2014 REPORT ON SANITARY AND PHYTOSANITARY MEASURES

UNITED STATES TRADE REPRESENTATIVE

2014 Report on Sanitary and Phytosanitary Measures

Ambassador Michael B.G. Froman
Office of the United States Trade Representative

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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
BiH	Bosnia and Herzegovina
BSE	Bovine Spongiform Encephalopathy
CAFTA-DR	Dominican Republic-Central America-United States Free Trade Agreement
CAN	Andean Community
Codex	Codex Alimentarius Commission
CTPA	United States - Colombia Trade Promotion Agreement
CU	Customs Union of the Russian Federation, Kazakhstan, and Belarus
ECJ	European Court of Justice
EEC	European Economic Commission
EPA	U.S. Environmental Protection Agency
EFSA	European Food Safety Authority
END	Exotic Newcastle Disease
EU	European Union
FAO	United Nations Food and Agriculture Organization
FAS	USDA's Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FGIS	Federal Grain Inspection Service
FSIS	USDA's Food Safety and Inspection Service
FTA	Free Trade Agreement
GE	Genetically Engineered
GFSP	Global Food Safety Partnership
HPAI	Highly Pathogenic Avian Influenza
IFSTL	International Food Safety Training Laboratory
IICA	Inter-American Institute for Cooperation on Agriculture
IPPC	International Plant Protection Convention
JCCT	Joint Commission for Commerce and Trade
JIFSAN	Joint Institute for Food Safety and Applied Nutrition

KB	Karnal Bunt
LMO Act	Korea's Living Modified Organisms Act
LPAI	Low Pathogenic Avian Influenza
MAPA	Brazil's Ministry of Agriculture, Livestock and Food Supply
MARD	Vietnam's Ministry of Agriculture and Rural Development
MOU	Memorandum of Understanding
MRL	Maximum Residue Limit
MT	Metric ton
NAFTA	North American Free Trade Agreement
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
SADC	South African Development Community
SCC	Somatic cell count
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
SWD	Spotted Wing Drosophila
TBT	Technical Barriers to Trade
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TIFA	Trade and Investment Framework Agreement
TPP	Trans-Pacific 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

VEA	U.S.-EU Veterinary Equivalency Agreement
WHO	World Health Organization
WTO	World Trade Organization

FOREWORD

In 2013, the Obama Administration eliminated unwarranted barriers to U.S. food and agricultural exports, helping these exports exceed $148 billion, an all-time high. By eliminating these barriers, we are helping to increase farm income, grow manufacturing jobs in the food sector, and provide consumers around the world access to safe, high-quality American food and agricultural goods.

I am pleased to publish the fifth annual *Report on Sanitary and Phytosanitary Measures* (*SPS Report*), which identifies the Administration's ongoing efforts to eliminate discriminatory or otherwise unwarranted barriers to U.S. food and agriculture. This report was created to maintain an inventory of the concerns of U.S. farmers, ranchers, manufacturers, and workers who confront sanitary and phytosanitary (SPS) trade barriers as they seek to export high-quality American food and agricultural products globally.

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 unwanted pests and diseases. Many SPS measures are fully justified, but too often, some governments cloak discriminatory and protectionist trade measures in the guise of ensuring human, animal, or plant safety.

Some of our successes in 2013 include expanding U.S. beef exports by 12 percent to reach over $6 billion by expanding access for U.S. beef to Japan, the European Union, Indonesia, Mexico, Panama, and the Dominican Republic. In 2013, the European Union also opened its market to live swine. Peaches, nectarines, and cherries may now be exported to Australia and Japan. In 2014, USTR will continue to work across the U.S. Government, as well as with interested stakeholders, to encourage other governments to remove their unwarranted SPS measures.

We are committed to continuing to engage other governments in all available bilateral, regional, and multilateral fora as part of 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. farm and ranch products. We look forward to making further progress on behalf of America's farmers, ranchers, manufacturers, and workers, as well as the families who depend on export-supported American jobs.

Ambassador Michael Froman
U.S. Trade Representative
March 2014

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I. EXECUTIVE SUMMARY

The *2014 Report on Sanitary and Phytosanitary Measures* (*SPS Report*) is a specialized report dedicated to describing significant barriers to U.S. food, farm, and ranch exports arising from measures that foreign governments apply on the grounds that such 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) terminology 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 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 unwarranted measures.

Section II of this report presents an overview of SPS measures, describes the relevant international agreements governing these measures, and discusses the transparent 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, agricultural 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, Bahrain, Bangladesh, Bolivia, Bosnia and Herzegovina, Brazil, Chile, China, Colombia, Costa Rica, Ecuador, Egypt, Ethiopia, the European Union, Hong Kong, India, Indonesia, Iraq, Israel, Jamaica, Japan, Kazakhstan, Kenya, Korea, Kuwait, Kyrgyzstan, Macedonia, Malaysia, Mexico, Morocco, Namibia, Nigeria, Norway, Peru, Philippines, Russia, Saudi Arabia, Senegal, Serbia, Singapore, South Africa, the South African Development Community, 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, and help eliminate impediments to U.S. food and agricultural exports.

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.

Since 2009, the USTR has redoubled efforts to break down barriers to U.S. exports. One type of non-tariff measure poses increasing challenges to U.S. producers and businesses seeking to export products abroad are 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.

