and that otherwise meet requirements set out in the U.S.-Russia Bilateral Agreement on Trade in Beef. The United States and Russia continue to negotiate a certificate to allow for the export of U.S. deboned beef, bone-in beef, and beef by-products from cattle over 30 months of age from facilities that have been inspected and certified for export to Russia.

Current BSE attestations in Russia's sanitary certificate for prepared meat preclude any U.S. cooked beef from eligibility for export to Russia. Russia also maintains a ban on imports of ground beef from cattle of any age. The United States will continue to press Russia to open its market to U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Dairy

Russia requests that all health certificates, including those for dairy products, provide broad statements that the products meet Russia's sanitary and veterinary rules and requirements for chemical, microbiological, and radiological indicators. Many of these requirements appear unwarranted. In addition, Russia requests a list of exporters that meet Russia's requirements and which would be subject to audit by Russian veterinarians.

During meetings in January 2010, Russian authorities stated that without such a list by February 15, they would halt dairy imports from the United States. Dairy shipments continued through September 2010, but ceased when Rosselkhoznadzor (Russia's Federal Service for Veterinary and Phytosanitary Surveillance) instructed customs officials to allow shipments only from exporters on Rosselkhoznadzor-approved lists. At the same time, Rosselkhoznadzor requested that the United States stop signing the dairy certificates previously issued for export because they were not compliant with Russian requirements. The U.S. Government continues to work with Russian officials to reopen the market to U.S. dairy products.

Animal Health

Grains and Oilseeds

Exports to Russia of U.S. grain and oilseed products are severely limited due to Russia's requirement for veterinary certificates for many grains and seeds certifying that these plant products are free of animal diseases. The United States maintains that this certification is unnecessary because these products do not pose any animal health risks. As a result, to date, the United States has not agreed to provide certificates for fodder grains, soybeans, soybean meal, and animal feeds of plant origin, and Russia permits imports of these products only on a case-by-case basis.

Pet Food

Russia does not allow the importation of pet food containing U.S. beef due to alleged BSE concerns. For those imports that are allowed, Russia requires apparently unwarranted heat treatment processing procedures (in addition to microbial testing).

See section III.C for an explanation of the BSE trade issue.

SAUDI ARABIA

Food Safety

See discussion of Gulf Cooperation Council food safety requirements.

SINGAPORE

Food Safety

Beef and Beef Products

Due to BSE concerns, Singapore prohibits the importation of all U.S. beef and beef products, except for deboned beef from animals under 30 months of age. For the past several years, Singapore has informed the United States that it is in the process of performing a risk

assessment of U.S. beef and beef products. The United States continues to press Singapore to complete this risk assessment and to open its market based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

SOUTH AFRICA

Food Safety

Beef and Beef Products

In June 2010, South Africa opened its market to U.S. deboned beef from cattle of all ages, but it continues to ban the importation of all other beef cuts and beef products, as well as other U.S. ruminant animals and products. The United States is engaging with South Africa to open fully its beef market to U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Pork

South Africa currently maintains a 20-day freezing requirement on U.S. pork to prevent the transmission of pseudorabies. The risk of transmission of pseudorabies to domestic herds through imported U.S. pork is extremely low. In 1989, the United States started a voluntary eradication program for pseudorabies and, in 2004, the United States achieved the successful eradication in commercial herds through all 50 states. The U.S. Government continues to work with South Africa to address the current freezing requirement for pseudorabies.

SOUTH AFRICAN DEVELOPMENT COMMUNITY

Biotechnology

The South African Development Community (SADC) members, with the exception of South Africa, have banned the importation of agricultural biotechnology products since 2005.[5] Pursuant to this ban, importers of agricultural products must present documents certifying that their goods do not include agricultural biotechnology products. However, there are limited exceptions to the ban. For example, grain from biotechnology-derived varieties can be imported for food aid, but it must be milled or sterilized so as to render the grain

[5] The SADC is a 15-country socio-economic cooperation and integration group composed of Angola, Botswana, the Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe.

incapable of germinating after arriving in the country. In addition, products of agricultural biotechnology imported for scientific research may be allowed, but subject to regulations and controls to be established by the various SADC member countries. The United States will continue to engage the SADC on these issues.

See section III.B for an explanation of the biotechnology trade issue.

SOUTH KOREA

Food Safety

Beef and Beef Products

In April 2008, the United States and Korea signed an agreement to re-open fully Korea's market to U.S. beef and beef products in a manner consistent with international standards and science. In June 2008, following massive public protests in Seoul, Korean beef importers and U.S. exporters reached a voluntary, commercial understanding that temporarily limits U.S. exports to beef and beef products from cattle less than 30 months of age, as a transitional measure, until Korean consumer confidence improves. U.S. beef sales resumed in June 2008. In 2010, U.S. exports of beef and beef products to Korea reached nearly 113,000 metric tons, valued at $518 million, making Korea the fourth largest U.S. beef export market. This represents a 140 percent increase by value over 2009 sales.

Achieving full market access for U.S. beef and beef products exports to Korea remains a top priority. The U.S. Government will continue to attach importance to the beef issue and will continue to urge Korea to open its market fully based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Maximum Residue Limits

In June 2009, Korea notified the WTO that it would eliminate its existing MRLs for certain pesticides if those pesticides are not registered for domestic use in Korea. This elimination would include even those MRLs that have been established as safe following a scientific risk assessment. The United States is concerned that once Korea's proposal is implemented, it will block the importation of certain products treated with U.S.-approved pesticides that are not registered in Korea. Without an established MRL in Korea, any trace of the pesticide in question would preclude exports of the product to Korea. The United States will continue to encourage Korea to maintain the current list of import MRLs, based on the most current available scientific data, or until Korea completes the appropriate risk assessments. The United States will also continue to seek guidance from Korea on how exporters and governments with objections regarding acceptable MRLs may submit relevant information and requests for import tolerances.

In June 2010, Korea's Food and Drug Administration (KFDA) imposed a 100 percent inspection policy on all imports of U.S. cherries as a result of a reported pesticide MRL violation on a shipment of California cherries to Taiwan. This inspection policy has caused a significant disruption for U.S. cherry exports. In response to concerns raised by the U.S. Government, KFDA implemented a two-month sampling and testing protocol in August 2010 for a variety of domestically produced and imported fresh fruits and vegetables. This data collection exercise, while still somewhat burdensome, was much less problematic than the 100 percent inspection policy and, ultimately, has not resulted in the detention of any U.S. horticultural exports.

