

ACKNOWLEDGEMENTS

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March 2012

LIST OF FREQUENTLY USED ACRONYMS AND ABBREVIATIONS

AI	Avian Influenza
APEC	Asia Pacific Economic Cooperation
APHIS	USDA's Animal and Plant Health Inspection Service
AQSIQ	China's General Administration of Quality Supervision, Inspection, and Quarantine
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
CU	Customs Union of Russia, Kazakhstan, and Belarus
EPA	U.S. Environmental Protection Agency
EFSA	European Food Safety Authority
EU	European Union
FAO	United Nations Food and Agriculture Organization
FAS	USDA's Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FMD	Foot and Mouth Disease
FSIS	USDA's Food Safety and Inspection Service
FTA	Free Trade Agreement
GCC	Gulf Cooperation Council
GE	Genetically Engineered
HACCP	Hazard Analysis and Critical Control Points
HPAI	Highly Pathogenic Avian Influenza
IIBI	Institute of Innovation in Biotechnology and Industry
IICA	Inter-American Institute for Cooperation on Agriculture
ILRI	International Livestock Research Institute
IPPC	International Plant Protection Convention
JCCT	Joint Commission for Commerce and Trade
LPAI	Low Pathogenic Avian Influenza
MOU	Memorandum of Understanding
MRL	Maximum Residue Limit
MT	Metric ton
NAFTA	North American Free Trade Agreement
NEI	National Export Initiative
NTE	National Trade Estimate Report on Foreign Trade Barriers
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
SME	Small and Medium-sized Enterprises

SPS	Sanitary and Phytosanitary
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
SPS Committee	WTO Committee on Sanitary and Phytosanitary Measures
SRM	Specified Risk Material
STDF	Standards and Trade Development Facility
TBT	Technical Barriers to Trade
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TCB	Trade Capacity Building
TIFA	Trade and Investment Framework Agreement
TPP	TransPacific Partnership
TPSC	Trade Policy Staff Committee
TRQ	Tariff Rate Quota
TWG	Trade Working Group
USAID	U.S. Agency for International Development
USDA	U.S. Department of Agriculture
USTR	Office of the U.S. Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

FOREWORD

The Office of the United States Trade Representative (USTR) is pleased to publish its third annual *Report on Sanitary and Phytosanitary Measures (SPS Report)*. This report was created to respond to the concerns of U.S. farmers, ranchers, manufacturers, and workers who confront SPS trade barriers as they seek to export high-quality American food and 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, manufacturers, workers, and their families, they also deprive consumers around the world of access to high-quality American food and agricultural goods. USTR is committed to identifying and combating unwarranted SPS barriers to U.S. food and agricultural exports. USTR's efforts to remove unwarranted 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 specific SPS barriers in Japan and Korea for U.S. cherries and citrus, as well as barriers in South Africa and Sri Lanka for apples and seed potatoes. The United States also worked with Kuwait and Taiwan to lift unwarranted restrictions on U.S. exports of poultry and poultry products, and the United States negotiated for full market access for U.S. beef to the United Arab Emirates.

In 2012, 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. food and 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, manufacturers, and workers, as well as families who depend on export-supported American jobs.

Ambassador Ron Kirk
U.S. Trade Representative
March 2012

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I. EXECUTIVE SUMMARY

The *2012 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 grounds that the measures are necessary to protect human, animal, or plant life or health from risks arising from the entry or spread of 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 through robust regulatory frameworks to protect their people, animals, and plants from health risks of this kind. This report focuses 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 (FTAs); (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 unwarranted SPS barriers that impede U.S. exports to multiple foreign markets. Among the most significant of these cross-cutting barriers are restrictions related to export certifications, biotechnology, bovine spongiform encephalopathy (BSE), avian influenza (AI), and maximum residue limits (MRLs) for pesticides.

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, Croatia, 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, Kyrgyzstan, Malaysia, Mexico, Morocco, New Zealand, Nicaragua, Norway, Peru, Philippines, Russia, Singapore, South Africa, the South African Development Community, South Korea, Sri Lanka, Switzerland, Taiwan, Thailand, Turkey, Ukraine, 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 in 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 WTO system of multilateral trading rules. The President's 2009 Trade Policy Agenda outlined 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: 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 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 unwarranted 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 [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. food and agricultural 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.

First published in 2010, the *SPS Report* serves these goals. 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

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

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 *2012 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 (*2012 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 cross-cutting SPS trade barriers that U.S. producers face in a number of different markets. The next 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 those laws, decrees, regulations, requirements, and procedures that governments apply to protect human, animal, or plant life or health from risks arising from the entry or spread of 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. Many countries also have established maximum residue limits (MRLs) for pesticide residues in food to promote the safe use of pesticides on food, as well as requirements that imported vegetables be treated to eliminate a particular pest to protect plant health. In addition, governments often require live animals to be subject to veterinary health examinations, disease testing, and sometimes pre- or post-entry quarantine.

At times, however, some governments impose SPS measures that are really disguised protectionist barriers to trade, not grounded in science, or that are otherwise unwarranted, and which create substantial obstacles to U.S. exports. For example, many countries have used the threat of avian influenza (AI) or bovine spongiform encephalopathy (otherwise known as BSE)

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.

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 \$140 billion in 2011. According to USDA's Economic Research Service, each \$1 billion in U.S. 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 and sovereign 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 therefore, that do not serve to guard against legitimate health and safety 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 WTO 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 WTO 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 to publish promptly all adopted SPS measures in a manner that enables other interested WTO Members to become acquainted with them prior to their entry into force. 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, and 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 157 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.

Since 2002 the United States has raised 188 items of trade concern during the formal, on the record WTO SPS Committee meetings.

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 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 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.

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 U.S. – Colombia Trade Promotion Agreement (TPA), the Dominican Republic – Central America – United States FTA (CAFTA – DR), the U.S. – Korea FTA, the U.S. – Oman FTA, the U.S. – Panama TPA, and the U.S. – Peru TPA. The U.S. – Morocco FTA does not have a stand-alone SPS chapter, but does include various SPS provisions in its agriculture chapter.

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, however, do not 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, an agency within 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 agencies, the Foreign Agricultural Service (FAS), the Animal and Plant Health Inspection Service (APHIS), and the Food Safety and Inspection Service (FSIS), are engaged actively 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 public health 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 Chile, China, Costa Rica, India, Italy, Jordan, Mexico, South Africa, and the United Kingdom. FDA takes an active role in assessing foreign SPS measures, participates in the SPS interagency process to address food safety issues, 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 for other U.S. FTAs.

U.S. Department of Commerce

The Market Access 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 250 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. and Foreign Commercial Service (U.S. & FCS) works with U.S. companies to help them expand market access opportunities abroad. The U.S. & FCS operates in 93 U.S. cities and in 73 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 that may be subject to unwarranted trade barriers. 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 unwarranted barriers to U.S. exports. USTR and other agencies learn of issues directly from concerned U.S. businesses and industries, farm and 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 coordinates 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 2011 alone, the interagency group reviewed 1,030 SPS notifications by 51 WTO Members and provided comments to these trading partners on 37 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 16 comments, Brazil (9), European Union (8), Republic of Korea (8), and Chinese Taipei (7).

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 Trade Investment Framework Agreement (TIFA) 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.

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

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 metric tons (MT) 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. The MOU provides the possibility of the United States and the EU entering into a second phase starting in August 2012, in which the EU would increase the tariff rate quota (TRQ) to at least 45,000 MT, and the United States would lift the remaining additional duties. At this time, the MOU is operating successfully by providing increased access to U.S. beef producers. The United States will continue to monitor EU implementation of the MOU and other developments affecting market access for U.S. beef products.

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 provide access for U.S. apples to Japan's market.

European Communities – Agricultural Biotechnology

In 2003, the United States challenged the EU's *de facto* moratorium on approvals of U.S. agricultural products derived from modern biotechnology, such as certain corn and soybean varieties, as well as 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 70 applications remains pending in the EU approval system, which has the effect of blocking U.S. exports of certain agricultural products. The EU approved

six products in 2011, taking an average of 52 months to authorize them. The United States continues to press the EU for fundamental improvements in its regulatory system with the goal of normalizing trade in agricultural products derived from modern biotechnology.

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.

India – Restrictions on Certain U.S. Agricultural Products

On March 6, 2012, the United States requested consultations with India under the dispute settlement provisions of the WTO regarding India's import prohibitions on certain U.S. agricultural exports. India's import prohibitions are purportedly for the purpose of preventing the entry of avian influenza. The United States is concerned that India has not provided a valid, scientifically-based justification for the import prohibitions.

Technical Assistance

In addition to these efforts, the U.S. Government has put into 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 2011, the U.S. Government obligated to provide funds for SPS trade capacity building (TCB) in excess of \$18.5 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

Some U.S. food and agricultural exports are subject to similar unwarranted SPS barriers in multiple markets. This year's *SPS Report* describes these cross-cutting trade barriers and the efforts the U.S. Government has made to remove them. The leading cross-cutting SPS barriers arise in connection with: export certification requirements, biotechnology, bovine spongiform encephalopathy, avian influenza, and maximum residue levels for pesticides. The individual country reports contained in section IV provide details on these barriers in specific markets.

Underlying these cross-cutting SPS trade barriers (and many of the other unwarranted SPS barriers described in section IV) is the disturbingly common failure by some U.S. trading partners to base their SPS measures on science, as the SPS Agreement requires. Unfortunately, some trading partners place other factors ahead of, or consider them together with, scientific principles when establishing or applying certain SPS measures. Some trading partners apply SPS measures with an eye toward protecting domestic producers, for example, or catering to perceived local consumer preferences. Such practices are reflected in the debates over SPS standards in relevant international fora, such as discussions in Codex regarding standards for ractopamine, an animal feed ingredient, where it is clear that certain trading partners consider factors other than science in imposing SPS measures.

The United States is committed to establishing SPS measures based strictly on science, consistent with both the letter and spirit of the SPS Agreement, and to pressing U.S. trading partners to do the same.

A. Export Certification Requirements

Many countries require food imports to be accompanied by a written certification from the producer and exporting country setting out a variety of SPS-related assurances. These assurances may include, for example, declarations that the products have been produced under sanitary conditions and in disease-free areas. In recent years, however, many trading partners have begun requiring export certificates to include cumbersome and often unnecessary "attestations" that, for example, may subject imports to unwarranted or overly burdensome testing requirements.

This new type of export certification has created a significant and growing impediment to trade. The attestations required as part of these export certifications often appear to be scientifically unwarranted or to impose requirements that are inconsistent with the recommendations of the relevant international standard setting organizations (Codex, OIE, and IPPC). In other cases, the export certifications may call for attestations that are simply unnecessary. For example, certain importing countries require individual food shipments to be accompanied by an export certification that addresses the prevalence of certain animal or plant diseases in the exporting country when information on this subject is often freely available on websites that the exporting government or an international SPS standard setting body, such as the OIE, maintains.

The United States supports the work of international standard setting bodies in establishing guidelines for export certifications. Guidelines of this type, such as the Codex "Principles for

Food Import and Export Inspection and Certification,” provide that certification requirements should be confined to eliciting information essential to meeting the objectives of the importing country’s food inspection and certification system. The Codex guidelines also call for importing countries to specify the reasons for requiring specific attestations to be included in export certifications and to apply their certification requirements in a non-discriminatory manner. The guidelines specify that the importing country may require, for example, access to production facilities and relevant documents of the exporting country. The OIE and IPPC have adopted similarly useful guidelines governing export certification requirements.

Many countries, however, do not observe Codex, OIE, or IPPC guidelines when they impose export certification requirements. Moreover, U.S. exporters often first learn that a government has imposed new or different certification requirements, or has decided to implement them in a new way, only after the exporters find that their shipments have been detained at the port of entry.

Following are examples of the sorts of unwarranted certification requirements certain U.S. trading partners impose that create unnecessary barriers to U.S. food exports:

- Attestations and testing requirements that are not based on internationally accepted norms (*e.g.*, attestations that shipments of certain foods are entirely free from *Salmonella* bacteria or genetically engineered ingredients).
- Attestations that are not appropriate for purposes of addressing a legitimate human health or safety concern, such as a requirement to certify that shipments of pork and pork products are free from H1N1 virus, a pathogen that cannot be transmitted through food.
- Requirements for exporters to provide information regarding U.S. surveillance programs for various animal diseases when the importing government has ready access to this information through U.S. Government and international organization websites.

In February 2010, the United States and Australia sponsored an Asia Pacific Economic Cooperation (APEC) export certification roundtable in Australia.⁴ Representatives of 20 of the 21 APEC Member Economies reached several conclusions and observations regarding the issuance and usage of official certificates in the APEC region, including avoiding redundancy in certifications and requiring attestations only when essential information is necessary to ensure food safety or fair practices in food trade. The representatives further discussed common challenges arising from certification requirements and options to address those challenges, the basis for requirements on export certificates, and common understandings and best practices in dealing with export certificates. These ideas are currently under discussion and expected to be a major focus for the Trans-Pacific Partnership (TPP) Agreement countries in the future in an effort to forge common certification requirements among TPP countries.

⁴ http://fscf-ptin.apec.org/docs/events/export-certification-roundtable/ECR_event_report.pdf

B. Biotechnology

Over the past 15 years, farmers around the world increasingly have planted crops developed through modern biotechnology or genetic engineering (GE) techniques. According to the International Service for the Acquisition of Agri-Biotech Applications, the number of countries growing biotechnology crops has increased from six in 1996 to 29 in 2011. Crops produced using agricultural biotechnology that are consumed in the United States for food, feed, or fiber include alfalfa, canola, corn, cotton, papaya, soybeans, squash, and sweet corn. USDA's National Agricultural Statistics Service estimates that in 2011, 94 percent of soybean acreage, 88 percent of corn acreage, and 90 percent of cotton acreage in the United States were planted with biotech varieties. New GE crops will continue to be brought to market, leading to more acceptance of biotech crops on the one hand, and potentially more trade challenges on the other.

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. The country-by-country section of the *SPS Report* includes numerous examples of unwarranted import bans and restrictions currently being applied to U.S. biotech products. In addition, some trading partners impose mandatory labeling requirements on foods derived from biotech products that create technical barriers to trade by wrongly implying that these foods are unsafe.⁵ Some U.S. trading partners have continued to impose restrictions on these products even though repeated dietary risk assessments have shown no food safety concerns, and these biotech products have proven safety records.

The United States actively engages with trading partners to remove these unwarranted trade barriers as well as 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 the safety assessment of, and trade in, agricultural biotechnology products. For example, the United States contributed to the establishment of Codex plant guidelines for assessing the safety of biotech crops. The United States has also supported the development of Codex safety assessment guidelines for nutritionally enhanced biotech crops and for cases where small amounts of biotech products approved in the exporting country are found in food products destined to countries that have not approved those products. Although the United States is not a party to the Cartagena Protocol on Biosafety, which governs transboundary movement of living modified organisms (another term for living genetically engineered plants and animals, including, for example, biotech corn, fish, and soybeans), the United States regularly participates in meetings of the Protocol parties and related capacity-building efforts to promote science-based approaches involving international trade in these substances. The United States is also actively involved in regulatory and policy dialogues in APEC that address agricultural biotechnology.

C. Bovine Spongiform Encephalopathy

BSE 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. As of January 2012, the OIE indicated that in 2011, the number of cases had decreased to 28 cases globally, only one of which was outside of

⁵ These labeling requirements are addressed in the *TBT Report*.