USTR has stepped up monitoring of trading partners' SPS practices that act as unwarranted obstacles to U.S. trade. USTR has also 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 the SPS 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. In February 2012, President Obama established the Interagency Trade Enforcement Center (ITEC), bringing together resources and expertise from across the federal government into one organization with a clear, "all hands on deck" commitment to strong trade enforcement. ITEC has staff from a variety of agencies – including subject matter experts from the U.S. Department of Agriculture (USDA). ITEC enhances the U.S. government's capability to proactively enforce U.S. trade rights through investigation of unfair trade practices, including SPS-related trade barriers.

This annual report has brought new energy to the process of identifying SPS 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 these barriers; and to document ongoing efforts to give greater transparency and confidence to American farmers, ranchers, workers, businesses, consumers, and other stakeholders with regard to the actions this Administration is taking on their behalf.

First published in 2010, the *SPS Report* is dedicated to describing significant and unwarranted SPS barriers in foreign countries. Many of these measures were previously addressed in the

National Trade Estimate Report on Foreign Trade Barriers (*NTE Report*).[1] By addressing significant foreign trade barriers in the form of SPS measures, the *SPS Report* meets the requirements under Section 181 of the Trade Act of 1974, as amended, to report on significant foreign trade barriers with respect to SPS measures. Accordingly, the *2014 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 (*2014 Report on Technical Barriers to Trade*, or *TBT Report*) is being released in parallel with the *SPS Report*.

As noted above, 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 SPS trade barriers in other countries. 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 notice published in the *Federal Register*;
- reports from U.S. embassies 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

As noted above, 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 agricultural products or animals that may

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

introduce a plant pest or animal disease into the country. Many countries also have established MRLs for pesticide residues in food to promote the safe use of pesticides on food, as well as requirements that imported fruits, vegetables, and feed products 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 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 AI or BSE as a reason to block trade in U.S. poultry meat and beef, 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 $148 billion in 2013. According to USDA's Economic Research Service, each $1 billion in U.S. agricultural exports in 2012 supports approximately 6,577 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 for 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 thus do not serve to guard against legitimate health and safety risks but rather act to protect domestic or favored foreign products.

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 governments 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 products 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 each WTO Member 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 are

required to 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 the:

- Joint Food and Agricultural Organization of the United Nations (FAO)/World Health Organization (WHO) Codex Alimentarius Commission (Codex) for food safety;
- FAO International Plant Protection Convention (IPPC) for plant health; and
- World Organization for Animal Health (OIE), for animal health and zoonoses.

A WTO Member may depart from an international standard, guideline, or recommendation only 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 158 SPS notifications per year.

SPS Committee

The SPS Agreement established 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, such as the General Council. The U.S. delegation to the SPS Committee is led by USTR, and includes representatives from 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. Representatives from Codex, the OIE, the IPPC, and the WHO have been among the observers.

The agenda for SPS Committee meetings varies, but several items appear regularly. WTO Members routinely discuss matters related to how the SPS Agreement is being applied and implemented and specific trade concerns, such as minimum residue levels for pesticides. 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 195 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), the Inter-American Institute for Cooperation on Agriculture (IICA), and Asia-Pacific Economic Cooperation (APEC). 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. APEC is a forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region, by creating an environment for the safe and efficient movement of goods, services and people across borders in the region through policy alignment,

and economic and technical cooperation. Effective and targeted capacity-building and technical assistance play important roles in creating a transparent and science-based environment as envisioned under the SPS Agreement, thus supporting APEC's trade and investment liberalization agenda.

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. 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 of this report.

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 enforceable 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 Party's right to protect consumers from unsafe products, or to protect domestic crops and livestock from the introduction of foreign agricultural pests and diseases via imported cargo.

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 Party's right to determine its appropriate level of protection. Such flexibility permits each Party 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 Parties 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 established 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 discuss 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

As noted above, 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 governments in formulating their own national SPS measures and, ultimately, to help avoid and resolve disputes over appropriate SPS measures. As discussed below, various USDA agencies lead the U.S. delegations to these three international bodies. The United States strongly encourages its trading partners to adopt the standards set by Codex, IPPC, and the OIE.

In recent years, the United States has supported a number of important standards developed by these international bodies. For example, the OIE has worked to promulgate science-based guidelines to be followed in the event that a potentially dangerous strain of AI is detected. According to these guidelines, unprocessed poultry products from countries that report detections of low pathogenic AI (LPAI) may be traded with minimal restrictions, and countries reporting highly pathogenic AI (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 avian influenza.

More recently, on July 5, 2012, Codex adopted eight standards for the maximum residue levels for ractopamine in beef and pork. Ractopamine is an animal drug approved for use in feed for cattle and swine, which results in increased weight gain, an increase in the yield of red meat, and leaner meat production. The Codex standards, which are based on science and a risk assessment, provide clear guidance to countries on the safe use of ractopamine. Ractopamine has been approved by the U.S. Food and Drug Administration and is being used safely in the United States and 25 other countries.

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

F. U.S. Government Agencies

The Executive Branch has robust policies and procedures in place for addressing and resolving SPS trade barriers in other countries. 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 obtain 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. agricultural 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 interagency teams dealing with SPS issues.