The United States continues to work with Korea to resolve issues related to Korea's MRL enforcement policies.

See section III.D for an explanation of the MRL trade issue.

Plant Health

Cherries

Korea requires that exports of U.S. cherries undergo fumigation with methyl bromide before shipping in order to control various pests of quarantine concern. Removal of the fumigation requirement will increase shelf life and allow cherries to be shipped via ocean vessel rather than air freight, thus reducing costs. Lower costs combined with improved fruit quality should help increase sales. The United States has been engaged with Korean quarantine officials since 2008 to address this issue and will continue to work with Korea to find an alternative approach to methyl bromide fumigation.

Biotechnology

Korea's regulatory system for biotechnology has generated concern in recent years with regard to its level of predictability and transparency. In 2008, Korea implemented the Living Modified Organisms Act (LMO Act), which regulates trade in agricultural biotech products. The United States has raised a number of issues related to the LMO Act and its implementation, including concerns that certain import documentation requirements go beyond the current provisions of the Cartagena Protocol on Biosafety. The United States is also concerned about Korea's definition for "adventitious presence," as well as aspects of Korea's risk assessment review, which may lead to delays in new product approvals. The United States has noted that the LMO Act, while nominally applying to all LMOs, has been written solely with LM plants in mind and thus does not readily apply to the transboundary movement of LM animals. The U.S. and Korean governments are working together to address these concerns and have made some progress, including the establishment of a mechanism for regular communication between technology developers and Korean regulatory agencies during the review process.

With respect to biotech approvals, Korea approved five single trait biotech events and five multi-trait biotech events in the fall of 2010, but U.S. concerns with regard to predictability in the review process and the LMO Act will require continued U.S. engagement with Korea to avoid significant disruptions in U.S. exports.

See section III.B for an explanation of the biotechnology trade issue.

SRI LANKA

Food Safety

Beef and Beef Products

Sri Lanka continues to ban all imports of U.S. beef and beef products as a result of the detection of a BSE positive animal in 2003 in the United States. The United States continues to engage with Sri Lanka to open its market for all U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Microbiological Testing of Meat Imports

In September 2009, Sri Lanka started 100 percent testing of all imported meat products for various pathogens. Importers have complained that the additional demurrage costs associated with the testing are unnecessary, and that the government testing methods are unsound. During the October 2009 TIFA meeting, the United States requested that Sri Lanka provide its regulations on microbiological testing, especially those relating to the testing protocol, targeted pathogens, and acceptable pathogen levels.

Biotechnology

Sri Lanka currently prohibits the sale of biotechnology seeds or products containing biotechnology organisms intended for human consumption without the approval of the Chief Food Authority. Sri Lanka does not currently have a functioning approval mechanism, therefore this regulation acts as a *de facto* ban for whole grains and other products that are biotech-derived. Further, Sri Lanka requires all commodity imports to be accompanied by a "non-GE" certification on import licenses. USDA and USTR raised these issues with the Sri Lankan government during the October 2010 TIFA meeting. The United States will continue to engage Sri Lanka on these measures, which effectively prohibit all trade in biotech-derived crops and other products.

See section III.B for an explanation of the biotechnology trade issue.

SWITZERLAND

Biotechnology

Switzerland has a burdensome and slow-moving process for approving agricultural biotechnology products for food and feed use. In addition, in November 2005, Switzerland implemented a five-year moratorium on approvals for the commercial cultivation of biotechnology crops. This moratorium has been extended by an act of Parliament until November 2013. This moratorium does not apply to field trials. U.S. officials will continue to urge Switzerland to address the cumbersome aspects of its regulatory review system and remove the moratorium on cultivation.

See section III.B for an explanation of the biotechnology trade issue.

TAIWAN (CHINESE TAIPEI)

Food Safety

Beef and Beef Products

Taiwan banned imports of U.S. beef and beef products following the detection of a BSE-positive animal in the United States in 2003. In 2006, Taiwan began allowing imports of U.S. deboned beef derived from animals under 30 months of age.

In October 2009, the United States and Taiwan reached final agreement on a Protocol expanding market access for U.S. beef and beef products (for human consumption) based on science, the OIE guidelines, and the United States' controlled risk status. The Protocol defines the conditions for the exportation of U.S. beef and beef products to Taiwan and ultimately provides for a full re-opening of the market.

However, after the Protocol entered into force in November 2009, Taiwan's legislature adopted an amendment to Taiwan's Food Sanitation Act in January 2010 that, in effect, banned imports of ground beef and certain offals and other beef products from the United States, contrary to Taiwan's obligations under the Protocol. Moreover, Taiwan announced additional border measures, including a licensing scheme for permitted offal. Taiwan also imposed even stricter inspection requirements for certain "sensitive" beef offals (e.g., tongue), which discourages imports of these products. More recently, Taiwan has imposed additional testing on some imports of U.S. bone-in beef. While this additional testing has not resulted in the rejection of any shipment of U.S. bone-in beef, it has delayed delivery of the product into commercial channels and created uncertainty in the market.

The United States has raised these issues with Taiwan in various venues, including in a September 2010 visit by USTR officials. At each opportunity, the United States has stated that it expects Taiwan to act consistently with its obligations under the Protocol. The U.S. Government will continue to attach importance to the beef issue and will continue to urge

Taiwan to open its market fully based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Ractopamine in Pork and Beef

Taiwan has delayed the implementation of its proposed MRL for ractopamine, which it notified to the WTO in 2007, but remains unapproved. Taiwan's lack of progress in adopting this MRL has raised a significant trade concern by forcing U.S. pork producers to ship pork products selectively sourced from animals not treated with ractopamine.

In January 2011, Taiwan publicly announced that two shipments of U.S. beef inspected at the port of entry had tested positive for ractopamine. Taiwan began to conduct extensive market surveillance, including additional testing of packages of beef in supermarkets. In the course of this market surveillance, three packages of U.S. beef already on the shelf also tested positive for the presence of ractopamine. Taiwan authorities have indicated that they will continue to carry out enhanced inspection and testing of U.S. beef due to concerns over ractopamine. There is considerable uncertainty as to the exact details of the inspection and testing measures Taiwan is applying to U.S. beef shipments at the port of entry and to product that has already entered the Taiwan market. This uncertainty, which has resulted from Taiwan's failure to approve the MRL and the unpredictability in Taiwan's inspection and testing regime, raises serious concerns both for U.S. beef producers and for beef importers in Taiwan and negatively impacts the bilateral beef trade.