Europe. The United States has had only three animals test positive for BSE: an animal imported from Canada in 2003, a U.S.-born 12 year old animal in 2005, and another 10 year old U.S.-born animal in 2006.

The OIE

The OIE is the international organization responsible for improving animal health worldwide. The 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 to ensure the production of safe beef and beef products. With respect to BSE, all cattle parts that the OIE has not designated as SRMs are safe for human consumption.

U.S. BSE-Related Controls

The United States implemented an OIE-consistent feed ban in 1997, which prohibits feeding ruminants most mammalian protein. The U.S. feed ban was further strengthened in 2009 by prohibiting the use of the highest risk cattle tissues in all animal feed. A feed ban of this type is the most important step a country can take to protect its cattle population from BSE via feed. Both U.S. born cows infected with BSE were born prior to the feed ban being put into place in 1997. 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. On March 9, 2012, USDA issued a proposed rule to further tailor its BSE regulations to the OIE guidelines.

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 the close of 2011, U.S. beef and beef product exports had rebounded, totaling nearly \$5.4 billion.

The increased value of sales is attributable to favorable exchange rates as well as higher consumer demand for meat (and thus higher prices) in countries with expanding economies. For the first time since 2003, the quantity of U.S. beef exported exceeded 2003 levels, reaching 1.3 million metric tons in 2011. Nevertheless, U.S. beef exporters continue to face unwarranted and burdensome BSE-related import restrictions, including bans by some countries of all U.S. beef and beef products, selected bans on certain products (e.g., bone-in and ground beef), and restrictions on U.S. beef and beef products produced from animals over certain ages.

Moreover, the discrepancy in BSE-related measures in different markets represents a separate trade burden and undercuts the comparative advantage of U.S. exporters. This discrepancy not only burdens producers, who must alter production and packing processes based on the requirements of the specific export market, but USDA, which must maintain an export verification program to confirm that these alterations in production and packing processes meet those requirements. 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.

Some 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 unwarranted 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.

D. Avian Influenza

AI is a virus that can infect wild birds and poultry. The OIE divides AI viral strains into two groups based on the ability of the particular virus to produce disease: LPAI and HPAI. LPAI naturally occurs in wild birds and can spread to domestic birds. In many cases, LPAI causes either no, or only minor, symptoms in infected birds. HPAI is more virulent than LPAI and can, accordingly, spread easier. HPAI infections are often fatal in certain avian species, such as chickens and turkeys.

U.S. AI-Related Controls

While there have been three minor outbreaks of HPAI in U.S. poultry since 1924, none of these outbreaks has caused significant human illness, and there is no evidence that HPAI currently exists in the United States. The success of the United States in preventing the establishment of HPAI can be attributed to various safeguards implemented by U.S. Federal and state governments. For example, Federal agencies work with states and the poultry industry to monitor U.S. bird populations in four key areas: live bird markets, commercial flocks, backyard flocks, and migratory bird populations. Inspectors conduct extensive testing in live bird markets

and commercial flocks. In addition, any birds that show signs of illness are tested for 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. U.S. HPAI control policies are consistent with the relevant science-based standards, guidelines, and recommendations issued by the OIE.

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

Despite these measures, many countries have imposed unwarranted import bans on U.S. poultry products based on professed concerns over AI, often citing isolated LPAI or LPNAI outbreaks. For example, China has banned imports of poultry and poultry products from six U.S. states since 2007. India prohibits imports of various U.S. poultry products based on purported AI-related concerns as well. Many of these restrictions appear to be inconsistent with OIE guidelines, which provide recommendations on steps governments can take that help to ensure that poultry products can be safely traded in light of AI concerns.

The United States remains highly concerned about unwarranted AI-related import bans that are inconsistent with the OIE guidelines. Removing such bans remains a high priority for the U.S. Government, and the United States has raised this issue with many trading partners, including China and India, in a wide range of fora. At U.S. Government prompting, U.S. trading partners have lifted 96 AI-related bans since 2008. Section IV of the *SPS Report* provides additional information on countries with unwarranted AI import restrictions.

E. Maximum Residue Levels for Pesticides

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) 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 tolerances 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 EPA tolerances. Inspectors from the FDA and USDA monitor both domestic and imported food and feedstuffs to ensure that tolerances are observed.

Codex develops and maintains international standards for MRLs. The SPS Agreement encourages countries to base their MRLs on those that Codex has set. Nevertheless, it is not uncommon for countries – including the United States – to set their own, stricter MRLs. When a government sets an MRL that is more stringent than the relevant Codex standard, the government must do so consistently with Article 3 of the SPS Agreement, which calls for the government to provide either a scientific justification for that stricter standard or apply the standard in accordance with Article 5 of the SPS Agreement.

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 MRLs. For example, in 2011, the United States, Canada, and Mexico initiated a new NAFTA TWG on regional regulatory cooperation for pesticides. The 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 in the country reports that follow, various countries have either set pesticide MRLs at unreasonably low thresholds, have failed to establish a MRL for certain pesticides that have established Codex or U.S. MRLs, or have a significant backlog of reviews for newer, safer pesticides. This situation has created significant trade barriers for U.S. horticultural exports. MRL enforcement policies in the EU, 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 positive pesticide MRL lists or systems that are based on the Codex standards are best suited to facilitate trade. However, 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 scientifically based U.S. MRL in the interim, U.S. growers could be subject to onerous penalties and serious trade barriers for using pesticides that have been established as safe to use.

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 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.⁶

The U.S. goal is to work as vigorously and expeditiously as possible to resolve the concerns 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, and more broadly the U.S. Government, does not believe the matter raises significant concerns; it may simply reflect the fact that other Federal agencies are working to resolve the matter directly with their counterpart foreign ministries. It may also mean that USTR requires additional consultations or information to consider. 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 this 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 *SPS 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 strategic approach to measures of this kind, deploying resources where they can be most effective. In

⁶ 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 Agreement as opposed to the TBT Agreement).

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 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. 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

Pork

Argentina requires pork produced in the United States either to be shipped frozen or tested for trichinosis. Argentina's requirements constitute a significant impediment to U.S. fresh and chilled pork exports to Argentina. The United States does not consider these requirements to be necessary as U.S. producers maintain stringent biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. The United States will work with regulatory authorities in Argentina to resolve this trade concern.

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 due to concerns over AI and Exotic Newcastle Disease. Argentina has promulgated new rules that reaffirm the current import restrictions when there are findings of AI or Exotic Newcastle Disease in the exporting country. 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 state, 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 Exotic Newcastle Disease and will continue to press this issue.

See section III.D 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 efficacy of post-harvest treatments for *Erwinia amylovora* (the bacterium that causes 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. The United States will continue to work with Argentine officials to address the issue and reinstate the issuance of permits for importation.

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 requirements, a country interested in exporting beef and beef products to Australia must request Food Standards Australia New Zealand, a regional food safety agency, to conduct an individual country risk assessment. 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. Biosecurity Australia has not yet concluded its risk assessment for the United States. The United States continues to engage on the technical aspects of BSE and BSE-related trade issues with the relevant Australian government agencies 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

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.

Poultry

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

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.

Plant Health

Apples

Australia currently prohibits the importation of apples from the United States based on concerns about fire blight, a contagious, bacterial disease which can infect 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, symptomless 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 and identified three additional fungal pathogens of concern to Australian regulatory authorities. Research is currently being conducted to address Australia's concern about the three fungal pathogens. 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 continues to monitor Australia's ongoing PRA process regarding U.S. apples in light of the WTO rulings and recommendations in this case.

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 (SWD) in the United States. As a result, U.S. stone fruit exporters will not be able to ship U.S. stone fruit to Australia until Australia and the United States agree on a mutually acceptable mitigation for SWD for stone fruit. The United States is engaged in an active dialogue on mitigation measures for SWD and is 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.

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. Australia has recently indicated that it would complete a risk assessment to initiate the process to consider 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 States (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 States 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 following 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 with 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 the basis of 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 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 U.S. pork can be imported into Brazil only if the product is tested to be free of trichinae. The United States does not consider these requirements to be necessary as U.S. producers maintain stringent 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 2012 to continue discussions and encourage Brazil to lift its current restrictions.

Plant Health

Planting Seeds

In December 2010, Brazil's Ministry of Agriculture, Livestock and Food Supply (MAPA) published Normative Instruction 36 (Norma 36), a regulation establishing burdensome and unnecessary new pest and disease requirements for the importation of 118 seed species into

Brazil. Following coordinated engagement by the U.S. Government, the U.S. seed industry, and other trading partners of Brazil, MAPA temporarily revised Norma 36 in March 2011, allowing for field inspection of quarantine pests instead of laboratory testing as originally outlined in the regulation. The temporary revisions allowing field inspection, however, are set to expire in March 2012. Brazil committed to provide a seed-pest list no later than November 30, 2011, but as of March 2012, it has not provided that list. USDA continues to engage its Brazilian counterparts on the issue, but it remains unclear when, and in what form, Brazil may implement Norma 36.

CHILE

Food Safety

Pork

Chile requires pork produced in the United States to be shipped frozen or tested for trichinosis. Chile's requirements constitute a significant impediment to U.S. fresh and chilled pork exports to Chile. The United States does not consider these requirements to be necessary given that U.S. producers maintain stringent biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. As an alternative, the United States 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 Chile to resolve this trade concern.

CHINA

Biotechnology

Under Chinese regulations, a biotech product developed in a foreign country must first be approved for use in that country before Chinese authorities will begin to consider approving the product for use in China. The United States is concerned that such a practice creates significant and unwarranted delays in China's approval of biotech products, which could result in substantial disruptions in exports of certain U.S. agricultural products.

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

Food Safety

Ractopamine

China bans imports of pork containing any residue of ractopamine, a veterinary drug that promotes lean meat growth in pigs and certain other farm animals. 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. MRL 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 in conjunction with the U.S.-China Strategic and Economic Dialogue in 2011, U.S. officials asked China to adopt an interim MRL while awaiting Codex's final adoption of an MRL. China's Ministry of Agriculture declined this request, claiming that China needs to await a final decision by Codex. The United States continues to press China on this issue in bilateral and multilateral fora.

Dairy Products

On April 21, 2010, China informed the United States that it would suspend imports of U.S. dairy exports 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 U.S. requests, 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. In July 2011, China sent a proposed export certificate to USDA. USDA and FDA reviewed the proposal and delivered a counterproposal to China in November. China responded in December 2011. U.S. technical experts continue to refine the certificate language with their Chinese counterparts. In the meantime, U.S. dairy exports to China have continued without interruption.

See section III.A for an explanation of the export certification trade 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, however, 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 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. In October 2011, another high-level USTR and USDA delegation met with Chinese counterparts in Beijing to set an agenda for further technical engagement. At the U.S.-China Joint Commission for Commerce and Trade (JCCT) meeting in November 2011, both sides agreed to increase future technical engagement.

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

Meat and Poultry

China has imposed a zero tolerance limit for the presence of *Salmonella*, *Listeria*, and other pathogens in imported meat and poultry. This tolerance standard 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 they have yet to do so. The United States continues to engage China on this issue.

Animal Health

Animal Feed

In 2004, United States 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 August 2011, 153 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 prevents or inhibits products from entering the Chinese market. For example, before shipping pet food to China, a U.S. producer must first obtain a certification from U.S. authorities that the producer's facilities meet the Chinese requirements under a bilateral 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)). It is unclear whether U.S. companies are expected to register first with MOA or with AQSIQ, and many companies find themselves caught between the two agencies, unable to achieve either registration.

MOA's requirements 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. The United States continues to engage China on the issue.

AQSIQ published Decree No. 118 in 2009 and has slowly begun enforcement activities in 2010. These activities include: requiring foreign regulatory agencies to maintain a list of facilities approved to export feed products, requiring plant-by-plant audits, and requiring manufacturers to provide proprietary information, including photographs of processing facilities. Many of the requirements do not appear to have a scientific basis. Industry estimates that U.S. animal feed exports to China are experiencing a significant decline as a result of Decree No. 118. The United States and China are currently discussing possible alternative mechanisms to ensure that U.S. exports meet China's SPS requirements.

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.

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

Poultry

China currently bans poultry and poultry products from Arkansas, Minnesota, and Virginia based on reported detections of LPAI in those states. In addition, China bans imports of U.S.-origin poultry and poultry products that are transshipped through these three states. China's current AI-related import bans do not appear to be science-based or consistent with OIE guidelines.

During bilateral meetings in 2011, including JCCT working group meetings, the United States pressed China to remove its AI-related bans and to adopt OIE-consistent policies governing imports of U.S. poultry and poultry products. During the course of the November 2011 JCCT meeting, China announced that it would lift its AI-related bans on poultry from Texas and Pennsylvania. The two sides agreed to hold further technical talks to address China's remaining bans on imports from the remaining states.

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

Plant Health

Apples

Since 1995, China has only allowed imports of two varieties of U.S.-origin apples from three states (Idaho, Oregon, and Washington) based on concerns over fire blight, a bacterial disease. 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 a fourth state, California. To support this request, U.S. authorities provided China 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 2011, 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 PRA 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 U.S. request, 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 2011, China agreed to continue technical discussions regarding imports of U.S. pears, with the aim of completing a risk assessment in 2012.

Potatoes

China has not permitted imports of U.S.-origin table stock potatoes based on concerns over various 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. 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

The United States is seeking to establish permanent market access to China for California strawberries. In 2008, AQSIQ allowed California strawberries to be imported for the Olympic and Paralympic Games in Beijing. At that time, Chinese authorities acknowledged that California strawberries were safe. However, USDA has since sought permanent access, and

while China has not provided any scientific justifications for its delay, a decision on permanent access has not been granted.

COLOMBIA

Food Safety

Poultry

In 2006, Colombia formally agreed to recognize that the U.S. poultry inspection system is equivalent to Colombia's system. In August 2007, however, the Colombian Ministry of Health began implementing a zero tolerance standard for *Salmonella* on imported raw poultry products, which restricted U.S. exports. 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 destined 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. Colombia is in the process of establishing a new tolerance level for *Salmonella*, although specific details remain unclear. The United States engaged Colombia on this subject in January 2012 and will continue to work with Colombia to address U.S. concerns about these requirements.

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 States (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 States could establish their own requirements for imports of U.S. live cattle in accordance with the CAN risk assessment.

In June 2010, Colombia purported to allow live cattle imports from the United States, but at the same time imposed such restrictive requirements that they effectively prevented any such imports. On January 20, 2011, USDA proposed a protocol to Colombia that covers trade in live cattle as well as further comments to Colombia regarding its requirements. The United States

will continue 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.

Pork

Colombia requires pork produced in the United States to be shipped frozen or tested for trichinosis. Colombia's requirements constitute a significant impediment to U.S. fresh and chilled pork exports to Colombia. The United States does not consider these requirements to be necessary as U.S. producers maintain stringent biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. The United States will work with regulatory authorities in Colombia to resolve this trade concern.

Poultry

Despite agreeing in 2006 to impose AI-related requirements consistent with OIE recommendations, Colombia has for several years imposed OIE-inconsistent bans on U.S. poultry and poultry products, resulting from detections of LPAI in the United States. While Colombia subsequently lifted bans of poultry produced in various states in June 2011, a ban on poultry from Polk County, Missouri remains in place. The U.S. Government is working with Colombian officials to address this issue in the context of the countries' ongoing efforts to implement the U.S.-Colombia Trade Promotion Agreement, and more generally.