As a way to streamline processes and make information more accessible for U.S. agricultural exporters, FAS has also established a trade facilitation desk. The one-stop service helps U.S. exporters navigate the complexities of the export process and makes it easier for them to access opportunities in every corner of the world. The trade facilitation desk assists U.S. exporters to obtain information on export certification, registration, and the documentation requirements for international trade, as well as alert USDA when U.S. food and agriculture shipments are detained or refused.

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 do not face 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 participant in addressing all animal health and plant health-related SPS issues.

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 interagency teams dealing with SPS issues.

U.S. Environmental Protection Agency

EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) regulates pesticide 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 SPS measures of other countries, particularly pesticide MRLs and agricultural biotechnology. EPA is a member of the U.S. delegation to the WTO SPS Committee and is an active member of all other interagency teams dealing with SPS issues.

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 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 Belgium, Chile, China, Costa Rica, India, Mexico, and South Africa. FDA takes an active role in assessing foreign SPS measures, participates in the 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 interagency teams dealing with SPS issues such as those arising under U.S. FTAs.

U.S. Department of Commerce

In 2013, the Department of Commerce's International Trade Administration re-organized to better align key functions to support U.S. businesses and their workers. The new units are Global Markets (GM), Industry and Analysis, and Enforcement and Compliance (E&C). E&C contains the Office of Trade Agreements Negotiation and Compliance (TANC), which works closely with its interagency colleagues to address unwarranted SPS barriers, as well as all matters pending before the SPS Committee. In addition to TANC's work specifically (and the Department's work more generally) in removing unwarranted SPS barriers to U.S. exports, the Department's GM unit, also known as the United States 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 is a member of the U.S. delegation to the WTO SPS Committee and is an active member of all other interagency teams dealing with SPS issues.

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 treatment 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 Member on the potential trade effects or scientific concerns that may arise from the changes it is considering. In 2013 alone, the interagency group reviewed 1005 SPS notifications by 50 WTO Members and provided comments to these trading partners on 98 proposed or in-force SPS measures.

Approximately 25 percent of the comments were on measures regarding processed products; 37 percent of the comments addressed requirements for live animals and fish (and their products, including dairy products); and the remainder covered a variety of products including bulk commodities and horticultural products. The leading recipients of U.S. Government comments included the newly acceded WTO Member Russia with 13 and Saudi Arabia, also with 13. The United States also submitted comments to Vietnam 11 times, to Chinese Taipei eight times and to China and Chile six times each.

In these comments, the United States requested its trading partners to take a number of actions, including but not limited to the following: change or reduce product certification requirements; modify requirements of a measure; clarify the intent and/or scientific justification for a measure, and delay implementation of a measure. The United States also requested its trading partners to adopt the international standards of Codex, the IPPC, and the OIE 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 other federal agencies that participate in addressing 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. In addition, USTR may decide to address the issue in the contest 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. 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.

WTO Dispute Settlement

If none of these methods of engagement is successful in resolving a particular concern, USTR may conclude that a bilaterally agreed approach is not possible. 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 other Members' SPS measures in four separate proceedings. Additionally, one proceeding is suspended and a sixth proceeding is currently underway. These proceedings are described below.

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 measures that serve to preclude the import of certain U.S. agricultural products. India's measures 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 its measures.

The United States and India held consultations on April 16-17, 2012, but were unable to resolve the dispute. The United States requested the establishment of a WTO panel on May 24, 2012. At its meeting on June 25, 2012, the WTO dispute settlement body established a panel.

During 2013, the United States and India, as well as third parties, filed written submissions with the panel. The panel also held two meetings with the Parties: one in July 2013 and one in December 2013. The panel is expected to issue a final report in July 2014.

EC Measures Concerning Meat and Meat Products (Hormones)

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.[3] 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 exports.

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 cattle that have not received growth-promoting hormones. The MOU took effect in August 2009. In August 2012, the United States and the EU entered into the second phase of the MOU, resulting in an increased EU tariff rate quota (TRQ) for high-quality beef. In August 2013, the TRQ was extended for an additional two years. Consistent with its obligations under the second phase of the MOU, the United States is no longer applying increased duties on EU products pursuant to its authorization from the Dispute Settlement Body in the EC – Hormones dispute. The United States continues to monitor EU implementation of the MOU and other developments affecting market access for U.S. beef products.

Japan – Measures Affecting Agricultural Products – 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 – Measures Affecting the Importation of 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 found 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. In 2005, a WTO compliance panel found 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.

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

European Communities – Measures Affecting the Approval and Marketing of Biotech Products

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 agricultural 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. As of December 31, 2013, a large backlog of 68 applications (for approval of import, renewal, and cultivation) remains pending in the EU approval system, which has the effect of blocking U.S. exports of certain agricultural products. In 2013, the EU approved five products (two new approvals for import, one renewal of an approval, and two approvals of an extension of the scope of the use of the product) taking an average of 45 months to reach a decision.

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.

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, agricultural biotechnology, BSE, AI, and MRLs for pesticides and veterinary drugs. The individual country reports contained in section IV provide details on these barriers in specific markets and actions taken to address them.

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 products, 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 drug approved for use in feed, 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/or exporting country for a variety of SPS-related assurances. These assurances may include, for example, declarations that the products have been produced under sanitary conditions or in disease-free areas. In recent years, many trading partners have begun requiring that export certificates accompany each shipment and include burdensome and unnecessary "attestations" that, for example, may subject imports to unwarranted or overly burdensome requirements, such as testing, as a condition of entry.