U.S. officials have raised these issues at several meetings of the WTO SPS Committee and at numerous bilateral meetings with Taiwan, as well as most recently at the highest levels of the Taiwan government. Taiwan authorities appear to have acknowledged, in public statements and in various bilateral meetings with the United States, that trace amounts of ractopamine do not present a health risk. However, Taiwan continues to insist on a zero tolerance policy for ractopamine. The United States continues to encourage Taiwan to implement its proposed MRL for ractopamine without further delay.

See section III.E for an explanation of the ractopamine trade issue.

Maximum Residue Limits

Taiwan's slow and cumbersome process for adopting MRLs has resulted in a substantial backlog of over 1,500 MRL applications and is creating a significant level of uncertainty within the U.S. agricultural export industry. Since 2006, this backlog has resulted in the rejection of various U.S. agricultural shipments (e.g., cherries, apples, wheat, barley, strawberries, and corn) due to the detection of pesticide residue levels that are within U.S. or Codex standards, but for which Taiwan has not yet established MRLs.

To avoid continuing trade disruptions, the United States has urged Taiwan on several occasions to act consistently with the 1999 U.S.–Taiwan agreement on MRLs, which provides that Taiwan will defer to Codex MRLs, or U.S. MRLs where Codex has not set a tolerance, until Taiwan establishes a more comprehensive set of MRLs. While the United States is encouraged by Taiwan's recent efforts to work through the backlog of MRL requests more expeditiously, shipments of U.S. agricultural products remain at risk of rejection due to the absence of MRLs for a large number of pesticides that are commonly used internationally. U.S. agricultural products that rely on newer, safer alternatives to older, more dangerous chemicals that are being phased out in the United States, are particularly at risk of being rejected. The U.S. Government has worked extensively with Taiwan through data sharing and technical assistance to facilitate Taiwan's establishment of MRLs for these newer, safer chemicals. The United States continues to raise this issue with Taiwan in order to reach a solution.

See section III.E for an explanation of the MRL trade issue.

Animal Health

Animal and Pet Feed

Taiwan bans the importation of all ruminant-origin and nearly all non-ruminant-origin ingredients intended for use in animal feed and pet food, such as tallow (including protein-free tallow), lard, and porcine meal, due to BSE-related concerns. Additionally, U.S.-origin pet food exported to Taiwan must originate from U.S. facilities that have been visited and cleared by Taiwan's Bureau of Animal and Plant Health Inspection and Quarantine.

See section III.C for an explanation of the BSE trade issue.

Plant Health

Apples

The Codling Moth is a pest of apples in the United States and a pest of quarantine concern to Taiwan, where it is not known to exist. Following a Codling Moth detection in Taiwan in November 2002, Taiwan suspended the importation of all U.S. apples. In June 2003, the United States and Taiwan signed a protocol with a penalty structure that allowed Taiwan to suspend imports of U.S.-origin apples if three Codling Moth detections occurred in a single shipping season (often referred to as "three strikes"). While this penalty structure has facilitated continued trade, there is the possibility of another market closure if there are "three strikes" in a single shipping season. To date, it appears that Taiwan has not conducted a PRA for Codling Moth in apples. U.S. regulatory authorities have provided Taiwan with U.S. research demonstrating that the risk associated with Codling Moth transmission and establishment in Taiwan via U.S.-origin apples is extremely low. Taiwan authorities continue to review this research, but have not yet met with U.S. officials to

discuss the U.S. findings in detail. During a technical bilateral held in January 2011, Taiwan agreed to evaluate an alternative penalty structure proposal. The United States submitted a new proposal to Taiwan in February 2011 and is awaiting a response.

THAILAND

Food Safety

Pork

In January 2010, Thailand lifted its ban on U.S. pork and pork products that had been in place based on H1N1-flu concerns. However, U.S. producers have not resumed exporting unprocessed pork products and offals to Thailand, due to Thailand's requirement that exporters agree to a number of burdensome requirements, including the requirement that each producer's facility be inspected by Thai officials. The United States has urged Thailand to agree to a protocol adopting a systems-based approach that analyzes the entire U.S. food safety system relating to pork production, rather than relying on individual plant inspections for all exporting facilities. Thailand also imposes other trade restrictions on imports of U.S. pork and pork products, including a prohibition concerning trace residues of ractopamine in pork.

See section III.E for an explanation of the ractopamine trade issue.

Beef and Beef Products

Thailand has banned the importation of U.S. beef and beef products due to the detection of a BSE-positive animal in the United States in 2003. Currently, Thailand allows imports of U.S. deboned beef from animals under 30 months of age. The United States continues to engage Thailand to fully open its beef market to U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

TURKEY

Biotechnology

On October 29, 2009, Turkey adopted a biotechnology regulation that was implemented immediately, without notification to the WTO, and resulted in immediate market closure for U.S. agricultural biotechnology products. Subsequently, the regulation was challenged in Turkey's courts and revised multiple times by the Ministry of Agriculture and Rural Affairs (MARA). In April 2010, MARA's final revision of the regulation permitted Turkey to approve products incorporating EU-approved biotech events, in effect restoring market access for most biotechnology products. However, on September 26, 2010, Turkey implemented a new, overarching Biosafety Law which immediately negated the approvals

granted under the previous regulation and effectively stopped all trade in products containing biotech events (primarily soy and corn products).

Under the new law, MARA has pressed biotech developers to re-apply for approval of their events. However, these developers are reluctant to re-apply given that MARA has yet to determine a number of essential details of the approval process. For example, MARA has yet to clarify which documents are needed, what criteria will be used to evaluate the application, what may constitute a failure of compliance and, in situations of non-compliance, what level and kind of penalties will apply.

The United States has raised concerns about specific provisions of the 2010 Biosafety Law and its implementing regulations with Turkish officials. In addition, the U.S. Government and industry stakeholders have held a number of consultations with the Government of Turkey and Turkish industry about biotechnology and the biotechnology-derived products affected by this law and implementing regulations. The United States will continue to engage Turkey on this issue both bilaterally and in multilateral fora.

See section III.B for an explanation of the biotechnology trade issue.