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

Plant Health

Rice

In March 2009, Colombia rejected a shipment of U.S. paddy rice, claiming that it contained rice smut fungus (*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, 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 the ICA indicated that U.S. exports would be denied entry due to concerns with rice smut fungus. In April 2010, the ICA sent a request to the CAN SPS regulatory agency for help in developing a PRA for rice smut fungus. It could take up to five years for Colombia to complete the PRA. The United States has expressed concern both to the ICA and Colombia's Ministry of Trade regarding Colombia's handling of U.S. paddy rice exports. U.S. officials and their Colombian counterparts on this subject are working to find an approach that both addresses Colombia's legitimate concerns and allows trade to occur.

COSTA RICA

Food Safety

Poultry

In 2008, the Central American Common Market (CACM) Member States, 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 its concern with CACM Member States through written comments, meetings, and workshops 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*. Nevertheless, the final regulation that CACM adopted in 2009 retained the zero tolerance requirement language for *Salmonella*. Costa Rica formally adopted the final regulation on September 22, 2009. The United States continued to engage with CACM members, and their various ministries, on this issue through written comments and face-to-face meetings held in September 2010, April 2011, July 2011, and February 2012.

CROATIA

Biotechnology

Croatia prohibits the import of all food products that contain even trace amounts of food products derived from modern biotechnology. This restriction makes it extremely burdensome and expensive to export U.S. food products to Croatia.

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

DOMINICAN REPUBLIC

Food Safety

Beef and Beef Products

The Dominican Republic bans imports of U.S. beef and beef products from cattle 30 months of age and over 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 following the detection of a BSE-positive animal in the United States in 2003. Until April 2010, Ecuador and the other three CAN Member States (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 States could establish their own requirements for imports of U.S. live cattle in accordance with the CAN risk assessment. On August 30, 2010, Ecuador published Regulation 20137, which proposed certain import requirements related to several animal diseases including BSE, Brucellosis, and Foot and Mouth Disease (FMD) for U.S. live cattle, beef, and beef products. The United States continues to engage with Ecuador to re-open its market to U.S. live cattle, beef, and beef products based on science, the OIE guidelines and the United States' controlled risk status. The United States continues to review the proposed regulation.

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

EGYPT

Food Safety

In June 2011, Egypt began testing imported meat, poultry, dairy products, and fish for dioxin. Domestic products are not tested. In September 2011, Egypt stopped testing fish but decided to continue testing 20 percent of all shipments of the other products from all origins. The United States provided information on the regulation of dioxin in the United States, including the 2008 USDA FSIS survey of dioxin in meat and poultry, and requested that Egypt adopt a risk-based approach in conducting its testing program. The United States also raised concerns about Egypt's dioxin testing procedures, which are not in line with accepted practices in the United States and the EU. The United States will continue to engage with Egyptian authorities on this issue.

Plant Health

Seed Potatoes

Egypt is one of the last of the world's largest seed potato importers that bans imports of most varieties of U.S. seed potatoes due to phytosanitary concerns regarding *Ralstonia* (brown rot). The United States considers that the U.S. seed certification process effectively mitigates *Ralstonia*, and USDA has informed Egypt of that. Nevertheless, Egypt requires registered

varieties to undergo mandatory field trials for three seasons, as well as compliance with a host of other plant quarantine conditions. The United States has urged Egypt to develop a mutually agreeable work plan for conducting the field trials to address their concerns and facilitate commercial shipments of U.S. seed potatoes to Egypt.

Wheat

In 2010, Egypt's Central Administration for Plant Quarantine (CAPQ) of the Ministry of Agriculture imposed a zero tolerance policy for the presence of *Ambrosia* (ragweed) in wheat imports, although 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 the risk that shipments could be rejected because of this restriction. The U.S. Government and U.S. industry are working together to convince CAPQ to remove this unnecessary restriction.

EL SALVADOR

Food Safety

Live Cattle, Beef, and Beef Products

Citing concerns over BSE, El Salvador prohibits imports of U.S. beef and beef products from cattle 30 months of age and over, as well as imports of non-breeding cattle. The United States continues to engage with El Salvador to open fully its cattle, 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.

Poultry

In 2008, the CACM Member States, including El Salvador, notified the WTO of their intent to establish microbiological criteria for a number of foods, including a zero tolerance for *Salmonella* on poultry meat. The United States shared its concern with CACM members through written comments, meetings, and workshops 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*. Nevertheless, the final regulation that CACM adopted in 2009 retained the zero tolerance requirement for *Salmonella*. El Salvador formally adopted the final regulation on June 17, 2009. The United States continues to engage with CACM members, and their various ministries, on this issue through written comments and face-to-face meetings in September 2010, April 2011, July 2011, and February 2012.

ETHIOPIA

Biotechnology

In September 2009, Ethiopia established a biosafety law that may impose unduly burdensome documentation and testing requirements for biotech products. Ethiopia has since issued implementing regulations. U.S. officials continue to engage Ethiopian officials to express concerns about this 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 biotech products have resulted in substantial barriers to trade. Restrictions on biotech products can result in import prohibitions on U.S.-produced commodities and foods, 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 proceeds to the “comitology” process.

Under 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 comprised of representatives from 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 2011, the EU approved only six biotech products with an average approval time of 57 months. In addition, with respect to approvals for cultivation use, the EU has not approved a single biotech product of commercial significance to the United States in over 12 years.

EU delays in biotech product approvals can result in prohibitions not only on the products subject to the delays, but also on shipments of approved varieties. Under the EU’s implementation of its biotechnology legislation, the presence in U.S. grain or oilseed shipments of trace amounts 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, EU Member States approved a Commission proposal to address the presence of trace amounts of EU-unapproved biotech products in import shipments. The new rules, which entered into force on July 20, 2011, only cover shipments of imported animal feed (thus excluding food for human consumption) and provide what appears to be an impractically low threshold level. The Commission has announced that it will assess the need to include food within the scope of the rules, but not before June 2012.

The EU has taken steps to address some but not all of the Member State bans that the WTO panel found to be inconsistent with the EU’s WTO obligations. Member States have continued to adopt new bans on products approved at the EU-level, however. In most cases, the Commission requests EFSA to 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. The proposal would allow Member States to restrict or prohibit the cultivation of biotech crops in all or part of their territory. The legislative proposal does not require Member States to base any such restrictions on safety concerns, but allows the Member States to take into account other societal concerns.

The EU continues to restrict imports of U.S. long grain rice following the discovery in 2006 of the genetically engineered Liberty Link 601 (LL601) trait. Since 2006, the U.S. rice industry has effectively removed the trait through rigorous seed testing under an industry-wide protocol (called “the Seed Plan”), but European rice importers and retailers have largely refused to purchase U.S. rice out of fear of the legal and commercial consequences should a detection of the LL601 trait occur again.

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

Food Safety

Beef and Beef Products – Hormones

In May 2009, the United States signed a memorandum of understanding (MOU) with the EU to resolve on a provisional basis their WTO dispute over U.S. 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 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 as of March 2009 but committed not to impose new duties on EU products during the initial three-year period and to eliminate all retaliatory import duties during the fourth year.

Pursuant to the MOU, the two sides may elect to begin a second phase of market openings in August 2012. Under this procedure, the EU would increase its beef import quota to at least 45,000 MT and the United States would lift its remaining additional duties. In compliance with a decision of the United States Court of Appeals for the Federal Circuit, USTR terminated the additional U.S. duties in advance of the August 2012 start date for the optional second phase. The EU has started its approval procedure to increase the EU quota to 45,000 MT.

The United States will continue to monitor EU implementation of the MOU, as well as other developments affecting access to the EU market for U.S. beef products.

Beef – Pathogen Reduction Treatments

In December 2010, USDA requested the Commission to approve the use of lactic acid as a pathogen reduction treatment (PRT) in processing of beef carcasses and meat. The Commission subsequently requested EFSA do a risk assessment on the use of lactic acid as a beef PRT. In July 2011, EFSA issued its risk assessment, which concluded that beef treated with lactic acid as a PRT is safe for human consumption. The Commission has since drafted a proposed regulation on lactic acid. The United States continues to closely monitor developments.

Cherries

The EU requires cherries to be free of *Monilinia fructicola* (brown rot) and requires documentation that controls have been applied in the field. This requirement limits the supply of U.S. cherries that would otherwise qualify for export to the EU. While brown rot is known to also exist in some EU Member States, the EU does not require the same field trials for EU Member States where brown rot is found. The United States is currently engaged with EFSA to find a resolution to this issue.

Food Additives – Colors

On July 20, 2010, the EU implemented regulations that require manufacturers to apply hyperactivity risk warning labels on food products containing any of six synthetic colors (Sunset Yellow, Quinoline Yellow, Carmoisine, Allura Red, Tartrazine, and Ponceau 4R). The labels must state 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 about 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, it does not consider that warning labels are necessary. The United States is continuing to engage the EU in technical discussions on this issue. The U.S. confectionary

industry believes EU labeling requirements for color additives disadvantage U.S products in the EU market.

Poultry – Pathogen Reduction Treatments

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.

Seafood

Prior to 2008, the EU authorized imports of U.S.-origin molluscan shellfish under the terms of the United States-European Community Veterinary Equivalence Agreement. In 2008, the Commission’s Directorate General for Health and Consumers 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 all U.S.-origin molluscan shellfish other than 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. molluscan shellfish are safe to consume. The United States believes that the EU has the information it needs to allow imports of U.S. molluscan shellfish to resume.

Animal Health

Animal By-Products

In 2002, the EU published Regulation (EC) 1774/2002, which established problematic new requirements related to BSE 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.

In 2009, the EU published Regulation (EU) 1069/2009 to begin the replacement of Regulation (EC) 1774/2002. This regulation addressed many major U.S. concerns, but also raised additional concerns. Regulation (EU) 1069/2009 did not change the requirements for importing animal by-products into the EU, but laid the groundwork for Regulation (EU) 142/2011, which did replace the requirements for importing tallow.

Regulation (EU) 142/2011, which took effect in March 2011, does allow limited U.S. tallow to be exported for certain purposes, mainly for the production of biodiesel. However, U.S. industry has found the requirements, which exceed OIE recommendations for tallow processing and channeling protocols, to be overly burdensome. Notably, the regulation continues to block U.S. exports of products containing tallow, which the OIE does not consider a BSE risk. This includes products such as pet food and ingredients containing protein-free tallow, and tallow for livestock consumption, renewable fuel production, organic fertilizers, and soil. As a result, U.S. industry has not begun to export these products. In addition, the EU is currently revising its regulations to require processing techniques that are not practiced in the United States. The U.S. Government has requested an opportunity to comment on the upcoming changes before they are finalized, but the EU has not yet provided a current draft.

Milk

The EU limits the number of white blood cells in raw milk, as measured by the somatic cell count (SCC) level, as part of its public health requirements for dairy product imports. This requirement is burdensome for U.S. exporters as the FDA allows raw milk to be sold in the United States with higher SCC levels than the EU does. Moreover, the FDA considers the SCC level to be a quality rather than food safety criteria and as such SCC should not be required for public health purposes. The United States will continue to work with EU authorities to resolve this issue.

EU Country Specific Issues

Austria

Biotechnology

Since 1997, Austria has maintained a series of cultivation and import bans on agricultural products derived from modern 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 corn (a pest-resistant corn variety) 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 concerns with 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 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

Greece maintains a ban on all biotech cultivation as well as the importation of several biotech products. 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. Nevertheless, in August 2009, Greece extended the ban for another two years and expanded the measure to include cultivation. Greece now maintains its bans on MON 810 by invoking the "safeguard clause" discussed above.

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

Hungary

Biotechnology

In 2011 Hungary implemented new rules relating to biotech seed testing. The testing policy does not address any identifiable environmental or health risks, the testing methodologies are not transparent, and test results may not be challenged on technical grounds. In senior level meetings, USDA registered concern with how Hungary is handling the issue of seed testing and advocated the importance of science-based, transparent regulations to agricultural investment.

Hungary maintains three differing testing policies based on the origin of the seed. Seed produced in Hungary is subject to random testing for the presence of GE products, but no comprehensive testing and certification is required. Seed imported from another EU Member State is required to have a testing certificate from an accredited EU lab. Seed imported from a third country requires testing by a Hungarian government lab. As the Hungarian labs do not follow transparent processes, do not use standard methodologies, and do not allow test results to be challenged, non-EU seed producers appear to be at a disadvantage to EU seed producers.

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

Italy

Biotechnology

Numerous actions attest to the fact that Italy is pursuing a GE-free strategy. Italy has one of the most anti-biotech voting records in the EU and has failed to authorize biotech field trials despite EU ministerial approval. For the past decade, Italy has maintained a *de facto* ban on the cultivation of EU-approved biotech crops by creating fragmented national and regional biotech authorities in addition to the EU authority. Moreover, Italy has not established a national legal framework for the cultivation of GE products.

Italy did not notify the EU of its deviation, and as a consequence, jurisdiction for establishing if there is a conflict between the EU and Italian rules rests with EU and Italian courts. However, the courts have failed to find jurisdiction. Italy also requires mandatory co-existence (keeping GE and non-GE products separate during production) rather than the recommended EU regulations. Seed importers report that they are subject to criminal penalties for the adventitious (*i.e.*, accidental or unintended) presence of biotech seeds in commercial shipments of non-biotech seeds.

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, 95 percent of the 109 municipalities in Latvia have banned the cultivation of biotech crops in response to strong consumer activism and tacit support of the Ministry of Environment. 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 an 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 "GE-free." In 2006, Poland passed legislation that banned the sale and registration of biotech seeds, restricted Polish representatives to the European Parliament from supporting pro-biotechnology legislative proposals, and prohibited the importation, production, and use of animal feed derived from biotech crops beginning in August 2008. On July 27, 2008, Poland's president authorized a delay through January 1, 2013, in implementing the provisions of the law governing animal feed. Separately, the Polish Parliament is in the process of preparing comprehensive legislation to regulate registration, research, production, and trade in products derived from modern biotechnology. The new law is expected to be completed 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 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 States, 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 through written comments, meetings, and workshops, its concern that the proposed zero tolerance for *Salmonella* on poultry meat appeared to lack a scientific basis. The United States explained that 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*. Nevertheless, the final regulation that CACM adopted in 2009 included the zero tolerance requirement for *Salmonella*. Guatemala adopted the final regulation on July 19, 2009. The United States has continued to engage with CACM Member States on this issue through written comments and in face-to-face meetings held in September 2010, April 2011, July 2011, and February 2012.

GULF COOPERATION COUNCIL

Food Safety

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 appeared to lack a scientific basis and which would substantially disrupt food exports to GCC Member States. In early 2011, the GCC submitted proposed revised import procedures to the WTO. In September 2011, the United States provided written comments on the revised procedures to the GCC. The GCC is currently studying the comments, and the United States continues to monitor the issue closely.

HONDURAS

Food Safety

Poultry

In 2008, CACM member states, 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 through written comments, meetings, and workshops, its concern that the proposed zero tolerance for *Salmonella* on poultry meat appeared to lack a scientific basis. The United States explained that 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*. Nevertheless, the final regulations that CACM adopted in 2009 included zero tolerance requirement for *Salmonella*. Honduras adopted the final regulation on July 19, 2009. The United States has continued to engage with CACM members on this issue through written comments and in face-to-face meetings held in September 2010, April 2011, July 2011, and February 2012.

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 accompanied by numerous restrictions that appear to be inconsistent with the OIE guidelines. These unwarranted restrictions discouraged limited 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 from the site visits, to which the United States subsequently responded. The United States continues 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 U.S.-origin 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.