Such export certifications have created a significant and growing impediment to trade. The attestations required as part of these export certifications often appear to be scientifically unnecessary and, in many cases impose requirements that are inconsistent with the recommendations of the relevant international standard setting organizations (Codex, OIE, and IPPC). For example, certain importing countries require each individual food shipment to be accompanied by an export certification regarding the prevalence of certain animal or plant diseases in the exporting country even though this information is readily available on websites that the exporting government or an international SPS standard setting body 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 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 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.

- requirements for competent authorities to make attestations unrelated to SPS issues on an SPS official sanitary certificate.

In addition to working with the international standard setting bodies, the United States has been a leader in promoting work within APEC to address export certification issues. In 2010 and 2012, the United States organized workshops on export certification for APEC members. At these workshops, representatives discussed common challenges arising from certification requirements and options to address those challenges. The United States has drafted an APEC Export Certificate Roadmap that promotes harmonization to relevant international standards wherever possible. The Roadmap seeks to identify solutions for the growing trend in export certification towards duplicative, redundant, unavailable, and/or unnecessary export certification requirements. Ultimately, the objective is to develop a "tool box" that will facilitate the appropriate and efficient use of export certificates. There continues to be strong support from APEC economies for this work.

B. Biotechnology

For nearly 20 years, farmers around the world increasingly have planted crops developed through modern agricultural biotechnology or genetic engineering (GE) techniques. According to the International Service for the Acquisition of Agri-Biotech Applications, the number of countries growing agricultural biotechnology crops has increased from six in 1996 to 27 in 2013. GE crops have allowed farmers to use fewer and safer pesticides while improving crop yield, as well as increase the use of no-till agriculture. Crops produced using agricultural biotechnology that are consumed in the United States for food, feed, or fiber include alfalfa, canola, corn, cotton, papaya, soybeans, sugar beets, squash, and sweet corn. USDA's National Agricultural Statistics Service estimates that in 2013, 93 percent of soybean acreage, 90 percent of corn acreage, and 90 percent of cotton acreage in the United States were planted with GE varieties. New GE crops, including crops with new traits, will continue to be brought to market, leading to more farmer acceptance and use of GE crops on the one hand, and potentially more trade challenges on the other.

U.S. exports of GE corn, soybeans, and other agricultural products that contain - or may contain - GE-derived ingredients, face a multitude of trade barriers. The country-by-country section of the *SPS Report* contains numerous examples of unwarranted import bans and other restrictions currently being applied to U.S. biotech products. In addition, some trading partners impose mandatory labeling requirements on foods derived from GE products that create technical barriers to trade by wrongly implying that these foods are unsafe.[4] Some U.S. trading partners have continued to impose restrictions on these products even though repeated risk assessments have shown no food safety concerns, and these GE products have proven safety records.

The United States actively engages with trading partners to remove unwarranted trade barriers to GE products. 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 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CODEX plant guideline) for assessing the safety of food from GE crops. The United States has also supported the development of annexes to the Codex plant guidelines containing safety assessment guidelines for nutritionally-enhanced or 'bio-fortified' GE crops, and for cases where small amounts of material from GE plants authorized in the exporting country are found in food products in countries that have not authorized those products (i.e., low-level presence).

Although the United States is not a party to the United Nations Cartagena Protocol on Biosafety, which governs transboundary movement of living modified organisms (i.e., living GE plants and animals, including, for example, GE corn, fish, and soybeans), it regularly participates in meetings of the Protocol Parties and routinely organizes capacity-building efforts to promote science-based approaches to evaluate these organisms. The United States is also actively involved in regulatory and policy dialogues within APEC pertinent to the use and trade of products derived from agricultural biotechnology.

[4] These labeling requirements are addressed in the *TBT Report*.

C. Bovine Spongiform Encephalopathy (BSE)

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 2013, the OIE indicated that in 2013, the number of cases had decreased to five cases globally. The United States has had only four cattle test positive for BSE: an animal imported from Canada in 2003, a U.S.-born 12-year old animal in 2005, another 10-year old U.S.-born animal in 2006, and a U.S.-born 10-year old dairy cow in 2012. Importantly, all three cases of BSE detected in the U.S. born animals were classified as the atypical form of the disease, a very rare form of the disease not generally associated with an animal consuming infected feed.

The OIE

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 live cattle, beef and beef products from countries in each category. In May 2013, based on a review of the potential release and exposure to the BSE agent, surveillance, awareness, and history of the disease in the United States, the OIE classified the United States as having a "negligible risk" status for BSE. OIE guidelines specify that negligible risk countries may safely trade in live cattle and beef and beef products produced from animals of any age.

U.S. BSE-Related Controls

The United States implemented an OIE-consistent feed ban in 1997, which prohibits feeding ruminants most mammalian-origin proteins. The U.S. feed ban was further strengthened in 2009 by prohibiting the use of the highest risk cattle tissues in all animal feed (not just ruminant feed). The implementation of a ruminant-to-ruminant feed ban is the most important preventive step a country can take to protect its cattle population from BSE exposure. In 2004, the United States implemented BSE-related measures in U.S. slaughterhouses and meat production establishments, the most important of which requires removal of "specified risk materials" (SRMs). SRMs are those tissues (e.g., brain, spinal cord, etc.) where the BSE agent is known to accumulate and can therefore pose a human health risk. With respect to BSE and the BSE negligible risk status of the United States, all cattle tissues that the OIE has not designated as SRMs are safe for human consumption. As a result of these interlocking measures, beef and beef products produced in the United States are safe for consumption. On December 4, 2013, APHIS promulgated a final rule that sets out requirements that are generally consistent with OIE recommended BSE guidelines. This final rule became effective on March 4, 2014.