Food Safety

Meat

In September 2010, Turkey, for the first time since 1996, signaled a willingness to engage in discussions on the opening of its market to U.S. beef and beef products, plus cattle and sheep for feeding and slaughter. However, Turkey's proposed import conditions appear to deviate from OIE guidelines for BSE. The United States will continue to engage with Turkey to open fully its market to U.S. beef and beef products, plus live cattle and sheep, based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Plant Health

Wood Products

In February 2009, Turkey imposed regulations requiring wood products imported from the United States be free from bark; free from grub holes; contain less than 20 percent moisture or be kiln dried, heat treated, or fumigated; and be accompanied by a phytosanitary certificate stating that the product is from an area free from *Bursaphelenchus xylophilus* (pinewood nematode). The United States engaged Turkey on these regulations and Turkey amended its wood quarantine regulations on August 23, 2010, allowing trade in wood products to resume. As part of these amendments, Turkey removed the requirement that an area be free from pinewood nematode when a treatment is performed to the wood product.

UKRAINE

Biotechnology

Ukraine's parliament enacted a law establishing the framework for the creation, testing, and use of products of agricultural biotechnology in 2007, but most of the implementing regulations necessary to open the market are still under development. In October 2010, the Cabinet of Ministers of Ukraine approved a procedure for state registration of biotech events used in feed, feed additives, and veterinary drugs. Ukraine also recently issued a temporary approval of a soybean event to facilitate the importation of soy in animal feed. However, Ukraine continues to lack regulations permitting the use of approved biotech products for cultivation or import, which has led to unpredictable trade conditions for biotech-derived food, feed, and seed products. The United States continues to work with Ukraine to establish a functioning and predictable biotech regulatory framework based on science.

See section III.B for an explanation of the biotechnology trade issue.

UNITED ARAB EMIRATES

Food Safety

Food Safety Requirements

See discussion of Gulf Cooperation Council for food safety requirements.

Beef and Beef Products

In July 2009, after having previously fully opening its market to U.S. beef and beef products, the United Arab Emirates (UAE) reduced market access by requiring that all imports of fresh and frozen beef and beef products be derived from animals less than 30 months of age due to BSE-related concerns. The United States continues to engage with UAE to fully reopen its market for all U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status.

See Section III.C for a discussion of the BSE trade issue.

URUGUAY

Food Safety

Live Cattle, Beef, and Beef Products

Uruguay currently bans imports of all U.S. live cattle, beef, and beef products due to the detection of a BSE positive animal in the United States in 2003. The United States continues to engage with Uruguay to open its market for all beef and beef products from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Poultry

Uruguay currently bans imports of many U.S. fresh and frozen poultry products due to purported concerns over Newcastle's disease. In October 2007, the United States and Uruguay finalized an agreement that resulted in new market access for U.S. turkey exports. The U.S. consent to this agreement, however, was premised on the understanding that the two countries would complete negotiations to provide market access for all poultry and poultry products, consistent with science and the relevant OIE guidelines. In early June 2010, the two governments reached an agreement on export certificate language for U.S. processed chicken products. All other U.S. poultry and poultry exports to Uruguay remain banned.

The United States raised the issue of poultry market access during the October 2010 TIFA meetings with Uruguay. Uruguay informed the United States that a thorough review of U.S. fresh and frozen poultry was underway, and that a final decision on market access for these products based on international standards would be forthcoming. The United States continues to engage with Uruguay to open its market to all U.S. poultry and poultry products.

VENEZUELA

Food Safety

Live Cattle, Beef, and Beef Products

Venezuela bans all U.S. live cattle, beef, and beef products due to the detection of a BSE positive animal in the United States in 2003. The United States continues to engage with Venezuela to open its market based on science, the OIE guidelines, and the United States' BSE controlled risk status.

See section III.C for an explanation of the BSE trade issue.

Animal Health

Poultry

Venezuela bans imports of poultry and poultry products if they have not been manufactured by processes that guarantee the elimination of AI viruses. In addition, Venezuela does not issue sanitary import permits for U.S. poultry on the basis that it may have been infected with AI. These restrictions do not appear to be consistent with OIE guidelines.

See section III.A for an explanation of the AI trade issue.

VIETNAM

General

Vietnam is working to ensure that its SPS regime is consistent with international standards. However, in April 2010, Vietnam proposed a series of SPS measures purportedly to address broad food safety concerns, but which have unnecessarily restricted trade.

The United States continues to urge Vietnam to adopt SPS measures consistent with international guidelines, recommendations, and standards, specifically as they relate to the importation of meat and meat by-products. In May 2006, the United States and Vietnam concluded an agreement in which Vietnam agreed to recognize the U.S. food safety and inspection systems for beef, pork, and poultry as equivalent to its own inspection system. Although granting equivalency was an important and welcome step that signaled Vietnam's commitment to developing a science-based system for furthering trade, Vietnam does not appear to have yet adopted other food safety standards promulgated by international standard-setting organizations, such as the OIE.

Food Safety

Beef and Beef Products

In bilateral negotiations with the United States over its accession to the WTO, Vietnam agreed to allow imports of U.S. beef and beef products from cattle less than 30 months old. Since 2007, the United States and Vietnam have been working to agree on the animal health requirements to facilitate the trade in live cattle, beef, and beef products. The United States continues to engage with Vietnam to open its market for all beef and beef products from the United States based on science, the OIE guidelines, and the United States' controlled risk status.

See section III.C for a description of the BSE trade issue.

Offal Ban

On July 7, 2010, Vietnam implemented a "temporary ban" on the importation of offals from all countries, including the United States. Vietnam cited food safety concerns as justification for implementing the ban, but it provided no scientific data to the WTO or any trading partner to support this justification. On August 17, 2010, ambassadors from the United States, Canada, the EU, Australia, and New Zealand sent a letter to the Prime Minister of Vietnam requesting Vietnam to justify the ban and provide greater specificity with respect to the products covered by the ban. U.S. officials, along with representatives from the other countries, reiterated this request in a meeting with Vietnamese officials in November 2010. U.S. officials have also raised this issue on the margins of the WTO SPS Committee meeting in Geneva. To date, Vietnam has not lifted this ban or provided any justification for it. The United States will continue to engage with Vietnam on this issue.

Products of Animal Origin

In May 2010, Vietnam issued a new regulation outlining food hygiene and safety standards for imported foods of animal origin. The U.S. Government and industry have raised concerns regarding the need for the regulation, its burdensome requirements, and the potential proprietary nature of some of the company-specific information requested in the regulation. As a result of requests by the United States and other trading partners, Vietnam extended the original effective date of the regulation three times, allowing countries until the end of February 2011 to provide company-specific information. While immediate trade disruption has been avoided, the United States continues to work with Vietnam on resolving longer term issues related to this regulation.