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

Pork

The Indian import certificate for pork requires that importers make an attestation that the imported pork does not contain any residues of pesticides, veterinary 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 vague animal health attestations, and demands extra inspections that do not appear to be consistent with international standards. India also 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. The United States has requested India's authorities to perform a risk assessment to support its restrictions on pork imports and continues to press India to lift the restrictions.

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

Animal Health

Poultry and Swine

Since 2006, India has banned imports of U.S. poultry, swine, and related products purportedly because of LPPI outbreaks in the United States. The United States has repeatedly raised concerns in the WTO SPS Committee about India's import bans, and has discussed these concerns with Indian officials numerous times, including in a high-level dialogue under the U.S.-India Trade Policy Forum. The United States and other trading partners have demanded that India lift its ban.

India also continues to require AI certification statements for dry processed pet food. This requirement does not appear to be consistent with OIE guidelines and has effectively stopped imports of the product.

While the United States continues to raise these concerns in bilateral and multilateral fora, the United States requested consultations with India regarding its import ban pursuant to the WTO dispute settlement procedures on March 6, 2012.

See section III.A for an explanation of the export certification trade issue and section III.D for an explanation of the AI trade issue.

Plant Health

Wheat and Barley

India maintains zero-tolerance standards for certain plant quarantine pests, such as weed seeds and ergot, which block U.S. wheat and barley imports. Bilateral discussions to resolve these issues, including at the senior official level, have achieved little success to date. On June 28, 2011, U.S. and Indian officials discussed this issue, and India agreed to collaborate further by exchanging ergot strains and testing them on barley under controlled conditions.

INDONESIA

Animal Health

Animal Derived Products

In October 2009, Indonesia announced Law 18/2009, which requires companies that export animal-derived products, such as dairy and eggs, to Indonesia to complete a pre-registration process with the Indonesian Trade Ministry. The law allows imports of these products only from facilities that the Indonesian authorities have individually audited and approved. Indonesia issued implementing regulations in November 2011 that impose overly stringent requirements concerning animal health and food safety. To date, Indonesia has not notified the WTO of Law 18/2009.

In an effort to resolve Indonesian concerns about U.S. dairy exports, in September 2011 the United States hosted a team of Indonesian inspectors that audited the U.S. food safety system for dairy products as well as a representative sample of dairy establishments. The Indonesian team provided the United States an audit report within two months after the audit concluded, and agreed to a simplified questionnaire for U.S. dairy facilities seeking to pre-register. The United States and Indonesia are currently working together to develop a new, transparent system for U.S. establishments to become eligible to export dairy products to Indonesia. At the same time, the United States will continue to work to resolve impediments under Indonesian law to imports of U.S. meat and poultry, including the restrictive regulations that Indonesia has put in place to implement Law 18/2009.

Plant Health

Port Closure

On January 3, 2012, Indonesia announced plans to close the Port of Jakarta to fruit and vegetable imports effective March 19, 2012. Under pressure from several trading partners, including the United States, on March 6, 2012, Indonesia announced a three month delay in the port closure moving the date from March 19 to June 19. The port closure regulation will restrict entry of fresh fruits and vegetables into Indonesia to four ports. Due to the distance between the ports and Jakarta, a major population center, this port closure will be commercially burdensome. If implemented, the port closure would seriously disrupt U.S. exports of fresh fruits and vegetables to Indonesia, which totaled about \$111 million in 2011. Indonesia announced the planned closure without notifying trading partners in advance. Indonesia has provided various conflicting explanations for the proposed closure, including certain phytosanitary control risks. The U.S. Government is engaging at the highest levels to dissuade Indonesia from closing the port.

ISRAEL

Food Safety and Animal Health

Live Cattle, Beef, and Beef Products

In 2003, Israel restricted U.S. exports of live cattle, beef, and beef products following the detection of a BSE-positive animal in the United States. These restrictions were not consistent with OIE requirements. Although Israel's 2011 policy on BSE permits imports of U.S. cattle, small ruminants, and associated breeding material, the United States and Israel have not agreed on a protocol for the import of live cattle, beef, and beef products, which is necessary for trade in these products to occur. In December 2011, to further the process of agreeing on a protocol, the United States provided detailed responses to an extensive questionnaire from Israel concerning U.S. veterinary services. Israel is reviewing the U.S. response. 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' classification as a controlled BSE risk country.

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

Plant Health

Apples and Pears

In March 2009, Israel's Plant Protection and Inspection Service (PPIS) informed the United States that U.S. apples and pears would be subject to new cold treatment requirements to mitigate the risks of two pests, the apple maggot and the 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 initially granted the United States an exemption from these requirements until June 1, 2010. The exemption has been renewed twice and currently extends until September 1, 2012. USDA has asked PPIS to consider adopting a new approach for controlling the risk of entry of apple maggots. USDA and PPIS continue to discuss the U.S. proposal.

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

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 has stated that it intends to conduct a risk assessment in response to the U.S. request for pork market access. In January 2011, APHIS officials returned to Jamaica for additional consultations. Despite numerous requests from the United States, Jamaica has not provided a risk assessment. The United States will continue to press Jamaica to open its market to 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, conditions imposed by Japan, including certain border measures, are restrictive and have made it difficult for the United States to regain a level of trade that approaches historic levels of exports to the Japanese market.

In December 2011, Japan started a process for reassessing its BSE-related trade restrictions, which the United States views as an important step that puts the United States and Japan on a path to addressing the longstanding issue of U.S. beef trade with Japan. As the first step of the process, in December 2011, at the request of Japan's Ministry of Health, Labor and Welfare (MHLW), the Japanese Food Safety Commission initiated a risk assessment to examine raising the maximum age of the cattle from which U.S. beef can be exported to Japan, as well as revising the definition of specified risk materials. The United States will continue to press Japan on this important issue at all levels and at every opportunity and is working to open Japan's market to U.S. beef and beef products based on science, the OIE guidelines, and the United States' controlled risk status and in a manner that is commercially viable.

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

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 Japan created a list of 46 food additives that would be subject to an expedited approval process. As of March 2012, six of the 46 additives remained unapproved. The United States understands that Japan is currently reviewing the remaining six additives. The United States has urged Japan to complete work on the reviews and to develop a meaningfully expedited process for reviewing all future requests for food additive approvals. U.S. officials have also requested Japan to use such an expedited review process for additional, globally-used additives.

In August 2010, Japan proposed to remove 80 food additives not used domestically from its official list of additives approved for use in food sold in Japan. Some of these additives are used by U.S. producers, and their removal threatened U.S. exports to Japan. The U.S. Government and U.S. industry submitted comments and supplemental information to Japan. After reviewing these comments, MHLW agreed to continue to allow the use of 25 of the 80 additives. Many of the 25 additives are used by U.S. producers. Japan's decision – which covered all additives that the United States asked Japan to retain on its list of approved additives – averted potential disruptions to U.S. exports.

Gelatin

Japan banned the importation of U.S.-origin ruminant gelatin for human consumption (along with the importation of most other ruminant origin tissues from the United States) following the detection in December 2003 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, no modification has been made 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 Fungicides

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 a separate risk assessment. As a result, registrants of fungicides that may be used both pre- and post-harvest must ensure that two risk assessments are performed, a process that is redundant and that can take as long six years to complete. The requirement for dual risk assessments deters registrants from pursuing approval for new and safe products.

Japan's dual risk assessment requirement does not have a significant impact on domestic producers, as Japanese farmers do not generally apply fungicides 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 fungicide is applied and focuses on the characteristics of the residue and the amount of residue present, regardless of the time of application to the crop.

In May 2010, Japan announced a decision to streamline the review process for agricultural chemicals applied both as pesticides (pre-harvest application) and as food additives (post-harvest application). However, it remains unclear as to whether this modified process will reduce the length and duplication of the previous process. The United States will continue to monitor this process and work with Japan to eliminate duplicative review requirements.

Maximum Residue Limits

In July 2009, the United States and Japan concluded an MOU on MRLs that changed the way in which MRL violations are handled by establishing a mechanism under Japan's import and food monitoring policy for U.S. shippers to address violations quickly. While there has been progress in how U.S. violations are handled, the United States remains concerned that Japan's procedures for dealing with MRL violations still place a burden of industry-wide enhanced surveillance for a given product after a single violation.

In addition, Japan's slow and burdensome review process for approving pesticides and fungicides and the lack of established MRLs continue to create risk of unnecessary trade disruptions. The United States continues to work closely with Japan on these issues, including through data exchanges aimed at assisting Japan in its approval of new MRLs.

See section III.E 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 that do not appear to be based on risk. 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 require, at its option, an additional test for shipment insurance purposes. Although the insurance test is technically optional, MAFF is the only legal buyer of imported rice and always requires the insurance test, effectively making it mandatory. The United States will continue to urge Japan to streamline its apparently excessive testing requirements.

Animal Health

Poultry

U.S. poultry meat and poultry products, including egg products, are currently exported to Japan in accordance with a 2002 animal health protocol purportedly aimed at preventing AI. 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.D for an explanation of the AI trade issue.

Plant Health

Fresh and Chipping Potatoes

Until January 2006, Japan banned all imports of fresh potatoes from the United States due to phytosanitary concerns. On February 1, 2006, MAFF and USDA reached an agreement to allow limited imports of U.S. fresh potatoes from 13 states to produce potato chips. The agreement limited shipments to a single chipping facility and provided for a shipping period of just five months (February to June).

Once the agreement was implemented, USDA began working steadily with MAFF to expand access for U.S. potatoes. This work has resulted in a \$5 million per year increase in exports. In 2010, an additional state (Washington) was added to the list of states eligible to ship chipping potatoes to Japan. In June 2011, MAFF approved a second chipping facility to process U.S. potatoes. In July 2011, MAFF extended the eligible shipping period to include July. USDA continues to negotiate with Japan for increased access for U.S. potatoes.

Pears

Japan currently prohibits the importation of pears from the United States due to concerns about fire blight, a bacterial disease. The United States continues to urge Japan to acknowledge that mature, symptomless fruit produced under commercial conditions has not been shown to transmit the disease, and to allow imports of U.S. pears on that basis.

Requirements for New Cherry Varieties

Japan only approves imports of new fresh cherry varieties based on individual fumigation trials. 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 under a single fumigation protocol, which would mean that all varieties may be imported without the need for separate testing. The United States continues to urge rapid resolution of this concern.

KAZAKHSTAN

Systemic Issues

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.

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 many additional agreements that harmonize SPS measures. These agreements create a unified list of goods subject to veterinary, phytosanitary, and sanitary-epidemiological control at the customs border and within the territory of the CU, set unified veterinary and sanitary epidemiological and hygienic requirements for those goods, and establish a single form of documentation used to confirm the safety of those goods. On July 1, 2010, the CU implemented harmonized veterinary requirements, which stipulate that imports of 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. The CU’s SPS measures have the potential to restrain U.S. exports.

Pursuant to those measures, Kazakhstan now requires any importer or domestic producer of certain types of goods to obtain a Certificate of State Registration before the product can be sold. In Kazakhstan, the Ministry of Health's Committee of State Sanitary and Epidemiological Supervision is responsible for issuing these certificates. Goods subject to this certification requirement include:

- mineral water, drinking water in bottles, tonic water, and 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).

During 2011, the CU amended several of its SPS agreements, including aligning certain SPS requirements with international standards. The U.S. Government is working with Kazakhstan to encourage improvements in the CU’s SPS regime and to ensure that implementation of the CU’s SPS measures is not trade disruptive.

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 and lacks clarity with respect to liability and the protection of confidential business information. The draft law also establishes a

ban on the use of biotech products in food for children. The United States has requested Kazakhstan to provide a risk assessment supporting the draft law, but it has not done so. The United States has raised concerns about these issues urging Kazakhstan, if it approves and implements the law, to consider an interim system for biotech approvals to avoid disrupting imports of products currently sold in Kazakhstan.

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

Food Safety

Pork

Kazakhstan requires imported pork to be shipped frozen to mitigate the risk of trichinae. The United States does not consider this mitigation measure to be necessary for U.S. pork as U.S. producers maintain stringent biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. The United States will continue to work with the regulatory authorities in Kazakhstan and the CU to resolve this trade concern.

KUWAIT

Food Safety

Beef and Beef Products

In 2006, following the detection of a BSE-positive cow in Alabama, two government offices in Kuwait – the Kuwait Public Authority for Agriculture and Fishery Affairs and the Municipality of Kuwait – banned all live cattle and beef from Oklahoma, not Alabama. USDA has worked to rectify the situation, and was able to convince both offices to remove the ban on live cattle from Oklahoma. However, the Municipality of Kuwait has refused to remove the ban on beef produced in Oklahoma, despite continued the continued engagement of USDA. Live cattle and beef from Alabama remains eligible for export to Kuwait. The United States will continue to engage with Kuwait to open fully 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 a discussion of the BSE trade issue.

KYRGYZSTAN

Food Safety

Pork

Kyrgyzstan maintains a ban on U.S pork exports from several U.S. states due to concerns regarding the H1N1 virus. Kyrgyzstan instituted the H1N1-related ban on U.S. pork even though there is no evidence to indicate that the virus can be conveyed to humans through the consumption of pork. The WTO, OIE, FAO, and WTO all issued statements shortly after the

H1N1 outbreak reminding countries that import bans on pork based on H1N1 concerns are unjustified in light of this fact.

MALAYSIA

Food Safety

Malaysia's Department of Veterinary Services (DVS) requires a permit for all pork imports, and limits imports to 10 cuts of meat. The permits are granted on a case-by-case basis and are sometimes refused without explanation. In June 2011, the DVS instituted a series of measures that further restrict imports of U.S. pork. For example, all pork exporters must complete an extensive and burdensome application form and must submit to an audit by DVS for which the producer must pay. DVS approves plants for a maximum of two years, at which time a plant must repeat the entire inspection process to obtain a new approval. The United States has raised concerns over these requirements with Malaysia on multiple occasions and is actively working towards a resolution to avoid further disruption of U.S. pork exports.

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 due to BSE concerns 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 any age, including ground beef, are banned.

In August 2010, the United States hosted a Mexican technical team that conducted a verification visit to review the efficacy of U.S. BSE-related safeguard measures. In June 2011, Mexico provided the United States with a copy of its trip report for the August 2010 visit and the draft results of its risk assessment. These documents are now the basis for continued multi-agency bilateral dialogue and negotiation on access to the Mexican market for 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.

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 testing requirement, under which 100 percent of combos would be tested at the border, until the publication of new regulations for combo import inspection. However, Mexico has yet to develop a risk-based inspection system for chilled meats that is not unnecessarily burdensome to trade. Uncertainty surrounding the nature of Mexico’s new inspection system, as well as uncertainty about its date of implementation, has concerned U.S. meat exporters. The United States continues to monitor the development of Mexico’s new inspection regime.

Plant Health

Potatoes

Mexico prohibits the shipment of U.S. fresh potatoes beyond a 26 kilometers zone along the U.S.-Mexico border. Although the two countries reached an agreement in 2003 that provided a process for allowing U.S. potatoes access to the whole of Mexico over a three-year period, Mexico has been slow to implement the agreement. In late 2011, Mexico advised that it would modify the existing potato regulation as part of a technical administrative process that could take several years to complete.

The United States and Mexico have had significant engagement on this issue. USDA sent a risk mitigation proposal to Mexico in early November 2010. In December 2010, the U.S. and Mexican Secretaries of Agriculture agreed to explore alternative approaches to resolve this issue, including third-party mediation. Subsequently, Mexico and the United States agreed to mediate this issue under the auspices of the North American Plant Protection Organization. The mediation has now concluded. The United States will continue to press Mexico for a science based solution.