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 economic 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 (1.3 million metric tons) 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. Despite lower volumes, U.S. beef and beef products exports reached a record $ 6.16 billion in 2013.

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 disparity in BSE-related measures in different markets represents a separate trade burden and undercuts the comparative advantage of U.S. exporters. This disparity 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 the relevant 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)

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: low pathogenic avian influenza (LPAI) and highly pathogenic avian influenza (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 more easily. 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 potential 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 and poultry products based on professed concerns over AI, often citing isolated LPAI outbreaks. For example, China currently bans imports of poultry and poultry products from four U.S. states, Arkansas, New York, Virginia, and Wisconsin. India maintains AI-related measures that serve to preclude the importation of poultry products from the entire United States. 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. 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 117 AI-related bans since 2008. Section IV of the *SPS Report* provides additional information on countries with unwarranted trade restrictions ostensibly related to AI.

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 establishes 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 significant amount of data, staff training, and financial resources. In most cases, many years are required for a country 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 under prescribed conditions.

Similarly, FDA establishes tolerances for veterinary drugs in the United States. USDA enforces the FDA tolerances for veterinary drugs on both domestic and imported products. The United States is an active participant in the respective Codex committees for pesticides and veterinary drugs and supports the use of international standards to help address MRL-related trade issues. The U.S. regulatory authorities also provide technical assistance and participate in various fora intended to foster collaboration and harmonization of requirements related to MRLs.

IV. COUNTRY REPORTS

This section sets out specific SPS concerns in reports on individual countries. The issues discussed in this section are the subject of U.S. Government engagement with U.S. stakeholders concerning unwarranted SPS barriers that U.S. exporters have encountered in these countries. 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.[5]

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 concerns are significant; 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 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 some instances, the U.S. Government elects to focus its efforts on a few countries where the

[5] 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).

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 regarding BSE and the importation of bovine products, but the new regulation did not correct many of the unwarranted restrictions in force previously, nor did it allow for the import of U.S. live cattle, beef, and beef products. The United States will continue to urge Argentina to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

Animal Health

Pork

Currently, U.S. pork does not have access into Argentina. Argentina has indicated that for the United States to be approved to export pork to Argentina, U.S. pork must either be shipped frozen or tested for trichinosis. 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. Discussions between the United States and Argentina on access to the pork market began in 2011, after years of impasse. In October 2012, the United States provided the necessary information to Argentine authorities to complete a risk assessment process. Argentine authorities continue to review the U.S. response. Further actions are anticipated throughout 2014, including an audit of the U.S. system by Argentine authorities and negotiation of an export certificate.

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 (END) in the exporting country. However, there are no incidents of END or HPAI in the United States. 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.

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

Plant Health

Apples and Pears

Since 2009, Argentina has blocked 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.

The U.S. industry has stated in the past that they believe Argentina would be a small but good market for U.S. apples and pears during Argentina's off-season. However, the Argentine fruit industry has recently improved its cold storage capacity and has expanded its marketing season. We see a potential market of $1 million annually for both apples (70 percent share) and pears (30 percent share) during Argentina's off season.

AUSTRALIA

Food Safety

Beef and Beef Products

Australia currently restricts the importation of bovine products from countries that have reported one or more indigenous cases of BSE. In March 2010, Australia modified its food safety import policies to allow imports of beef and beef products from countries that have had BSE cases. Under these requirements Food Standards Australia New Zealand (FSANZ), a regional food safety agency, conducts an individual country risk assessment. In August 2013, an audit team from FSANZ conducted an inspection of U.S. production and processing facilities, and the United States is reviewing the draft report from that inspection. In addition to the FSANZ review, Biosecurity Australia conducts 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 U.S. beef and beef products.

The United States will continue to urge Australia to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

Animal Health

Pork

Access for U.S. pork to Australia is limited to frozen, boneless pork due to concerns about the introduction of porcine reproductive and respiratory syndrome (PRRS) and post-weaning

multisystemic wasting syndrome (PMWS). The United States has requested that Australia remove unwarranted PRRS and PMWS related restrictions to allow importation of all U.S. pork products. Citing these diseases, Australia also requires that all solid waste from pork imports, regardless of whether the pork is cooked or uncooked, be treated as a quarantine waste product. The new requirements have unnecessarily raised the costs of handling imported pork.

Poultry

Australia bars imports of fresh, frozen, and cooked poultry meat, including turkey meat from the United States. In 2009, the United States requested Australia to prioritize granting market access for U.S. cooked turkey meat. In 2012 Australia initiated an evaluation of U.S. cooked turkey meat to assess the existence of a virus that causes Infectious Bursal Disease. In a letter dated July 15, 2013, APHIS Veterinary Services provided Australia with information about the U.S. turkey industry and the National Poultry Improvement Plan, as well as requested data about the status of certain turkey diseases in the United States. Australia has not requested any additional information.