Products of Plant Origin

In August 2010, Vietnam issued regulations affecting imported goods of plant origin, and notified them to the WTO. The United States has raised a number of questions about the regulations' requirements, including how the measures will be implemented domestically and to what extent Vietnam has taken into account the different levels of risk associated with different goods of plant origin from different countries. The United States also has raised concerns regarding exporter registration requirements, sampling rates, and the coverage of MRLs, among others. The measure was scheduled to take effect on January 1, 2011, but it appears this date has been extended to July 1, 2011. The United States will continue to work with Vietnam to address its concerns.

Zero Tolerance Level for Salmonella

Vietnam currently applies a zero tolerance level for *Salmonella* on uncooked poultry meat. The United States has raised concerns with the scientific basis for this measure. Although Codex has yet to publish maximum allowable levels for *Salmonella* bacteria on raw poultry

meat, it is generally accepted by food safety experts and scientists that such pathogens cannot be removed entirely from raw meat and that proper storage, handling, and cooking of raw poultry meat reduce significantly the risk of a number of food-borne diseases caused by these pathogens. Vietnam, however, has not officially accepted this approach as sufficient. The United States continues to work with Vietnam on this issue.

V. TECHNICAL ASSISTANCE

The United States is committed to cooperating with trading partners on SPS issues and to providing technical assistance, where appropriate, to help other countries meet their international obligations and facilitate trade in agricultural products. To accomplish these goals, the United States has incorporated SPS objectives into a wide variety of bilateral cooperation and assistance programs. The United States seeks to ensure that other governments base their SPS measures on scientific risk assessments and refrain from using SPS measures as disguised restrictions on international trade. The technical assistance provided by the United States has helped many developing countries build their SPS regulatory infrastructure, which in turn has opened new markets for U.S. agricultural products. In 2010, the U.S. Government obligated to provide funds for SPS trade capacity building in excess of $10.4 million.

Article 9 of the SPS Agreement provides that "Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations." This type of assistance is intended to help Members comply with SPS measures they face in export markets. The SPS Agreement, however, does not address technical cooperation and assistance with respect to Members' efforts to implement the SPS Agreement in their own markets. For this reason, Members have raised concerns in the SPS Committee about technical constraints affecting the ability of developing countries to comply with certain provisions of the SPS Agreement. In particular, some Members have noted the substantial technical and resource demands associated with quantitative or other advanced risk assessment techniques, and have requested assistance to improve the capabilities of developing countries to conduct such assessments. The United States strongly supports increased technical cooperation and assistance, including efforts in the Standards and Trade Development Facility (STDF) and the APEC forum, to improve the risk assessment capabilities of all Members.

Trade Capacity Building

U.S. trade capacity building efforts in the SPS area seek to foster a clear understanding of key SPS provisions in international and bilateral trade agreements, including the important requirement that SPS measures be supported by science, as well as the fundamentals of risk assessment, and the most effective way to build and administer SPS regulatory programs. Forms of assistance provided by the United States include regional trade capacity building workshops, conferences, hands-on training programs, and visits.

The United States administers a number of programs to build foreign expertise in biotechnology, food safety, animal health, and plant health. For example, USDA's trade and scientific exchange programs, such as the Cochran Fellowship Program and Norman E. Borlaug International Science and Technology Fellows Program, provide training and research opportunities for individuals from middle-income countries, emerging democracies, and emerging markets in agricultural trade and policy; agribusiness

development and management; animal, plant, and food sciences; extension services; agricultural marketing; and many other areas. Individuals selected for participation in these U.S.-based programs come from both the public and private sectors. Training programs are designed and organized in conjunction with U.S. universities, USDA, and other government agencies, agribusinesses, and consultants.

USDA's Food for Progress program administers 39 agreements which focus on SPS issues in 22 countries. Many of these agreements were reached with private voluntary organizations, while others were concluded with the governments of Ecuador, Guatemala, Nicaragua, Honduras, the Dominican Republic and the Philippines. Food for Progress supports projects and activities tailored to the SPS needs of each country.

Trade capacity building is one way that the U.S. Government works to ensure that foreign governments do not use SPS measures to restrict trade. By supporting the adoption and effective implementation of science-based standards in other countries, the U.S. Government helps to lower unjustified barriers to trade and expand market access for U.S. agricultural and food products.

The following section provides a description of U.S. technical assistance on SPS-related issues for various regions and countries. This list is not meant to be comprehensive, but highlights some of the most important activities during 2010.

Regional Activities

Africa

A collaborative effort between USDA and the U.S. Agency for International Development (USAID) supports four resident SPS Advisors and Coordinators in Sub-Saharan Africa to cover the East, West, and Southern Africa regions. In 2010, the SPS Advisors and Coordinators directly supported government SPS agencies in their respective regions to develop institutional capacity for science-based regulatory systems consistent with international standards. As part of the SPS capacity building program, USDA contributed to a seminar on trade and risk-based disease control for chief veterinary officers from African Union member countries in Entebbe, Uganda. The seminar discussed principles of risk analysis relating to trade in livestock and animal products. The United States used fellowship and exchange programs such as the Cochran Fellowship Program, the Norman E. Borlaug International Science and Technology Fellows Program, and the Faculty Exchange Program, to complement the SPS capacity building program.

The United States sponsored a Codex Delegates Colloquium, which brought together Codex delegates from throughout Africa to discuss enhancing regional cooperation on the adoption and implementation of science-based food safety standards. This colloquium also provided an opportunity to develop areas of mutual agreement in advance of the official Codex technical committee meeting.

USDA also conducted Codex capacity building workshops in Mozambique, Senegal, and Zambia. These workshops strengthen these countries' ability to participate effectively in Codex and help ensure the adoption of science-based food safety standards.

In 2010, APHIS provided training to West and Central African countries on surveillance of transboundary diseases in West and Central African Countries. FAS also sponsored a two-week Plant Health Systems Analysis Course for African government officials and researchers in the international plant health community. Participants learned how APHIS confronts the complex challenges posed by global and domestic plant health issues, which included reviewing fundamental concepts of plant health, identifying relevant government agencies, international organizations, and industries, and studying key international standards and agreements.

Asia

The U.S. Government's participation in the APEC Food Safety Cooperation Forum (FSCF) and related events signifies an important investment in the development of the food safety systems of U.S. trading partners in the Asia-Pacific region. Under the FSCF's Partnership Training Institute Network, FDA and its federal partners assembled 90 food safety and training experts from APEC economies, academia, and the private sector at the World Bank in Washington, D.C. in May 2010, to create a partnership aimed at building effective food safety training capacity across the APEC region. The group strategized on best practices to disseminate training materials and discussed mechanisms for evaluating the effectiveness of training with respect to risk analysis, supply chain management, laboratory capacity, and management of food emergencies.