Stone Fruit

U.S. peach, nectarine, and apricot growers encounter problems due to Mexico’s approach to controlling the oriental fruit moth and a number of other pests.

California

Under the California Stone Fruit Work Plan, Mexico imposes a high level of oversight on the operations of California stone fruit producers shipping to Mexico as a condition for access to Mexico’s market. This program requires the industry to pay for a large number of inspectors representing the Mexican government to inspect their operations for the oriental fruit moth and other pests. The United States has sought to reduce the expensive and high level of Mexican government oversight of U.S. producers through on-going

bilateral discussions and meetings. A draft protocol that would reduce oversight requirements is under discussion.

Georgia and South Carolina

In 2008, USDA asked Mexico to open its market for stone fruit from Georgia and South Carolina. Mexico agreed to complete a PRA in connection with 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 Work Plan. Although the work plan is more stringent and expensive to implement than necessary, it allowed Georgia and South Carolina producers to begin shipping to Mexico in late summer 2011.

Pacific Northwest

USDA is awaiting a PRA from Mexico to address a request to allow peaches from the Pacific Northwest to be shipped to Mexico. Mexico has stated that in the absence of the PRA, it would accept peaches from this region only if they were produced under oversight similar to that conducted in California. Pacific Northwest producers believe that due to the low risk associated with the region, any Mexican export program should require minimal oversight. The United States and Mexico met in January 2011 to discuss the issue and committed to engage in further discussion. Mexico is in the process of completing its PRA. In that regard, Mexico completed a site visit in November 2011 in the Pacific Northwest.

MOROCCO

Food Safety and Animal Health

Morocco restricts imports of U.S. live cattle, beef, and beef products due to concerns over BSE and growth hormones, and restricts imports of U.S. poultry and poultry products due to AI and *Salmonella* concerns. Morocco and the United States are working to reach agreement on sanitary certificates consistent with international standards that would allow U.S. producers to export these products to Morocco.

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

NEW ZEALAND

Animal Health

Pork

New Zealand restricts imports of all U.S. pork except 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 additional cuts of uncooked pork. However, New Zealand has not yet approved these provisional standards. The United States continues to engage with New Zealand on this issue.

NICARAGUA

Food Safety

Poultry

In 2008, the CACM Member States, including Nicaragua, 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 through written comments, meetings, and workshops, its concern that the proposed zero tolerance for *Salmonella* on poultry meat appeared to lack a scientific basis. The United States explained that it is generally accepted by food safety experts and scientists that this pathogen cannot be entirely eliminated from raw meat but that proper storage, handling, and cooking of raw meat reduce significantly the risk of a number of food-borne diseases caused by *Salmonella*. The final regulation that the CACM adopted in 2009 included a zero tolerance requirement for *Salmonella*. Nicaragua formally adopted the regulation on September 10, 2009. The United States has continued to engage with CACM members on this issue through written comments and in face-to-face meetings held in September 2010, April 2011, July 2011, and February 2012.

NORWAY

Biotechnology

With limited exceptions, since 1996 Norway has effectively banned 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 applies 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

Biotechnology

In December 2011, Peru enacted a ten-year moratorium on imports and production of GE products and animals. Although the moratorium exempts those GE products or GE-derived products for human consumption, feed, or processing for which a risk assessment has been performed, to date Peru has not conducted any GE-related risk assessments. The United States is concerned that Peru's potential lack of capacity to conduct risk assessments for GE products, as well as test for the presence of GE products in imported commodities could create uncertainty in the market and potentially disrupt U.S. exports.

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

Food Safety

Pork

Peru requires U.S. pork be shipped to its market either frozen or tested due to concern over trichinae. The United States believes that this requirement is unnecessary as U.S. producers maintain stringent biosecurity protocols that serve to limit the incidence of trichinosis in the United States to extremely low levels. The United States continues to work with regulatory authorities in Peru to resolve this trade concern.

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 States (Bolivia, Colombia, and Ecuador) 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 that stipulated that only live animals under 24 months of age could be imported. CAN Resolution 1314, published April 2010, stipulated that all CAN Member States could be able to elaborate their own requirements regarding the importation of live cattle from the United States in accordance with the CAN risk assessment. Peru has yet to lift its ban on U.S. live cattle.

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

Food Safety

Frozen and Chilled Meat and Meat Products

The United States continues to have serious concerns about the trade consequences of SPS policies affecting sales of imported meat in the Philippines, including a two-tiered system for regulating the handling of frozen and freshly slaughtered meat in the distribution system. This system imposes very high standards on the handling of frozen meat, which is primarily imported, that do not apply to the handling of freshly slaughtered meat, which is exclusively domestic. In addition, the United States is concerned about trade disruptive test and hold policies that have been administered prior to customs clearance. The United States has raised its concerns with the Philippine government on numerous occasions and will continue to do so.

Plant Health

Quarantine Clearance

The Philippine Department of Agriculture (DA) requires a plant quarantine certificate for processed plant products (*e.g.*, frozen french fries and raisins) as well as a phytosanitary certificate issued by the exporting country's regulatory authority. This requirement appears to be duplicative, because existing Philippine Food and Drug Administration requirements already address the food safety issues associated with these products. The United States continues to engage with the Philippines on this issue.

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

Market Access for U.S. Vegetables

The United States is concerned with the length of time that the Philippines takes to complete PRAs for fresh fruits and vegetables. The United States requested the Philippines to perform PRAs for U.S.-grown broccoli, cauliflower, lettuce, carrots, cabbage, and celery in 2006, and a PRA for U.S. fresh potatoes in 2009. The DA provided its PRAs for these products to the United States in May 2011, and USDA is currently evaluating them. Until the entire PRA process, including agreement on the PRA results and pest mitigations, is completed for each product, the DA will only allow a limited amount of these vegetables to enter the country, on a case-by-case basis, for "high-end markets," such as hotels, restaurants, and airline companies.

RUSSIA

Systemic Issues

On December 16, 2011, Russia was invited to accede to the WTO. When it accedes, Russia will be obligated, like all other WTO Members, to ensure that its SPS measures comply with the requirements of the SPS Agreement (*e.g.*, they are based on scientific principles, not maintained

without sufficient scientific evidence, and are only applied to the extent necessary to protect human, animal, or plant life or health).

The entry into force of the CU between Russia, Kazakhstan, and Belarus has complicated trade into and among the three countries as they harmonize and revise their SPS measures.

On December 11, 2009, Russia signed the Agreement of the Customs Union on Sanitary Measures and the Agreement of the Customs Union on Veterinary and Sanitary Measures. Russia, Belarus, and Kazakhstan subsequently concluded additional agreements to harmonize SPS measures and unify the list of goods subject to veterinary, phytosanitary, and sanitary-epidemiological control at the CU's customs border. These agreements also unify the veterinary and sanitary epidemiological and hygienic requirements on those goods within the CU, as well as the form of documentation importers must provide to confirm those requirements have been satisfied.

On July 1, 2010, the CU implemented harmonized veterinary requirements stipulating that imports for all controlled products subject to veterinary control are eligible for entry only if they are produced in facilities on a list approved by all three CU countries. The United States worked with Russia to remove products from the list of goods subject to veterinary control where no scientific basis supporting their inclusion was apparent, to eliminate the requirement that the United States provide a list of all facilities that meet CU requirements for goods subject to veterinary control, and to streamline the approval of U.S. facilities. In 2011, the CU countries amended the CU agreements to align some of the veterinary requirements with international standards, recommendations, and guidelines, but those efforts remain underway. In addition, the CU issued new decisions in preparation for Russia's accession to the WTO governing risk assessments and equivalence, harmonization with international standards, and inspection of facilities.

U.S. exporters continue to face systemic issues in Russia related to the certification of agricultural products. In particular, Russia requires export certificates for products for which certifications are unnecessary or are otherwise unwarranted. For example, Russian certifications require phytosanitary attestations for shipments of such processed agricultural products as soybean proteins, corn gluten, and distiller's grains, which, due to the nature of the processing process, do not present a pest risk. Likewise, Russia requests U.S. exporters to submit certifications stating that the United States is free from various livestock diseases, even where there is no risk of transmission from the product in question. To date, the United States has not received scientific justifications nor risk assessments for many of Russia's SPS requirements. The United States continues to engage with Russia to modify these requirements and supply the United States with scientific justifications, where appropriate.

In November 2006, the United States and Russia signed bilateral agreements to address SPS issues related to: trade in pork, beef and beef by-products, biotech agricultural products, and certifications for U.S. pork and poultry establishments that export 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 inspection of meat and poultry establishments, Russia agreed to grant U.S. regulatory officials the authority to certify new U.S. establishments

and U.S. establishments that have 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. In practice, however, Russia has not consistently recognized the authority of U.S. regulatory officials to certify additional U.S. facilities, and there have been delays in responding to U.S. requests to update the list of approved U.S. facilities.

The Customs Union now has competence for plant inspections, and consequently, the United States is currently seeking an agreement with the CU countries regarding inspections for meat and poultry plants. The United States worked closely with Russia to negotiate a new CU inspection regulation that allows the CU to accept guarantees provided by SPS authorities in third countries that certify new establishments.

Veterinary Certificates

Russia requires veterinary certificates to include broad statements by U.S. regulatory officials that the products satisfy Russia's sanitary and veterinary requirements, including meeting certain chemical, microbiological, and radiological standards. This requirement is problematic, because many of Russia's sanitary and veterinary requirements appear to lack scientific justification.

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

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 this system, including Russia's 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 specific concerns, as well as greater cooperation on biotechnology generally, with Russia through the U.S.-Russia Biotechnology Consultative Mechanism.

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

Food Safety

Pathogen Tolerances

Russia maintains a zero tolerance policy for *Salmonella*, *Listeria*, and *coliforms* in all food products, including raw meat and poultry. Such a policy is unwarranted, because it is generally accepted by food safety experts and scientists that these pathogens cannot be removed entirely from raw meat and that proper storage, handling, and cooking of raw meat and poultry significantly reduce the risk of a number of food-borne diseases caused by these pathogens.

Veterinary Drugs

Russia maintains zero tolerances for residues of unapproved veterinary drugs, many of which are commonly used in U.S. animal production, as well as zero or near-zero tolerances for approved veterinary drugs. There have also been indications that Russia intends to begin testing and implementing a zero-tolerance policy for residues of ractopamine in 2012. Findings of such agents during Russian border inspection of U.S. products have resulted in multiple delistings of U.S. beef, pork, and poultry facilities.

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 meet the requirements set out in the U.S.-Russia Bilateral Agreement on Trade in Beef. Following the completion of consultations regarding common CU veterinary requirements, the United States initiated with Russia and its CU partners, negotiations of a new 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 will resume.

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

See section III.A for an explanation of the export certification trade issue, and section III.C for an explanation of the BSE trade issue.

Dairy

Russia has effectively banned the importation of U.S. dairy products since September 2010, when Rosselkhoznadzor (Russia's Federal Service for Veterinary and Phytosanitary Surveillance) instructed customs officials to allow shipments only from exporters on Rosselkhoznadzor-approved lists. During WTO accession negotiations, the United States successfully obtained a commitment from Russia that it would no longer require any foreign producer to be included on Rosselkhoznadzor lists to be eligible to export dairy products. The United States is seeking to re-engage in negotiations with Russia to develop a new dairy certificate that would reopen the Russian market to U.S. dairy products.

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

Pork and Pork Products

Russia maintains near-zero tolerance levels for tetracycline-group antibiotics. The United States, in cooperation with industry stakeholders, reviewed Russia's risk assessment for tetracyclines and provided comments to Russia. Russia agreed as part of its WTO accession commitments to submit a risk assessment for tetracycline antibiotics conducted in accordance with Codex

methodology or align its tetracycline standards with Codex standards. The United States continues to press Russia to ensure that its measures on this subject are based on science.

Russia also requires U.S. pork to be frozen or tested for trichinosis. Russia's requirements constitute a significant impediment to U.S. fresh and chilled pork exports to Russia. The United States does not consider these requirements to be necessary because U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low levels. The United States will continue to work with regulatory authorities in Russia to resolve this trade concern.

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 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, despite calls to adopt alternative labeling requirements regarding water content. In addition, Russia continues to ban the importation and sale of certain frozen poultry for use in baby food and special diets. Russia has not yet provided the United States with risk assessments to support these various regulations.

Animal Health

Grains and Oilseeds

Exports to Russia of U.S. grain and oilseed products for use in animal feed are severely limited due to Russia's requirement for producers to provide veterinary certificates warranting that their products are free of animal diseases. As part of its WTO accession commitments, Russia has agreed that it will no longer require veterinary certificates for animal feeds of plant origin.

Pet Food

Russia does not allow the importation of pet food containing U.S. beef due to alleged BSE concerns. For those pet food imports that it does allow, Russia requires heat treatment processing procedures and microbial testing that appear to be unwarranted.

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

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.

Pork

Singapore currently prohibits the use of all PRTs in the production of pork and pork products. This prohibition adds significantly to the cost of exporting pork and does not appear to be based on science as pork treated by FDA-approved PRTs is safe for human consumption.

In addition, Singapore requires U.S. pork to be frozen or tested for trichinosis. The United States does not consider these requirements to be necessary since U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low levels. The United States will continue to work with regulatory authorities in Singapore to resolve this trade concern.

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 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 continues to engage with South Africa to fully open its market to the full range of 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 throughout all 50 states. The United States continues to work with South Africa to address the current freezing requirement for pseudorabies.

Plant Health

California Table Grapes

South Africa suspended imports of table grapes from California due to concerns over two plant pests: the European grapevine moth and the light brown apple moth. The California Department of Agriculture and USDA have implemented comprehensive quarantine programs to prevent the dissemination of these pests in California and throughout the United States, as well as to ensure that consignments of exported table grapes are free of both pests. The United States has asked South Africa to reconsider its suspension of table grape imports from California given the phytosanitary mitigation measures currently in place.

In addition, the United States and South Africa are reviewing options to harmonize both countries' mitigation measures for mites inspection rather than using fumigation.

SOUTH AFRICAN DEVELOPMENT COMMUNITY

Biotechnology

South African Development Community (SADC) Member States,⁷ with the exception of South Africa, have banned the importation of agricultural biotechnology products since 2005. 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 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 States. 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

Biotechnology

Korea's regulatory system for biotechnology has generated concern in recent years with regard to its lack of predictability and transparency. In 2008, Korea implemented the Living Modified Organisms Act (LMO Act), which regulates trade in agricultural biotech products, including food and seeds for use as feed or for processing. 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, and that Korea's process for reviewing the product risk assessments may be

⁷ 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.

redundant, lack scientific justification, and lead to delays in the approval of new products. The United States is also concerned about Korea's narrow scope of definition for "adventitious presence" which is defined in the LMO Act as "the not intended presence of a living modified organism in a non-living modified organism when the non-living modified organism is used." This definition fails to consider the possibility of unintended presence of an unapproved living modified organization present at low levels in shipments of approved living modified organisms. The United States also has noted that the LMO Act, while nominally applying to all living modified organisms (*i.e.* plants and animals), has been written solely with living modified plants in mind and thus does not readily apply to the trans-boundary movement of living modified 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.

In 2011, Korea announced draft revisions to the LMO Act to provide for greater transparency and predictability. The United States is working closely with the Korean government to provide input on the draft revisions to address U.S. concerns.