The United States will continue to work with Australia on any technical issues and will continue to press for progress on this issue.

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 more than 15 years, the U.S. Government and the U.S. apple industry have engaged 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 by USDA to address Australia's concern about the three fungal pathogens. The PRA also 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. The United States was an active third party in support of New Zealand in the case. 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. Apples from New Zealand are now authorized for importation into Australia. The United States continues to monitor Australia's ongoing PRA process regarding U.S. apples in light of the WTO rulings and recommendations in this case.

Pears

Australia currently prohibits the importation of pears from the United States due to the bacterial disease fire blight caused by the bacteria *Erwinia amylovora*. Australia has claimed that the disease might be transmitted to its domestic apple and pear crops. However, the United States has provided significant amounts of evidence to Australia demonstrating that mature, symptomless pears do not support populations of the fire blight bacteria and are not part of the pathway.

Seeds

For viruses associated with tomato and pepper seed, Australia has excessive testing requirements based on large sample (30,000 seeds) sizes. These tests are very expensive, time consuming, and the large sample sizes result in significant financial loss as these seeds are very high value. Many U.S. seed companies cannot meet these excessive phytosanitary requirements, and trade is being unnecessarily restricted.

Table Grapes

In 2010, Australia raised concerns regarding spotted wing drosophila (SWD) *Drosophila suzukii*, a species of fruit fly on table grapes from California. Australia requires a carbon dioxide/sulfur dioxide treatment plus a cold treatment to address SWD, despite the fact that SWD has never been found on California table grapes either before or since 2010 and despite no interceptions during pre-clearance inspections by Australian quarantine officials. In October 2013, USDA submitted new research to Australia on a revised cold treatment protocol for California table grapes. Other phytosanitary issues of importance include onerous pre-inspection requirements prior to shipping and access for table grapes from San Luis Obispo County. The United States will continue to work with Australian officials at the technical level to address these concerns.

BAHRAIN

Food Safety

Pork

Bahrain instituted a ban on U.S. pork exports from several U.S. states due to concerns regarding the H1N1 virus, even though there is no evidence to indicate that the virus can be conveyed to humans through the consumption of pork. The WTO, OIE, and FAO 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. The United States will continue to request that Bahrain provide official notification that the ban has been lifted.

BANGLADESH

Plant Health

Cotton

Bangladesh requires double fumigation at the port of loading and unloading out of concern over the possible presence of boll weevil. The United States has raised its concern that double fumigation is unnecessary with the government of Bangladesh on numerous occasions including at the Partnership Dialogue in May 2013. USDA estimates that if this measure were to be removed, it would allow for an increase in trade of $10 million.

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. In 2009, the United States submitted comments on a proposed Andean Community (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 United States will continue to urge Bolivia to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

BOSNIA AND HERZEGOVINA

Agricultural Biotechnology

Since Bosnia and Herzegovina (BiH) passed the Food Law of November 2004, GE products have not been permitted into BiH. A biosafety law passed in 2009 permitting the importation of licensed GE products. However, it took more than three years for BiH's Council of Ministers to adopt five implementing rules that establish procedures to import and market agricultural biotechnology products. BiH has not issued the regulation that describes the process for approving cultivation of agricultural biotechnology products. BiH is a potential candidate for EU accession, and these regulations are similar to EU regulations. BiH's anti-biotechnology position has impeded U.S. commercial exports, and the BiH government has opposed import of biotech corn and soybean food assistance shipments.

Almonds

BiH recently introduced a new requirement relating to aflatoxin levels – "Decision on Special Conditions for the Import of Foodstuffs from Certain Countries Regarding the Risk of Contamination with Aflatoxin" – which requires that almonds and nut and dried fruit mixes from the United States be tested for aflatoxin content and certified by USDA. According to this new requirement, the certificate for U.S. shipments is to be issued under a Voluntary Aflatoxin Sampling Plan and the laboratory test results on aflatoxin content must be included. USDA is working with BiH's Food Safety Agency to reconsider this new requirement for U.S. almonds, given the negligible risk that they represent.

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 2013, Brazil modified their import regulations, establishing a new regulatory pathway to allow imports of U.S. beef and beef products. For U.S. beef and beef products, the new pathway will require a bilateral agreement establishing conditions for import. On December 10, 2013, Brazil issued final sanitary import requirements for beef and beef products. The United States continues to work with Brazil to negotiate the necessary bilateral agreement open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

Pork

Brazil only allows imports of U.S. pork from establishments 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 not explained why an establishment by establishment inspection and approval system is required rather than the systems-based approach recommended by the WTO and used in FSIS' ongoing system equivalence process. 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 or if the risk is otherwise mitigated (*e.g.,* by cooking). The United States does not consider these requirements for trichinosis to be necessary as U.S. producers maintain stringent biosecurity protocols that serve to limit the presence of trichinae in the United States to extremely low levels in commercial swine.