The efforts of the United States in the region to coordinate technical training and share best practices will increase the capacity of APEC economies to regulate food safety consistent with international standards and will help to ensure the adoption of science- and risk-based approaches to food safety to help facilitate global trade.

Dominican Republic – Central America – United States FTA

The Trade Capacity Building program in CAFTA-DR countries, which is part of a broader U.S. capacity building effort in the area, includes SPS-related activities. Under this program, the United States helps CAFTA-DR countries to develop their institutional capacities to implement science-based regulatory systems consistent with international standards. Such systems create a more transparent, predictable, and favorable trade environment for U.S. exports. SPS assistance to CAFTA-DR countries is based on the national and regional needs identified during the CAFTA-DR negotiations and through the ongoing work of the CAFTA-DR Trade Capacity Building Committee. The United States utilizes programs such as the USDA's Cochran Fellowship Program and the Norman E. Borlaug International Science and Technology Fellows Program to complement the SPS program.

Other Latin American and Caribbean Countries

In 2010, the United States supported a number of food safety training activities in the Caribbean. The United States sponsored a Caribbean Food Safety Workshop in Miami, Florida for delegates from seven countries, representing their agriculture and health ministries, to discuss the status of food safety in the region, the possible establishment of a region-wide Caribbean Community and Common Market (CARICOM) technical committee for food safety, and how to improve coordination of SPS issues at the regional and national levels. The United States also hosted multiple Codex Delegates Colloquiums, which brought together delegates from throughout Latin America and the Caribbean for technical committees to enhance regional cooperation on the adoption and implementation of science-based food safety standards.

USDA provided training to national Codex contact points from throughout the Caribbean to help them participate in Codex, organize their domestic Codex offices more effectively, and improve coordination and collaboration with other countries. USDA also initiated an effort in Brazil and other Latin American countries to facilitate the global harmonization of pesticide MRLs to conform to Codex standards.

Country-Specific Activities

Argentina

Through the USDA-FAS Cochran Fellowship Program, four Fellows attended a biological control training program at the USDA Agricultural Research Service Invasive Plant Research Laboratory.

Bangladesh

The FDA and University of Maryland provided Bangladeshi government officials, industry representatives, and academics advanced training on a range of SPS-related topics, including U.S. food and drug law, seafood and aquaculture food safety systems, the drug and food/color additive approval process, human health hazards associated with fish feed, persistent chemicals and heavy metals, FDA import procedures and field operations, and third party inspections. The FDA also partners with the Bangladesh Shrimp and Fish Foundation to run the Aquacultural Food Safety Center. The center receives support from the government of Bangladesh and non-governmental organizations.

Barbados

FAS sponsored the participation of three Cochran Fellows from Barbados to attend a meat and poultry inspection training seminar conducted by FSIS. The seminar provided an overview of FSIS regulatory expertise, including an introduction to Hazard Analysis and Critical Control Points (HACCP), pathogen reduction, import and export policies and procedures, and equivalence.

Belize

APHIS provided Incident Command System (ICS) training on emergency response techniques for chief veterinary officers in Belize. APHIS experts addressed previous outbreaks of low pathogenic avian influenza and Newcastle's Disease, and lessons learned from emergency response plans. APHIS also provided ICS-related materials for program emergency planning. Additionally, the United States hosted training in Belize, with participation of both the public and private sector, under that country's National Poultry Improvement Plan. A poultry expert from APHIS reviewed Belize's current program, made suggestions on how best to administer it, and provided training about the operation of the industry-state-federal cooperative National Poultry Improvement Plan in the United States. This activity was an important part of U.S. efforts in helping Belize meet international SPS standards.

Cambodia

APHIS funded four APHIS-Cambodia staff and veterinary epidemiologists to train municipal and provincial officers on the prevention and control of avian influenza in Cambodia. APHIS also sponsored a one-week course on veterinary pathology to instruct Cambodian veterinarians on how to differentiate poultry diseases. In 2010, the Cochran Fellowship Program provided funding for activities such as training on U.S. food safety standards, including an overview of U.S. food safety systems with a focus on risk communication, certification systems, and the enforcement of food and agricultural standards. Participants had the opportunity to consult with representatives from U.S. regulatory agencies including APHIS, FDA, and FSIS. This training supported the development and adoption of science-based SPS regulatory systems. USDA also funded work under the Emerging Markets Program to help Cambodia establish its SPS Enquiry Point and Codex contact point.

Chile

The FDA held a seminar hosted by the Universidad Austral de Chile for 50 government officials, academics, and salmon industry representatives on good aquaculture practices, HACCP, food safety management systems, and veterinary drug residue testing.

China

The United States funded a number of programs to train Chinese officials on pesticide risk assessments, establishment of maximum residue levels, and the facilitation of pesticide registrations. This training will enhance China's capacity to conduct risk assessments based on internationally-accepted scientific standards. The University of Georgia, with funding from the U.S. Government, provided training to six Chinese officials on food tracing technologies, techniques to improve temperature monitoring, and the importance of utilizing international standards and risk assessments. APHIS and Iowa State University

trained six Chinese officials from the China Institute of Veterinary Control to assist the Chinese government with plans to establish an OIE collaboration center in Beijing. The training covered topics such as pre-license evaluation, risk assessment for genetically modified vaccines, standardized reagents, and post-marketing surveillance of veterinary biological products. FDA officials, joined by University of Maryland, provided technical assistance to approximately 50 producers and regulators of low acid and acidified foods through the Commercially-Sterile Processed Foods Training Program.

Colombia

The United States sponsored Cochran Fellows from Colombia to attend a training program in HACCP, food safety regulations, and inspection practices, designed in conjunction with Texas A&M University. This training provided the Fellows with an in-depth understanding of the food safety regulatory system in the United States.

Costa Rica

The United States sponsored three Cochran Fellows from Costa Rica to attend a two-week program organized by Michigan State University on food safety policy development, risk analysis, and SPS program implementation. Fellows also met with key U.S. Government officials and the International Food Policy Research Institute.

Croatia

USDA funded food safety training for three Croatian officials. This training, which was designed in conjunction with the University of Missouri, provided the officials with an in-depth knowledge of the agencies, practices, and methods involved in U.S. food safety procedures and regulations. This training will help decrease future food safety-related trade restrictions and lead to the expansion of U.S. agricultural exports to Croatia.