Korea completed approvals for three new GE plants in 2011. U.S. concerns continue, however, with regard to the lack of predictability in Korea's biotech review process. The United States will continue to engage with Korea to avoid significant disruptions in U.S. exports of U.S. biotech products.

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

Food Safety

Beef and Beef Products

In April 2008, the United States and Korea concluded a protocol 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 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 2011, exports of U.S. beef and beef products to Korea reached \$686 million, an increase of 33 percent over 2010. Now that the U.S.-Korea FTA is in force, the United States will be requesting consultations on beef under the beef protocol in the near future to discuss its full application, recognizing that the FTA and the protocol are separate agreements. The United States will continue to urge Korea to open its market fully 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.

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 MRLs that were previously accepted by Korea and have been established as safe based on a scientific risk assessment. The United States is concerned that if Korea implements its proposal, it will block the importation of certain products treated with U.S.-approved pesticides that Korean producers do not use. The elimination of an established MRL from the list of approved pesticides would mean that any trace of the pesticide in question would be considered a violation and could be precluded from import to Korea. The United States will continue to encourage Korea to maintain the current list of 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 U.S. pesticide manufacturers and registrants may submit to the Korea Food and Drug Administration relevant information and requests for the establishment of import MRLs for pesticides.

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

Plant Health

Cherries

Korea requires U.S. cherries to undergo fumigation with methyl bromide before shipping, on grounds that it is necessary 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 substantially reducing costs without raising phytosanitary concerns for Korea. The United States has been engaged with Korean quarantine officials since 2008 to agree on an alternative mitigation measure to methyl bromide. In July 2011, Korea agreed to send inspectors to California, Washington, Oregon, and Idaho during the 2012 growing season to evaluate the step by step process used by U.S. producers to ensure that various pests are controlled during the growing season. The United States will continue to work with Korea to identify an alternative mitigation measure to methyl bromide fumigation.

SRI LANKA

Biotechnology

Sri Lanka currently prohibits the sale of GE seeds or products containing GE organisms intended for human consumption without the approval of Sri Lanka's Chief Food Authority. Sri Lanka does not appear to have a functioning approval mechanism, and thus in effect imposes a *de facto* ban on sales of seeds and other agricultural products derived from modern biotechnology. Further, Sri Lanka requires all commodity imports to be accompanied by a certification that the

commodity is “non-GE”. The United States raised these issues with the Sri Lankan government during the 2011 TIFA meeting and will continue to engage Sri Lanka on these issues.

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

Food Safety

Beef and Beef Products

Sri Lanka continues to ban all imports of U.S. bovine products, including beef, beef products, and beef genetics following the detection of a BSE-positive animal in the United States in 2003. The United States continues to engage with Sri Lanka, including through the U.S.-Sri Lanka Trade and Investment Framework Agreement, 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.

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. U.S. officials will continue to urge their Swiss counterparts 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

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 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) that discourage imports of these products.

The United States has raised these issues with Taiwan in various venues. 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 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.

Pork and Beef

Taiwan has delayed the implementation of its proposed MRLs for ractopamine for both cattle and swine, which it notified to the WTO in 2007, but remain unapproved. Without approved MRLs for ractopamine, Taiwan has maintained a zero tolerance policy for ractopamine. Taiwan's lack of progress in adopting its MRL proposal has raised a significant trade concern by forcing U.S. pork producers to ship pork products selectively sourced from animals not treated with ractopamine.

Since 2007, U.S. officials have raised this issue at repeatedly at meetings of the WTO SPS Committee as well as in bilateral meetings with Taiwan, including meetings at the most senior levels. Taiwan authorities appear to have acknowledged in a number of public statements, that trace amounts of ractopamine do not present a health risk. However, Taiwan continued to maintain its zero tolerance policy for ractopamine.

In January 2011, Taiwan unexpectedly began heightened sampling, testing, and rejecting imports of U.S. beef and beef products for ractopamine residues. In addition, in January and February of 2012, some local governments and civic organizations began to test beef in retail outlets and restaurants for ractopamine. These actions caused increasing disruption to bilateral beef trade over the course of the year, and by the end of February, 2012, U.S. beef exports to Taiwan had slowed almost to a halt. In early 2012, members of Taiwan's Legislative Yuan introduced a variety of amendments to Taiwan's Food Sanitation Act, a number of which would establish a permanent ban on ractopamine in Taiwan law. On March 5, 2012, the Taiwan authorities announced a plan to implement a ractopamine MRL for beef, subject to several additional conditions, but without setting a clear timetable for establishing the MRL. Then, on March 15, 2012, the Taiwan authorities announced that they would conduct batch by batch testing of imported beef for ractopamine and other beta-agonists at the port of entry. It is unclear whether locally-produced beef and beef products would be subjected to equivalent inspections and testing for beta-agonists, one of which is ractopamine. As a result of these announcements and actions, there is considerable uncertainty about the current and future regulatory environment for U.S. beef exports to Taiwan, which continues to have a negative impact on imports of both U.S. beef and pork.

The United States continues to encourage Taiwan to implement its proposed MRLs for ractopamine without further delay. As of the date of publication of this report, the United States continues to seek additional information about how the plan to establish an MRL for ractopamine use in cattle will be implemented, as well as how the increased border inspections and testing will be carried out.

Maximum Residue Limits

Taiwan's slow and cumbersome process for adopting MRLs has resulted in a substantial backlog of 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 or other crop protection compound residue levels that are within U.S. or Codex standards but for which Taiwan has not yet established MRLs.

While the United States is encouraged by Taiwan's ongoing efforts to work through the backlog of MRL applications, shipments of U.S. agricultural products remain at risk of rejection due to the absence of MRLs for some commonly used pesticides, which have already undergone rigorous health and safety review in the United States. U.S. agricultural products that rely on newer, safer alternatives to older pesticides that are being phased out in the United States are particularly at risk of being rejected.

The United States is working closely with U.S. stakeholders to gather appropriate data for technical engagement with Taiwan to facilitate Taiwan's establishment of MRLs for these newer, safer compounds. The United States continues to engage with Taiwan 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

Under the current export work plan for the shipment of U.S. apples to Taiwan, the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) imposes a strict “three strikes” penalty structure for codling moth (CM) detections, which can result in a complete market closure for U.S. apples for the remainder of a shipping season if there are three confirmed detections of live CMs. APHIS and BAPHIQ have met on numerous occasions to discuss this issue and the work plan has been modified to include a 2-week grace period following each CM detection. This means that any CM detections that occur within the 2-week grace period do not count as an additional “strike.” However, each year the U.S. apple trade is faced with the possibility that the third largest market for U.S. apples may suddenly close, creating significant uncertainty among U.S. producers. U.S. apple exports to Taiwan totaled \$50.1 million in calendar year 2010, about six percent of total U.S. apple exports.

In October 2006, APHIS provided Taiwan with research demonstrating that the risk associated with CM transmission and establishment in Taiwan via U.S.-origin apples is extremely low. This research document was used in discussions with Taiwan counterparts in 2011 as additional modifications to the current “three strikes” penalty structure were negotiated. APHIS will continue discussions with BAPHIQ on the technical aspects of codling moth risk and modifications to the penalty structure of the work plan to eliminate the threat of market closure in 2012.

Potatoes

Taiwan currently limits imports of fresh potatoes from the United States to those grown in Alaska, California, Idaho, Oregon, and Washington. These restrictions exclude major producing states, including Colorado. In 2002, the United States requested that Taiwan add Colorado to the list of eligible states. In 2011, Taiwan agreed to complete its pest risk assessment for Colorado potatoes. Taiwanese authorities also asked to visit the Colorado potato growing region, but that visit has yet to occur. The field inspection must be completed before Colorado potatoes can be approved for export to Taiwan.

THAILAND

Food Safety

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.

Pork

In January 2010, Thailand lifted its ban on U.S. pork and pork products that had been in place based on H1N1 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 establishment 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 establishment inspections for all exporting facilities. Thailand also imposes other trade restrictions on imports of U.S. pork and pork products, including a prohibition on ractopamine residues.

Magnesium Silicate

In 2009, Thailand's Food and Drug Administration (FDA) banned the use of magnesium silicate as a filtering agent to prolong the life of frying oil. The United States exports significant quantities of magnesium silicate and it is generally recognized as safe for use as a filtering agent for frying oil throughout the world. U.S. producers and their local Thai customers have provided a significant amount of data to Thailand's FDA and allowed on-site testing to demonstrate that magnesium silicate is safe when used for this purpose. The United States expects a response from Thailand's FDA later this year and will continue to work with the relevant Thai officials to resolve this issue.

TURKEY

Biotechnology

In 2010, Turkey implemented a new, overarching Biosafety Law, which immediately negated the approvals of GE products granted under its previous biotechnology regulation and effectively stopped all trade in products containing biotech (primarily soy and corn products). Turkey has indicated that it intends to follow EU practices in implementing the Biosafety Law, including by limiting review of biotech products, at least initially, to those already approved in the EU. In October 2010, Turkey's Biosafety Board began an expedited review of three biotechnology soybean products already grown in the United States and approved for import into the EU. The Board approved these products for feed use in January 2011. In March 2011, the Biosafety Board began non-expedited reviews of all other EU approved biotech products, including soy for food use; corn for food and feed use; and canola, sugar beets, and potatoes for feed use. In December, 2011, the Biosafety Board approved 13 biotech corn products for food use. In February 2012, the Board approved three additional corn products, but rejected six others. Imports of U.S. corn will not resume until all petitioned products are approved, since all seed varieties are planted in the United States and consignments may contain any of these corn

products due to the commodity handling system of the United States. The United States has submitted comments and will continue to work with Turkey to obtain approvals for additional U.S. biotech products.

In April 2011, Turkey's Ministry of Agriculture and Rural Affairs (MARA) issued instructions to all port officials to begin testing imports for the presence of biotech products, including corn, soy, cotton, canola, sugar beets, potato, and tomato. This testing resulted in an immediate block of imports of U.S. cotton. Turkey subsequently allowed imports of U.S. cotton to resume, provided importers certified that the cotton was not genetically engineered.

In September 2011, Turkey adopted a measure that allows for up to 0.1% presence in animal feed of biotech products that are under review or whose approval has expired. Such a low threshold has little practical value, and the United States continues to urge Turkey to increase the 0.1% threshold and to extend the provision to food products.

The Biosafety Law also does not allow biotech products and by-products to be used in industrial goods. In 2011, Turkey began blocking the use of soybean oil produced from imported soybeans in the production of paint and other industrial goods. Following U.S. embassy-hosted educational seminars on the industrial use of biotech materials, Turkey issued an order allowing soybean oil to be used in the paint sector, but continued to bar all other uses in industrial products.

Under the Biosafety Law, MARA has pressed biotech developers to re-apply for approval of their products. However, developers have been reluctant to do so, because a number of essential details of the approval process remain unclear, including what may constitute a failure of compliance and, in situations of noncompliance, what level and kind of penalties will apply. In September 2011, U.S. and Turkish industry representatives began a dialogue with MARA to discuss these concerns.

The United States has repeatedly raised concerns about specific provisions of the 2010 Biosafety Law and its implementing regulations with Turkish officials. In addition, the U.S. Government and the U.S. agricultural industry 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 expressed its intention to engage in discussions on opening 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.

UKRAINE

Biotechnology

In 2007, Ukraine's parliament enacted a law establishing a framework for the creation, testing, and use of products of agricultural biotechnology, but most of the implementing regulations necessary to open the market are still under development. In October 2010, Ukraine's Cabinet of Ministers 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 for 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.

In January 2011, Ukraine approved a list of food products that require testing and monitoring for GE content. In February 2011, Ukraine approved a new law that uses scientific procedures for assessing the impact of GE organisms on the environment and provided the criteria that regulators would use to develop risk assessments. Starting in November 2011, and in accordance with legislation, Ukraine began testing all planting seed imports for GE presence at the zero level tolerance. Accordingly, any seed product with GE presence is not legally allowed for commercial production or sale in the country, disrupting the food and seed industry operations in the Ukraine. 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.

Food Safety

Pork

Ukraine requires U.S. pork to be shipped frozen or tested for trichinosis. Ukraine's testing requirement is costly and is a significant impediment to U.S. fresh/chilled pork exports to Ukraine. The United States does not consider such requirements to be necessary because U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low levels. The United States will work with regulatory authorities in Ukraine to resolve this trade concern.

URUGUAY

Food Safety

Live Cattle, Beef, and Beef Products

Uruguay continues to ban imports of all U.S. live cattle, beef, and beef products following 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 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

Uruguay currently bans imports of many U.S. poultry products due to concerns over AI and Newcastle's disease. In October 2007, the United States and Uruguay reached an agreement that permitted imports of U.S. turkey to resume. 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. The United States has raised the issue with Uruguay repeatedly, including at the October 2011 Trade and Investment Council meeting.

Uruguay recently completed its Exotic Newcastle Disease evaluation of the United States. The next step is for Uruguay to review the adequacy of the U.S. food safety system as it applies to poultry. The United States continues to engage with Uruguay on this issue to pave the way for U.S. poultry producers to export all their products to Uruguay.

Plant Health

Potatoes

In January 2009, Uruguay rejected 60 containers of U.S. seed potatoes for exceeding Uruguay's tolerance level for powdery scab. Although Uruguay considers powdery scab to be a quarantine pest, it has set a tolerance level for it. (Generally, tolerances are established only for non-quarantine pests.) In July 2009, APHIS and the U.S. potato industry hosted senior Uruguayan officials in Colorado to urge Uruguay to raise its powdery scab tolerance level, which the United States considered to be inappropriately low. Uruguay committed to adjust its tolerance level and to change the classification of the pest from quarantine to regulated non-quarantine status. Despite these changes, however, Uruguay's new tolerance level remains unacceptably low, and Uruguay has yet to respond to U.S. requests for further changes. While Uruguay has allowed seed potato shipments from the United States in recent years, U.S. exporters have had to source the shipments from specific areas and some exporters have not shipped due to the lack of

resolution on this issue. The United States most recently raised the issue with Uruguay at the October 2011 Trade and Investment Council meeting, and called on Uruguay to continue to work with the United States on finding a mutually acceptable solution to this issue.

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 requests that Venezuela 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. live poultry or raw poultry meat 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.D 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 appear to have unnecessarily restricted trade. The United States continues to urge Vietnam to adopt SPS measures consistent with international standards 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 equivalence 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

During 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 negotiating animal health requirements to facilitate the trade in live cattle, beef, and beef products. In July 2011, the two sides agreed on requirements for the exporting live cattle to Vietnam. 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.

Offals

In July 2010, Vietnam implemented a “temporary ban” on the importation of offal products from all countries. Vietnam claimed there were food safety concerns that justified implementing the ban, but, to date, has provided no scientific data to the WTO or any trading partner to support this allegation. In April 2011, Vietnam's Ministry of Agriculture and Rural Development (MARD) partially lifted the ban by allowing imports of pork and poultry hearts, livers and kidneys (what Vietnam describe as “red offals”). In May 2011, Vietnam lifted the ban with respect to imports of bovine-origin hearts, livers and kidneys. However, all other offal products (or “white offals”) remain banned.

The United States raised this issue at the June 2011 WTO SPS Committee meeting and was joined by numerous other WTO Members. In response, Vietnam indicated it would conduct a risk assessment to justify the remaining ban, but to date it has not shared a risk assessment. In November 2011, Vietnam informed the United States that it would need three months to complete the internal regulatory measures necessary to lift its remaining ban; however, as of March 2012, MARD has provided no indication that the ban's withdrawal is under consideration. The United States continues to engage with Vietnam on this issue.