The United States will continue to engage Brazilian authorities to address these 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 extensive treatments and seed testing 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 amended Norma 36 in February 2011, allowing for inspection of seed fields instead of laboratory testing as originally described in the regulation. MAPA has postponed the implementation of additional declarations, which were of concern to trading partners, while it developed the pest list for each species of seed. On May 10, 2012, MAPA notified the WTO of the modified regulation with a list of pests associated with the regulated seeds (now reduced to 69 seed species). Brazil provided for a comment period of 60 days. APHIS submitted comments and concerns on July 6, 2012. On October 30, 2012, MAPA published the Normative Instruction 24-2012, which postponed the enforcement of the additional declarations established by Norma 36 for another year, until December 1, 2013, to provide MAPA time to finish reviewing the comments it received. In September 2013, Brazil released another version of this proposed rule and recently extended the comment period until April 1, 2014. MAPA has also postponed the implementation of additional declarations, which were of concern to trading partners. A new version of the normative instruction, which associates seed species from each exporting country with pests of concern to Brazil, was communicated to trade partners on October 2013.

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 as U.S. producers maintain stringent biosecurity protocols that serve to limit the presence of trichinae in the United States to extremely low levels in commercial swine. 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. According to USDA estimates, removal of these requirements could result in a gain of $25-$100 million annually. The United States has raised this issue on the margins of the Trans-Pacific Partnership (TPP) SPS negotiations on numerous occasions as well as in high level bilateral meetings and will continue to work with Chile to resolve this trade concern.

Live Cattle

Chile bans imports of U.S. live cattle following the detection of a BSE-positive animal in the United States in 2003, despite its long standing commitment to adhere fully to OIE guidelines. The United States raised this issue on numerous occasions in 2013, including during technical discussions and high level official visits. The United States will continue to urge Chile to open

its market fully to U.S. live cattle based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

Salmonid Eggs

On July 14, 2010, Chile's Ministry of Fisheries, SERNAPESCA, suspended imports of salmonid species from all countries, including the United States, due to Chile's revised import regulations for aquatic animals, including salmonid eggs. Under the new regulations, U.S. industry can no longer export salmonid eggs into Chile under any conditions until SERNAPESCA completes a risk analysis of aquatic animal imports and an on-site audit of APHIS' oversight of aquatic animal exports and U.S. salmonid egg production sites. An audit was conducted in December 2011 on USDA's oversight of U.S. salmonid egg production sites in Washington and Maine. The United States had understood that the audit of Washington State was successful and that trade from that state could resume by the end of summer 2012. However, SERNAPESCA later informed USDA that additional information would be required to document the strength of the national surveillance program. USDA sent comments on SERNAPESCA's risk assessment in May 2013 and another communication to SERNAPESCA in August 2013. In August, SERNAPESCA added a new disease, *Totivirus*, which is not an OIE listed disease, to the list of diseases not present in Chile. As a result of this addition, SERNAPESCA suspended imports of all salmonid eggs from the United States, until an additional risk assessment is complete for this disease. USDA is currently preparing a response to SERNAPESCA's October 2013 communication on the risk assessment and additional information requested on the new disease. Market access for products from the state of Maine is also pending the resolution of technical concerns raised by Chile.

This issue has been raised on the margins of the TPP SPS negotiations on numerous occasions, as well as in technical discussions and high level official visits. While Chile has expressed an interest in working with the United States to resolve this issue through continuing review of U.S. and state surveillance programs, it has also recommended that the states of Washington and Maine apply for equivalence determinations. However, such determinations would be time consuming and appear to be unwarranted given that Chile has yet to identify a specific health concern relevant to U.S. products.

Plant Health

Table Grapes

In September 2011, Chile issued new provisional phytosanitary requirements for potential imported hosts of SWD, including U.S. table grapes, which require a methyl bromide fumigation or cold treatment. These restrictions continue to apply. APHIS has been working with Chile's Ministry of Agriculture to eliminate these restrictive treatment measures. SWD is not of quarantine concern for the United States, has never been intercepted in shipments destined to Chile originating from the United States, and is being controlled in place by industry's best management practices. As commercially produced table grapes are not a suitable host to SWD, USDA is pursuing elimination of Chile's emergency measures, has been working with

California's table grape industry, and is presenting options to the Chilean Ministry of Agriculture to eliminate these provisional SWD measures.

To address Chile's provisional phytosanitary requirements on SWD, in May 2013, USDA proposed a protocol to Chile for consideration as a phytosanitary option to mitigate SWD. Chile responded to USDA in January 2014, and stated it will maintain its current treatment requirement restrictions for SWD (as well as for Light Brown Apple Moth regulated areas), and requested further information from the United States on these issues. The United States will continue to work with Chilean officials to resolve these issues.

CHINA

Agricultural Biotechnology

Under Chinese regulations, an agricultural biotechnology 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 is creating significant and unwarranted delays in China's approval of agricultural biotechnology products. Such delays related to one biotech product resulted in substantial disruptions of U.S. corn exports in late 2013.

Post-application delays in the approval of biotech products have also increased. Approvals have slowed for both field trials of biotech products and for products in final stage of approval. The United States continues to raise both of these issues with China.

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

Food Safety

Ractopamine

China bans imports of pork containing any residue of ractopamine, an animal drug approved for use in feed that promotes feed efficiency in pigs and certain other livestock. China maintains this ban despite U.S. government approval, the establishment of a Codex standard, and scientific evidence indicating that ractopamine can be used safely. China has enforced this ban by barring imports that contained trace amounts of ractopamine from several U.S. facilities that previously shipped pork to China. The United States strongly disagrees with China's assertions 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 July 2012, Codex adopted MRLs for ractopamine use in pigs and cattle. The United States continues to press China on this issue in bilateral and multilateral fora. In 2013, China's implemented new testing requirements for U.S. pork exports to China, requiring that pork be accompanied by a test certificate showing that the meat is free from ractopamine residues. China is now testing pork at port, and holding shipments that were not free of residues of ractopamine, tetracycline, and sulfa drugs. USTR continues to work with USDA and industry to address these issues.