Dominican Republic

The United States sponsored several SPS-related activities in the Dominican Republic. As part of its activities, FAS sponsored a veterinary inspector and an expert in HACCP from the Inter-American Institute for Cooperation on Agriculture to provide training on HACCP and post-mortem and anti-mortem techniques for government inspectors and meat producers. This training is part of ongoing USDA efforts to assist the Dominican Republic in achieving equivalency with the United States for processed meat products in support of the CAFTA-DR. APHIS experts also worked with officials from the Dominican Republic to review its general strategy, work plans, and budgets for Classical Swine Fever (CSF) to help the Dominican Republic prepare for any occurrences of CSF. In collaboration with Texas A & M University, the U.S. Government provided technical training for Dominican officials on laboratory methods for detecting *E. Coli* and *Salmonella* bacteria in meats and fresh produce. FDA and FAS sponsored pesticide residue laboratory training to the Ministry of Agriculture's Pesticide Residue Laboratory, addressing laboratory quality

assurance systems; pesticide residue analytical capacities; and sampling, analysis, and instrumentation applications.

In 2009, utilizing Food for Progress grant funds, the U.S. Government began a four-year program to enhance the Dominican Republic's capacity to fully engage in commercial trade in food and agricultural products. The funded activities include upgrading of laboratory infrastructure, operations, and analytical testing capabilities; development of animal health surveillance, inspection, and sanitary standards for animal products; risk assessment methodologies and development of risk mitigation methods; traceability of agricultural products through the production and marketing chain; coordination and participation in international standard-setting organizations; and strengthening of domestic SPS institutions and infrastructure, such as animal and plant quarantine stations in ports and airports.

Egypt

The United States organized a conference for more than 100 regulators from countries in the North Africa and Middle East regions, coinciding with the opening of the new FDA Middle East-North Africa office. The program focused on the fundamentals of food systems, such as regulatory science, company registration, inspection, surveillance, risk assessment and food labeling. The United States also sponsored a technical workshop on food safety and biotechnology to assist Egyptian government agencies, academia, and trade and consumer groups in understanding the techniques of risk analysis as they apply to food safety and biotechnology issues. Cochran Fellows from Egypt also attended a two-week FSIS seminar on meat and poultry inspection for international government officials, and three Borlaug Fellows received training and conducted collaborative research on identifying and utilizing phytosanitary measures to prevent and control pest infestations both pre-and post-harvest.

El Salvador

The United States sponsored several activities in El Salvador, including training to build pesticide laboratory capacity for El Salvador's Ministry of Agriculture and Livestock Laboratory; pesticide residue laboratory training for El Salvadoran Ministry of Agriculture technicians; and training for El Salvadoran technicians on residue analysis and laboratory accreditation as part of a long-term capacity building program aimed to strengthen Central American national laboratories in operational and testing methods to meet U.S. and international standards. The United States also provided microbiological laboratory training on *Listeria* in ready-to-eat products to government officials of the El Salvadorian Ministries of Agriculture and Health National Laboratories.

Ethiopia

The United States sponsored several SPS-related trade capacity building activities for Ethiopia, including workshops, seminars, conferences, hands-on training programs, and

visits. Academic participants from Ethiopia trained at Texas A&M University to upgrade their technical subject knowledge; improve their teaching and research skills; and develop new and revised courses for introduction at their home institutions. They attended a two-week workshop on pest risk analysis, border/airport inspection, and the U.S. national surveillance system for plant diseases, among other courses. Additionally, a Borlaug Fellow received training on food safety standards and policy issues specific to fruits and vegetables at the University of Georgia.

Guatemala

FAS and FDA provided pesticide residue laboratory training for officials from the National Health Lab, addressing laboratory quality assurance systems, pesticide residue analytical capacities, and sampling, analysis, and instrumentation applications.

Honduras

The United States sponsored pesticide residue laboratory training for Honduran Ministry of Agriculture technicians and other government officials on residue analysis and laboratory accreditation as part of a long-term capacity building program aimed at strengthening the operational and testing methods of Central American national laboratories in order to meet U.S. and international standards.

India

During 2010, the United States sponsored several activities in India and the United States, including training related to allergen and toxin testing of genetically modified crops; HACCP plan development; econometric analysis of food safety measures from the farm to the consumer; and risk analysis models for food safety and food borne pathogens. USDA sponsored one scholar from India for a two-month program at Tuskegee University on risk analysis models regarding food safety and pesticides. FDA experts presented information on food safety requirements at the World Spice Congress, conducted food safety assessments, and worked with the India Spices Board to develop international technical assistance outreach materials to improve spice safety.

Indonesia

The United States helped Indonesia host the Codex Committee on Processed Fruits and Vegetables, which brought together committee delegates from around the world to discuss the adoption of applicable food safety standards. The United States also sponsored various SPS-related training activities for government officials, covering topics such as the U.S. regulatory system for processed products and the detection of and response to outbreaks of animal diseases. The United States also held workshops to assist Indonesian officials in preventing the spread of H5N1 avian influenza. FDA experts and other U.S. Government officials instructed Indonesian officials on the U.S. food safety system for processed foods.

Iraq

The United States funded an effort to help the Iraqi Veterinary Medical Syndicate (IVMS) increase knowledge and awareness of animal health issues and practices. In connection with this effort, the United States provided programmatic and financial support for meetings, training programs, and workshops for IVMS members and associates. Funding for this program runs through 2015.

Jamaica

USDA, with assistance from FDA, provided training to two Jamaican Veterinary Services Division veterinary medical officers in Washington, D.C. Workshop agenda items included export certification training/orientation for animal product food commodities exported to Jamaica, including processed foods, seafood, dairy, eggs and meat, as well as animal feed commodities that contain animal products. Follow up to this workshop was conducted in Kingston, Jamaica by USDA, with assistance from the Department of Commerce, and included discussions on pet foods and U.S. market access for swine meat, as well as certification for seafood.

Kazakhstan

The United States sponsored nine Cochran Fellows from Kazakhstan to receive training on food safety and animal health. Food safety training addressed various topics including advanced food safety standards; HACCP regulations; certification of exports; government inspection and control; laboratory analysis at production facilities; and modern safety equipment. Training on animal health examined veterinary diagnostics; animal products; import and export control systems; agricultural biosecurity; disease control; and quarantine programs. Fellows also visited university and state veterinary diagnostic laboratories in Texas.