Products of Animal Origin

In May 2010, Vietnam issued a new regulation, Circular 25, which outlines food hygiene and safety standards for imported foods of animal origin. The regulation requires producers to provide extensive information on their individual facilities in order for foods produced in those facilities to remain eligible for exportation to Vietnam.

Vietnam has not updated its list of approved U.S. exporting establishments since August 2011, despite the fact that several U.S. producers have submitted the required application materials. The United States continues to work with Vietnam on resolving long term issues related to this regulation, including exporting company registration requirements and the need for a transparent and consistent review and approval process for new applicants.

Products of Plant Origin

In July 2011, Vietnam began enforcing new regulations on imported goods of plant origin. The United States has raised concerns regarding exporter registration requirements, sampling rates, and the coverage of MRLs. 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 raw poultry meat. 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 pathogens such as Salmonella cannot be removed entirely from raw meat and that proper storage, handling, but that cooking of raw poultry meat significantly reduces the risk of a number of food-borne diseases caused by these pathogens, including Salmonella. 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 seeks to ensure that governments base their SPS measures on science and risk assessments and refrain from using SPS measures as disguised restrictions on international trade. To this end, 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 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 2011, the U.S. Government obligated to provide funds for SPS TCB in excess of \$18.5 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 Asia Pacific Economic Cooperation (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. Programs focus on the key 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 include regional trade capacity building workshops, conferences, hands-on training programs, and site visits to U.S. research facilities.

The United States administers a number of programs to build expertise in foreign countries biotechnology, food safety, animal health, and plant health. Fostering a cadre of specialists who can advocate for science-based health and safety measures improves the safety of products imported to the United States and facilitates transparent and predictable market access for U.S. exports. For example, USDA 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 to promote agricultural trade and to strengthen sustainable agricultural practices. Fellows selected to participate in these programs are from middle-income countries, emerging markets, and emerging democracies, and working

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 these U.S.-based programs come from 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 provides for the donation of U.S. agricultural commodities to developing countries that are committed to introducing and expanding free enterprise in the agricultural sector. A number of the program's agreements include SPS capacity building elements such as training farmers in animal and plant health. In 2011, USDA signed 12 agreements focusing on SPS issues in 11 countries. With the exception of the agreement concluded with the Government of Honduras, these agreements were reached with private voluntary organizations. Food for Progress supports projects and activities tailored to the SPS needs of each country and expands the reach of U.S. expertise in food safety and animal and plant health practices.

In response to multiple requests from many countries, as well as new obligations under the U.S. Food Safety Modernization Act, FDA, working with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), created a training laboratory to provide technical assistance and capacity building on food safety topics, including pesticide residues, other chemical contaminants, and food microbiology. JIFSAN also launched the International Food Safety Training Laboratory (IFSTL) with a pilot workshop on "Methods of Pesticide Residue Analysis." The goal of IFSTL is to deliver laboratory-based training to scientists suitable for monitoring food safety compliance. JIFSAN has also partnered with FDA in numerous food safety training programs on good agricultural practices, good aquaculture practices, and commercially sterilized processed foods to provide technical training to the international community. Support for this activity is part of a long-term capacity-building program aimed at strengthening the testing methods foreign government laboratories use to meet U.S. and international standards.

In fiscal year 2011, FDA coordinated and organized 78 visits for 319 foreign nationals from government, industry, academia and the public sector, seeking to learn more about FDA's food regulations and related food safety programs in order to meet U.S. food safety standards.

Trade capacity building is one way that the U.S. Government seeks 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 unwarranted barriers to trade and expand market access for U.S. agricultural and food products.

The following section provides descriptions 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 in 2011.

Regional Activities

Africa

An ongoing collaborative effort between USDA and the U.S. Agency for International Development (USAID) supports four resident SPS advisors and coordinators stationed in Sub-Saharan Africa to cover the East, West, and Southern Africa regions. These 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.

In 2011, USDA and USAID collaborated with the African Union – Interafrican Bureau of Animal Resources and the International Livestock Research Institute (ILRI) to organize a workshop for East African animal health officials on Geospatial Epidemiology (*i.e.*, the study of the ability of disease to spread globally). This workshop included training on using practical, low-cost technology for animal disease surveillance and to communicate relevant information effectively to veterinary and public health officials, the scientific community, and livestock importing nations. Animal health officials from the Intergovernmental Authority on Development and East African Community Regional Economic Communities participated, representing Ethiopia, Kenya, Somalia, Tanzania, Uganda, Sheikh Technical Veterinary School, and Makerere University.

In May 2011, the United States sponsored a Codex Delegates Colloquium, which brought together Codex delegates from Cameroon, Ethiopia, Ghana, Kenya, Mozambique, Nigeria, Senegal, South Africa, and Zambia to receive training on building domestic capacity for implementing Codex standards and guidelines and sharing information among domestic agencies, and to discuss enhancing regional cooperation on the adoption and implementation of science-based food safety standards. This colloquium also provided the delegates with an opportunity to coordinate regional positions in advance of Codex meetings. By more fully participating in international meetings and keeping Codex decisions grounded in science, Codex decisions will better reflect the views of all its members, protect consumers, and facilitate trade.

Also in 2011, USDA co-hosted a regional technical workshop to promote the qualitative analysis and management of biological risks associated with trade in livestock and animal products between the Horn of Africa and Arabian Peninsula. This workshop supported ongoing efforts by the GCC and the Common Market for Eastern and Southern Africa to harmonize trade standards and protocols for transboundary movements of livestock and animal products between these regions. Reducing the spread of animal disease worldwide helps contain infectious diseases and benefits U.S. animal health.

In addition, USDA funded an SPS advisor to provide technical advice in the design of the SPS Capacity Building Program in the East Africa region. Furthermore, as part of SPS capacity building efforts in West Africa, USAID and USDA have worked collaboratively to organize a cross-border meeting on Rift Valley Fever to strengthen communication between the animal health officials of Mali, Mauritania, and Senegal and to discuss reactivating the surveillance networks for Rift Valley Fever in these three countries.

The United States also funded Cochran Fellows from Ethiopia, Kenya, and Uganda to attend animal disease surveillance training focused on risk analysis, monitoring and surveillance of livestock diseases, and animal health emergency management.

Asia Pacific Economic Cooperation

In November 2011, the United States pledged technical support for a new Global Food Safety Partnership Program between the Asia Pacific Economic Cooperation (APEC) and the World Bank. The objective of the fund is to support food safety training programs designed to enhance food safety and facilitate global food trade. This new public-private partnership began with initial funding of \$1 million and is expected to eventually grow to \$15-20 million. The program will begin with a pilot program in the APEC region and then be expanded globally. The Global Food Safety Fund will enhance ongoing efforts of the United States in the APEC region to coordinate technical training and share best practices, which will, in turn, increase the capacity of APEC economies to produce safe foods, regulate food safety consistent with international standards, and help ensure science- and risk-based approaches to food safety to help facilitate global trade in safe food. These programs will also enable more growers, producers, and food safety officials to understand and use preventive controls, resulting in safer food for consumers and fewer safety incidents in food trade.

Under the APEC Subcommittee on Standards and Conformance, USDA co-hosted a laboratory capacity building workshop in August 2011 in Bangkok, Thailand. The workshop's objectives were to assess areas for improvement in laboratory capacity, design training programs, and increase data sharing between laboratories to increase public health. During workshop discussions, participants prioritized the training areas most necessary to improve laboratory testing results. More accurate testing results will increase global food safety as well as increase predictable trade. The United States will provide follow-up training in this area.

In September 2011, USDA and FDA co-sponsored with other APEC economies an APEC Regional Food Defense Awareness Workshop. Food defense is the protection of the food supply from tampering or other malicious, criminal, or terrorist acts. The workshop focused on food defense awareness initiatives, the identification of vulnerabilities to deliberate contamination, and the development of food defense plans to safeguard food trade. This collaboration sought to open and strengthen the international dialogue on these issues and build vital relationships in the region to enhance food supply chain security, secure the safe trade of agricultural products, and protect consumers and businesses against intentional food contamination. The workshop promoted increased regional awareness through the adoption of food defense measures by relevant industries, development of food defense guidance by appropriate government agencies, and the development of food defense curriculum by academic institutions. The United States will continue its efforts to increase global food defense awareness through the institutionalization of measures designed to prevent incidents that would otherwise have severe and negative social, economic, and public health implications.

CAFTA-DR

The Trade Capacity Building program in CAFTA-DR countries, which is part of a broader U.S. capacity building effort in the region, includes SPS-related activities. Under this program, the United States helps CAFTA-DR countries 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 uses programs such as USDA's Cochran Fellowship Program and the Norman E. Borlaug International Science and Technology Fellows Program to complement the SPS program. In addition to these programs, USDA provided El Salvador, Honduras, and Guatemala with technical assistance to improve the use of testing methodologies for detecting *E-coli* and *Salmonella* in foods and the implementation of international standards for quality control and assurance of testing results.

Pursuant to a cooperative agreement with the National Association of State Departments of Agriculture Research Foundation, EPA supports the development of cooperative pesticide safety training programs in Costa Rica, the Dominican Republic, El Salvador, Honduras, and Nicaragua. The program model brings together a broad coalition of stakeholders, including government ministries, non-governmental organizations, farmer cooperatives, agricultural exporters, pesticide manufacturers, and universities, to develop training programs on the safe use, storage, and disposal of pesticides. These programs benefit Central American participants, as well as the United States, by promoting better pesticide use practices, which can help avoid restrictions on trade while enhancing human health and environmental protection.

EPA, FDA, and USDA continued their collaboration in providing technical assistance to CAFTA-DR countries to improve laboratory capacity for analyzing commodities for chemical contaminants. These efforts facilitate trade by helping to ensure that agricultural products from the region meet international safety standards.

Other Latin American and Caribbean Countries

In 2011, the United States supported a number of food safety training activities in the Caribbean. USDA sponsored a second Caribbean Veterinary Epidemiologist Para-epidemiologist Program in San Jose, Costa Rica to improve animal disease surveillance and control outbreaks. Containing the spread of animal diseases in the western hemisphere is crucial for animal health in the United States. The United States also hosted multiple Codex Delegates Colloquiums, bringing together delegates from throughout Latin America and the Caribbean for technical meetings to enhance regional cooperation on the adoption and implementation of science-based food safety standards.

FDA officials hosted a workshop for animal drug regulators from across South America to promote the safe use of veterinary drugs in food producing animals. FDA officials made presentations on regulatory management of animal drugs throughout their life cycle, monitoring

the development of resistance related to the use of antimicrobials in animals, and FDA's program of drug review for limited use drugs.

USDA also provided training to national Codex contact points in the Caribbean to help them more fully 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 several other Latin American countries to facilitate the global harmonization of pesticide maximum residue levels to conform to Codex standards. USDA, in cooperation with the Food and Agriculture Organization, held a regional training workshop in Sao Paulo, Brazil on establishing pesticide residue standards and assessing risks from pesticide residues. In addition, USDA's Cochran Fellowship Program trained government officials from Barbados, Belize, Chile, Dominica, Jamaica, St. Lucia, and Suriname on food safety practices.

Country-Specific Activities

Afghanistan

The United States sponsored Cochran Fellows from a non-government organization in Afghanistan to participate in a veterinary training course coordinated by Colorado State University. The training program focused on preparing affordable and good quality feed to promote animal health and nutrition. In addition, USDA held a workshop to foster a greater understanding of the importance of developing SPS measures to help Afghan farmers export agricultural goods to international markets, as well as to monitor the importation of agricultural goods into Afghanistan.

Bahamas

USDA provided training to Bahamian government officials from the Bahamian Ministries of Agriculture, Fisheries, Environment, and Finance on the establishment of an SPS notification authority and enquiry point to address SPS questions raised by other WTO members. This assistance also covered training on inter-agency and industry coordination, SPS Agreement rights and obligations, and provided an overview of the operation of the U.S. national notification authority. This training facilitated the Bahamas's establishment of an official SPS National Notification Authority and Enquiry Point in the Ministry of Agriculture.

Brazil

USDA's Cochran Fellowship Program sponsored a training program for Brazilian Ministry of Agriculture officials on feed ingredients and additives for animal use. The program also covered U.S. regulatory procedures governing labeling, sampling, analytical testing, and mill inspections for feed production in the United States. In addition, USDA sponsored researchers from Brazil to work at USDA's Animal Parasitic Diseases Laboratory on porcine reproductive and respiratory syndrome, and on developing a vaccine for Toxoplasmosis (a disease primarily carried by cats but potentially fatal if transmitted to humans). USDA and the EPA officials also worked with their Brazilian counterparts to develop a process for establishing tolerance levels for pesticides.

Chile

The United States sponsored Cochran Fellows from Chile to participate in a training program on cattle evaluation and carcass grading, implementation of Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practices in slaughterhouses, meat quality evaluation, and meat handling and inspection.

In addition, FDA held a seminar hosted by the Universidad Austral de Chile for 50 Chilean government officials, academics, and salmon industry representatives on good aquaculture practices, HACCP, food safety management systems, and veterinary drug residue testing to improve safety of seafood imports and exports.

China

The United States funded several programs to train Chinese officials on a wide variety of research, capacity building, and information sharing projects pertaining to risk assessment for genetically engineered vaccines and post-marketing surveillance of veterinary biological products.

The United States also sponsored Cochran Fellows from China to participate in a training program on U.S. food safety procedures, standards and regulations, including discussions on HACCP system regulations and the implementation of HACCP in the food industry. Better food handling practices will improve China's food safety for domestic and international consumers. In addition, USDA sponsored several visiting researchers from China to work at USDA's Animal Parasitic Diseases Laboratory and USDA's Dairy and Functional Food Research Unit on food safety and SPS issues, such as Animal Parasitic Disease vaccines development, soybean genomics, molecular plant pathology, citrus greening antibodies, and orange seed immunology methods.

U.S. delegations from government and academia also met with Chinese officials and scientists to discuss efforts to improve disease control and prevention programs in China, as well as differences between U.S. and Chinese food safety programs and monitoring systems.

The United States and China have established a number of collaborative programs regarding pesticide use, including programs focused on pesticide risk assessment and risk management, building capacity for participation in the international harmonization of MRLs, and reviews of new pesticides on a more global basis. These projects facilitate the exchange of technical, scientific and regulatory information on pesticide registration requirements, standards, and supporting regulatory processes to improve quality control of pesticide products sold in international trade. The programs are designed to help safeguard public health, promote environmental and trade benefits, and encourage harmonization of SPS standards based on internationally-accepted scientific norms.

In September 2011, FDA officials met with Chinese officials and hosted workshops on animal drug safety for food producing animals. The FDA officials met with representatives of China's Institute of Quality and Standards for Agricultural Products in Hangzhou to present an overview

of the U.S. animal drug approval process and a review of U.S. participation in the Codex on animal drug safety. The FDA officials also presented a one-day workshop in Wuhan for veterinary students on a variety of topics related to animal drugs, including international challenges, such as antimicrobial resistance. In Weifang, the FDA officials cosponsored a workshop with China's Institute of Veterinary Drug Control on several animal drug related topics. Similar presentations were made to the China Drug Approval Association in Beijing.

In early November 2011, FDA officials and technical experts traveled to China to learn about the Chinese system for overseeing food product safety, including the safety of drugs used for food-producing animals, and to discuss FDA's plans to implement the Food Safety Modernization Act. The FDA delegation met with officials of AQSIQ's Entry-Exit Inspection and Quarantine Bureau in Guangdong, and representatives of AQSIQ's Certification and Accreditation Administration.

Colombia

The United States sponsored Cochran Fellows from Colombia to participate in a training program on HACCP, food safety regulations, and inspection practices. The program provided the fellows with an in-depth understanding of the U.S. food safety regulatory system, as well as laboratory and field techniques for diagnosing exotic animal diseases and taking emergency action to respond to disease outbreaks in livestock and poultry. Training on HACCP helps to reduce food contamination and improve consumer health.

Croatia

The United States sponsored Cochran Fellows from Croatia's Ministry of Agriculture and Fisheries and Institute of Public Health to participate in a training program on veterinary issues and food safety, including HACCP implementation, food processing and labeling regulations, and inspection service methodology. The training course also covered new technologies and methodologies for animal disease control and food safety used in the United States. The training program built confidence in the U.S. food safety regulatory system by familiarizing the Croatian officials with U.S. efforts to maintain animal health.

Dominican Republic

The United States assessed the Dominican Republic's current animal and plant health status and targeted points in its food production where food-borne illnesses may be introduced to determine the Dominican Republic's technical assistance needs and its potential to export agricultural products to the United States and other countries. The United States also provided Dominican officials with training on plant health assessments, conducted risk assessment courses and technical status visits, and held discussions of progress made in the Dominican Republic's Central Laboratory and IIBI Pesticide Residue Laboratories.

El Salvador

USDA sponsored technical assistance programs in El Salvador on writing slaughterhouse regulations, and provided training for government inspectors and meat producers on HACCP and post-mortem and ante-mortem techniques. These techniques will help reduce cross-contamination of carcasses and the spread of food-borne illnesses. USDA also provided Salvadoran officials with technical assistance to improve the use of testing methodologies for detecting *E. coli* and *Salmonella* in foods.

Grenada

The United States sponsored an expert specializing in Caribbean regional animal health to travel to Grenada to gather and compile data on the status of animal diseases and on import and export requirements for trade in live animals and animal products in the Caribbean Basin. These data were entered into a central database and made available to regional and international stakeholders to foster a greater understanding of animal health issues in the region and how these issues may affect trade. Working with public and private sector partners, the expert also provided technical expertise and supported efforts in Grenada to strengthen food security in the region.

Guyana

USDA sponsored the director of Guyana's Food and Drug Department to attend an advanced USDA workshop on the verification and validation of HACCP and food safety auditing. While at the workshop, the director developed a plan for Guyana to conduct risk assessments for pathogens of concern in commodities such as processed cheese and ready-to-eat processed meats.

USDA also sponsored the director's attendance at the Louisiana State University Agricultural Center to study analytical methodologies for determining pesticide residues in fresh fruits and vegetables.

Haiti

USDA provided technical assistance to Haitian government officials on developing a comprehensive quarantine program. USDA also worked with Haitian officials to conduct an initial analysis of gaps in Haiti's plant health system. Improving the integrity of Haiti's plant health system will ensure a safe and secure food supply and facilitate Haiti's ability to export agricultural products.

In addition, pursuant to a Food for Progress agreement reached with Haiti, USDA provided assistance to the IICA to address the capacity of port inspection and quarantine systems in Haiti. This assistance included visits to a port of entry to develop linkages between the work conducted by the IICA and USDA's Food for Progress program, and visits to regional IICA offices to discuss agricultural trade priorities. USDA provided training to assist Haiti's port officials detect pests that could spread both in Haiti and to other countries, including the United States.

Preventing the spread of pests to the United States facilitates U.S. trade by ensuring U.S. agriculture exports are not subject to trade restrictions elsewhere due to the presence of such pests.

Honduras

USDA provided training in Honduras to government inspectors and meat producers on HACCP and post-mortem and ante-mortem techniques for slaughtering animals to detect signs of disease and prevent cross-contamination of disease between carcasses. The goal of this training was to provide these inspectors and producers with a better understanding of how to conduct an official audit of a meat plant to meet FSIS regulations.

India

The United States sponsored several activities for Indian government officials, including training related to allergen and toxin testing of genetically engineered crops; HACCP plan development; analysis of food safety measures from the farm to the consumer; and risk analysis models for food safety and food borne pathogens. USDA also provided training to Indian government officials on advanced food safety standards, risk analysis methods, and inspection agency regulations. USDA also sponsored visiting researchers from India to study the microbial safety in fresh and fresh-cut produce, vaccines for livestock, avian influenza in poultry, and vaccines to protect against parasites.

FDA experts presented information on U.S. food safety requirements at the 2011 World Spice Congress in India. FDA experts also met with the Indian Spices Board to discuss issues associated with the microbiological contamination of spices. This discussion included a large audience of Indian farmers and regulatory officials. FDA experts also worked with the Indian Spices Board to develop international technical assistance outreach materials to improve spice safety.

FDA experts also provided a training program in India on Good Aquaculture Practices for members of the Indian industry, government, and academia. The training program included site visits to a fully integrated corporate shrimp farm and a family-owned farm to illustrate different food safety issues. The program was designed to improve safety practices and ultimately improve prospects for successful shrimp marketing by sharing information on HACCP applications for shrimp hatchery operations, aquaculture product safety, product traceability, good aquaculture practices, water quality management, and worker sanitation in shrimp production facilities.

Indonesia

USDA sponsored a training course for Indonesian government officials on food safety issues through its Cochran Fellowship Program, including on the spread of food-borne disease. The training program, conducted by Michigan State University, focused on food safety policy development, risk analysis, and program implementation.

Jamaica

USDA sponsored various SPS-related training activities for Jamaican government officials. For example, USDA provided training to a senior veterinary specialist in Jamaica on conducting a risk assessment for American Foulbrood disease in bees. USDA also sponsored a Jamaican veterinary public health inspector to attend a USDA workshop on HACCP and develop a plan for conducting risk assessments for *Salmonella* on fresh poultry and *Listeria monocytogenes* in ready-to-eat poultry products. USDA sponsored a Jamaican scholar to study the identification of mite plant pests in Florida and Ohio. The scholar was also trained to accurately identify arthropod pests and other disease-causing organisms in plants.

Kazakhstan

USDA sponsored a visit to the United States by four Kazakh officials to learn about the use of a vaccine against brucellosis in U.S. livestock. The officials met with APHIS and the Agricultural Research Service scientists to discuss technical aspects of using the vaccine in the United States, such as its safety and efficacy. USDA also hosted an international course on Introduction to Risk Analysis at the Centers for Epidemiology and Animal Health in Colorado where participants from Kazakhstan and other countries were introduced to the fundamentals of risk analysis and its use to assist in decision-making from the perspectives of both risk managers and technical risk analysts. The course also introduced participants to OIE guidelines for qualitative risk analysis and explained how risk analysis techniques can be used to help design programs for control of domestic animal diseases.

The United States also sponsored nine Cochran Fellows from Kazakhstan to participate in training courses on food safety and animal health. The food safety course addressed topics such as advanced food safety standards; HACCP regulations; certification of exports; government inspection and control; laboratory analysis at production facilities; and modern safety equipment. The animal health course examined veterinary diagnostics; animal products; import and export control systems; agricultural biosecurity; disease control; and quarantine programs. The Fellows also visited university and state veterinary diagnostic laboratories in Texas. The animal health course will assist the Cochran Fellows apply their training in veterinary medicine to address animal disease outbreaks.

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 a training program for 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 SPS standards.

Mexico

The United States provided training to representatives from government, industry, and academia in Mexico on SPS related issues, such as the molecular identification of the rice bacterial blight

disease, and the diagnosis and control of paratuberculosis in dairy cattle, a disease that reduces milk production.

Experts from FDA's Food Microbiology Laboratory conducted a training course for over 170 representatives of Mexico's private and government sectors on rapid detection methods to identify pathogens in foods.

Mongolia

USDA provided funding for a scientific exchange scholar from Mongolia to conduct research on surveillance and molecular diagnosis of AI and gene sequencing of the AI virus. The scholar observed and participated in the operations of a research laboratory in the United States focused on the development of immunoassays for the early detection and rapid sub-typing of AI viruses. This research is essential to controlling outbreaks of highly pathogenic viruses and the scholar's research and experience in the United States will increase Mongolia's capability to quickly detect virulent AI strains.

Nigeria

USDA continued work with Nigerian officials to identify next steps in implementing Nigeria's plan to apply HACCP procedures in food processing. USDA also sponsored an intensive, practical course addressing plant health and other SPS issues in import and export markets. The course was designed for government and private sector officials involved in the import and export of agricultural commodities, pest risk assessment, pest surveillance, detection, and border inspection.

Peru

The United States funded several SPS-related programs in Peru to improve Peru's ability to prevent contamination of its food supply and protect its agricultural sector from the spread of animal and plant diseases. USDA sponsored visits by Peruvian agricultural university instructors to the United States to improve their technical knowledge of SPS issues and develop new and revised SPS-related courses for incorporation into Peru's agricultural university curriculum. In addition, USDA sponsored the visit of Peruvian government officials to view USDA operations at U.S. ports of entry in an effort to strengthen Peru's inspection capacity. USDA also sponsored a review by U.S. specialists of port operations in Peru focusing on updating inspection manuals for all points of entry.

FDA collaborated with USDA to provide on-site laboratory training to Peruvian officials on testing methodologies for detecting pesticide residues in foods and on implementing laboratory standards for quality control and assurance.

USDA sponsored specialized training for Peruvian officials with experts from the Seafood HACCP Alliance, and provided specialized training to improve the use in Peru of testing methodologies for detecting heavy metals in seafood and assist Peru in implementing international standards for quality control and assurance. FDA provided training for Peruvian

officials in analytical methods for heavy metals in seafood and ocean water and food microbiology.

USDA conducted a workshop on epidemiology and risk analysis for Peruvian agricultural officials. USDA also sponsored an international course on Transboundary Animal Diseases and provided specialized training with FDA experts to help Peruvian laboratory diagnosticians and veterinary pathologists improve the use of testing methodologies for detecting *E. coli* in foods in Peru. USDA also provided technical training in Lima to Peruvian officials on EPA's pesticide registration processes.

Philippines

The United States sponsored several SPS-related training activities in the Philippines. For example, USDA funded Cochran Fellows to attend training in the United States on plant quarantine, clearance, and inspection, including import procedures, inspection requirements, risk management, and pest interception techniques.

USDA and FDA sponsored a Food Defense Training Program for Philippine industry participants and a Food Defense Education Exchange Program for Philippine academic participants.

The goal of these efforts was to provide participants with the skills and understanding necessary to increase awareness of food supply vulnerabilities among food handlers, who are the first line of defense in ensuring a safe food supply, and academic researchers, who help create food defense plans to deter deliberate food contamination.

Russia

USDA sponsored a collaborative research project with a Russian scientist to study the molecular mechanisms of plant-disease resistance to pathogens. This collaboration assisted in the development of new diagnostic approaches and safe control mechanisms for plant diseases.

In addition, a team of USDA animal health experts traveled to Russia to meet with representatives from Russia's Ministry of Agriculture (MOA) and discussed technical cooperation between the MOA and USDA in order to improve animal health.

Senegal

The United States sponsored Cochran Fellows to attend a four-week training course on biological controls for aflatoxin. By using strains of fungi that do not produce aflatoxins, which are poisons produced by fungi, farmers can reduce aflatoxin infection rates, reduce spoilage, and increase public health.

USDA led the implementation of plant health, animal health, and food safety programs and activities in Senegal managed by USDA and USAID. These programs developed technical agendas for SPS programs, applied new and innovative approaches in planning, designing, and

evaluating SPS programs, and recommended activities and approaches to advance the accomplishments of the programs.

USDA also provided training to small mango producers in Senegal on relevant plant diseases and pests, focusing on *Fusarium wilt* and fruit flies, and while providing training to producers on monitoring and controlling these and other quarantine pests. This assistance is important, because the control of pests worldwide helps facilitate trade and avoid entry of foreign pests into the United States that could lead to bans or other restrictive measures on U.S. exports.

Serbia

USDA sponsored several training activities for Serbian government officials, including a program on implementing a HACCP plan on food safety, a program for Serbian border inspectors on cut flowers, fruits and other plants for planting, and training on integrated pest management to assist Serbia in meeting international SPS standards necessary to export various agriculture products to the region and to the United States. Cut flowers and ornamental plants are potential hosts for pests, diseases, and invasive species.

In addition, USDA sponsored several visits to the United States by Serbian officials to conduct research on food quality and labeling, food sensory analysis, new methods for detecting, identifying, and controlling plant pathogenic bacteria and fungi in vegetable and ornamental crops.

USDA also provided training to 50 Serbian representatives from government, private industry, and academia on international standards for the safe use of food additives and safe slaughtering and processing practices for pork and beef. In addition, USDA Codex experts met with key stakeholders from the Serbian public and private sectors to finalize and define the responsibilities of the Serbian National Codex Committee and help Serbia participate more effectively in Codex.

Finally, USDA officials met with their animal health counterparts in Serbia's veterinary directorate and veterinary scientific institutes, and with veterinary faculty and students from universities in Belgrade and Novi Sad, focusing on building the capacity of the Serbian government to support animal health systems compatible with international norms and standards.

Thailand

USDA sponsored several training programs for Thai officials on various SPS issues, including on the U.S. animal health regulatory process, with a focus on how the United States incorporates OIE guidelines in its regulatory processes, the U.S. rulemaking process, and interagency collaboration.

FDA hosted Thai officials from the Cochran Program for three training sessions on U.S. regulations governing food production and processing, including food safety, aquaculture, pesticide analysis, and inspection procedures for fresh fruits and vegetables.

Uganda

USDA sponsored a pilot study on the spread of African Swine Fever in Uganda. USDA also funded capacity building efforts in Uganda focused on zoonotic disease preparedness, detection, and response capabilities. In addition, the United States and Uganda co-hosted the Codex Committee on Food Hygiene in Kampala, Uganda, bringing together delegates from around the world to discuss and adopt relevant food safety standards.

Vietnam

The United States funded visits to the United States by Borlaug Fellows from Vietnam to conduct research on biological control methods for rice pests, as well as on characterizing different strains of *E. coli* in ground beef, pork, and chicken. The Fellows also studied technical and policy issues related to food safety, with the goal of modernizing food standards and food safety risk assessments in Vietnam. In addition to their research, the Fellows also received training on the impact of U.S. food safety laws, regulations, standards, and policies on the production and processing of agricultural products in the United States, including meat, produce, fish and seafood. The Fellows also met with experts from U.S. regulatory agencies, including FDA, FSIS, and APHIS.

The United States also provided training to stakeholders from Vietnam's academia, industry, government, and trade associations as part of a pilot program on methods to deter intentional contamination of the food supply. Vietnam is the third APEC member economy to host this pilot program, the objective of which is to establish regional expertise in food defense awareness in the APEC region.

APPENDIX

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

American Frozen Food Institute
American Potato Trade Alliance
Biotechnology Industry Organization
California Cherry Advisory Board
California Table Grape Commission
Campbell Soup
Cranberry Marketing Committee
Grocery Manufacturers Association
Herbalife
National Confectioners Association
National Milk Producers Federation & U.S. Dairy Export Council
National Pork Producers Council
National Potato Council
Northwest Horticultural Council
Sunkist Growers
U.S. Grains Council
U.S. Hop Industry Plant Protection Committee
U.S. Meat Export Federation
U.S. Wheat Associates
USA Rice Federation
Yum! Restaurants, Intl.