Kenya

The United States funded several SPS-related technical assistance activities in Kenya. USAID and USDA jointly supported a resident SPS Advisor for the East Africa region based in Kenya. Under this program, USDA organized various plant health, animal health, and food safety activities, which included the training of pesticide regulatory officials from Kenya and fourteen other Sub-Saharan African countries in good laboratory practices to strengthen the ability of these countries to meet U.S. and international standards. The U.S. Government also trained Kenyan officials from the Ministries of Agriculture and Trade on SPS Agreement obligations, national notification authority and interagency coordination and integration, and SPS enquiry point management.

Laos

The United States sponsored several SPS-related trade capacity activities benefitting Laos, including a national workshop on testing and diagnostic protocols for highly pathogenic avian influenza. The workshop included participants from the Laos National Animal Health Center.

Macedonia

The United States, in conjunction with Tuskegee University, sponsored five Cochran Fellows from the Macedonian Ministry of Agriculture for training on various animal diseases and on the implementation of disease control measures. The Fellows received an overview of U.S. animal health functions and capabilities to gain first-hand knowledge on how to respond to disease outbreaks. The training was designed to expose the Fellows to new technologies, techniques, and procedures in combating and eradicating animal disease.

Malaysia

The United States funded several SPS-related activities for Malaysia, including trade capacity building workshops, seminars, conferences, hands-on training programs, and visits. The United States sponsored the travel of a Malaysian delegation to the United States to gain a better understanding of the U.S. biotech regulatory framework and safety protocols for the proper management of animal, plant, and human health issues. Members met with USDA regulators, food policy specialists, agricultural biotechnologists, and other experts.

Mexico

The United States sponsored several SPS-related activities for Mexico. USDA provided training to its Mexican counterparts to help strengthen Mexican pest and disease exclusion efforts. The EPA also worked with its Mexican counterparts to harmonize Mexican pesticide regulations with international and U.S. standards. Additionally, the United States provided training to representatives from Mexico's government, industry, and academia on topics including basic environmental, human health, and sanitary operational practices necessary for the production of safe, wholesome fruits and vegetables. FDA's Food Microbiology Laboratory experts conducted training in food safety-related rapid detection methods for over 170 people from the private and government sectors at workshops sponsored by the Mexican government.

Nicaragua

FAS and FDA provided pesticide residue laboratory training to Nicaraguan ministry officials on laboratory quality assurance systems, pesticide residue analytical capacities, and sampling, analysis, and instrumentation applications.

Pakistan

As part of a long-term project, the United States has provided funding to Pakistan under a Food for Progress Grant to promote cold chain development. APHIS also sponsored avian AI-related training for a Pakistan government official for three weeks at the National Veterinary Services Laboratories in Ames, Iowa. The effort is expected to increase the technical capacity of the poultry health laboratory in Pakistan.

Peru

The United States funded several SPS-related programs for Peru including, but not limited to: a review of Peru's avian influenza program to help prevent the spread of the H5N1 strain of the disease; food defense training with stakeholders from academia, industry, government, and trade associations to increase the capacity of participants to conduct vulnerability assessments, identify food defense mitigation techniques and develop food defense plans, ultimately improving Peru's ability to prevent intentional contamination of their food supply; sponsoring university instructors to visit the United States to upgrade their technical subject knowledge, improve their teaching and research skills, and develop new and revised SPS-related courses; providing visitors from Peru with overviews of APHIS operations at ports of entry in the United States to strengthen Peru's institutional capacity with the long-term goal of improving trade opportunities; and assisting the Peruvian government in drafting project work plans with respect to food safety, animal health, plant health, agricultural research, agricultural curriculum development, and participation in international standard setting organizations. FDA, in collaboration with FAS, provided on-site pesticide residue lab training to Peruvian officials on testing methodologies for detecting pesticide residues in foods and the implementation of laboratory standards for quality control and assurance.

Tajikistan

The United States funded SPS-related trade capacity building assistance for Tajikistan in the form of training programs. The United States sponsored four Cochran Fellows from Tajikistan (government and private specialists) to attend training on hygiene and sanitation practices in agriculture, including best practices, quality assurance methods, safety regulations, advanced food safety standards, HACCP regulations, and government inspection and control.

Tanzania

Beginning in 2010, and extending through 2013, the United States has been involved in a number SPS-related projects benefiting Tanzania. A collaborative effort between USAID and USDA supports a resident SPS Advisor for the East Africa region. In 2010, the SPS Advisor helped SPS agencies in Tanzania and elsewhere in the region develop institutional

capacity for science-based regulatory systems consistent with international standards. A pesticide regulatory official received training at the University of Missouri under the Borlaug Fellowship Program in SPS enquiry point management, pest management, and good laboratory practices.

Turkey

The United States funded programs to help build Turkey's SPS-related trade capacity. For example, the United States sponsored workshops for approximately 200 veterinarians and other disease control officials in Turkey on basic through advanced veterinary epidemiology, with a focus on brucellosis prevention, detection, and control.

Vietnam

The United States funded several SPS-related trade capacity building activities in Vietnam, including collaboration on animal health between U.S. and Vietnamese scientists to analyze viruses and vaccines for emerging influenza strains. The United States also conducted food defense training with Vietnamese stakeholders from academia, industry, government, and trade associations to increase the capacity of the participants to conduct vulnerability assessments, identify food defense mitigations, and develop food defense plans with a goal to improve Vietnam's ability to prevent intentional contamination of their food supply; and sponsored training for Vietnamese government officials on U.S. food safety systems, with a focus on risk communication, certification systems, and the enforcement of food and agricultural standards. The United States also funded and organized a national workshop on testing and diagnostic protocols for *Streptococcus suis*; undertook training to enable government and private sector officials to participate more effectively in Codex activities; and trained Vietnamese government officials on the U.S. WTO SPS notification process and the use of risk-based science in drafting SPS regulations, in order to facilitate Vietnam's participation in the WTO/SPS notification and comment process.

APPENDIX

USTR received public comments regarding this report from the following entities:

American Potato Trade Alliance
Biotechnology Industry Organization
Blue Diamond Growers
California Cherry Advisory Board
California Table Grape Commission
Distilled Spirits Council of the U.S.
Egyptian General Organization for Veterinary Services
National Potato Council
National Milk Producers Federation & U.S. Dairy Export Council
Northwest Horticultural Council
Sunkist Growers
U.S. Hop Industry Plant Protection Committee
U.S. Meat Export Federation
U.S. Wheat Associates
USA Rice Federation
USEC, Inc.
Wine Institute, WineAmerica, and California Association of Winegrape Growers
Yum! Restaurants, Intl.