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 the risk posed by BSE. The cumulative effect of these restrictions is that the market remains closed to U.S. beef and beef products.

The United States and China have continued to engage at senior and technical levels in 2013, including a visit to Beijing by U.S. regulators to meet with their Chinese counterparts in December 2013. During the meeting of the Joint Commission for Commerce and Trade (JCCT) that same month, the United States and China agreed to strive for the resumption of U.S. beef access by July 2014 on the basis of mutually agreed conditions. The United States will continue to urge China to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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 Monocytogenes*, and other pathogens in imported raw meat and poultry. Such a standard is unwarranted, because it is generally accepted by food safety experts and scientists that pathogens that are closely associated with raw meat and poultry products, such as *Salmonella*, cannot be entirely eliminated and that proper storage, handling, and cooking of raw meat and poultry reduce significantly the risk of the 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.

Processed Meat Products

In May 2012, U.S. processed meat manufacturers informed USDA that China's Customs, Inspection, and Quarantine officials had detained imports of processed meat products (sausages and rendered chicken fat) without notifying U.S. authorities of any specific concerns. In August 2012, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) notified USDA that the agreement under which U.S. producers had been shipping processed and unprocessed meat products to China applied only to unprocessed meat and not to processed meat, and U.S. producers would now be required to register with AQSIQ before shipping processed meat to China, allegedly to address unspecified food safety issues.

The United States does not consider the products in question to pose food safety concerns, but China continues to detain processed meat products if they are shipped without registration of the producer. Due to the uncertainty of regulations in China, U.S. producers sharply reduced processed meat exports and are looking for clear guidance regarding China's import requirements. The United States will continue to seek resolution of this issue with China.

Wine and Distilled Spirits

In January 2013, AQSIQ notified importers that, effective February 1, 2013, mandatory laboratory testing for the presence of certain phthalates in wines and distilled spirits would be required before imports could be released into the market. China did not notify the new requirements to the WTO, and due to the short lead time, a number of shipments were held up at Chinese ports pending completion of the newly-required tests.

Each port, through the local inspection agency, is interpreting the new requirements differently and test methods and procedures continue to vary from port-to-port. Although the port of Shanghai has eased the requirements applicable to repeat shipments of certain brands, importers are still required to submit test results before customs clearance. Other ports have not similarly adjusted their procedures to ease the burden on imports. China has signaled that the new testing requirements will remain until China completes a comprehensive, nation-wide risk assessment.

Animal Health

Bovine Products

China has banned U.S. exports of protein-free tallow due to BSE-related concerns following the detection of a BSE-positive animal in the United States in 2003. 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. Subsequent discussions and an AQSIQ delegation visit to evaluate industry in 2012 have resolved some of the disagreements on entry and certification requirements. However, the United States and China still have not reached a final agreement.

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

Poultry

China lifted the ban on poultry imports from Arkansas for two months in 2013, but reissued the ban following an LPAI detection. China continues to ban poultry and poultry products from Arkansas, Virginia, New York, and Wisconsin (or transshipped through those states) based on reported detections of LPAI in those states. China's current AI-related import bans appear not to be science-based or consistent with OIE guidelines.

During bilateral meetings in 2013, including JCCT working group meetings, China stated that it is continuing to look into this trade issue.

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). Other varieties of apples have not been authorized due to pest-related concerns especially with regard to the bacterial disease fire blight. 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. As part of 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 fire blight and several fungal pathogens as a reason for not approving additional apple varieties from the three approved states. AQSIQ finally provided the results of its risk assessment to the United States in October 2013. The United States is currently reviewing this document and will respond to AQSIQ in the near term. Additionally, in 2012 China suspended imports of apples from Washington due to concerns regarding three fungal pathogens.

Discussions are ongoing regarding the development of a mutually acceptable pest list to support the U.S. access request for additional apple varieties and to address China's quarantine concerns about apples from the state of Washington.

Avocados

China prohibits imports of California fresh avocados. In 2005, the United States submitted a formal written request to AQSIQ to complete a PRA and allow entry for California-origin avocados. Despite persistent U.S. government efforts over an eight-year period to open the Chinese market for California avocados, including by providing a pest list to China in 2005, China has not completed a PRA.

In June 2013, AQSIQ finally told U.S. government officials that a PRA for California avocados would be completed by a provincial entity in Guangdong, but no information has been forthcoming from China regarding progress on the PRA. The United States will continue to urge China to address this issue.

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. In October 2013, AQSIQ provided to USDA its PRA for U.S. fresh table stock potatoes from the Pacific Northwest. While this is a

long awaited step forward in the fresh potato market access request, significant work still needs to be done prior to opening the market. The United States continues to engage China on this issue in a variety of bilateral and multilateral fora.

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.

Wheat

Despite a 1999 bilateral agricultural cooperation agreement between China and the United States regarding *tilletia controversa* Kuhn (TCK) and Karnal bunt (KB), China maintains restrictive quarantine requirements on U.S. winter wheat. The agreement specifically allows discharge of vessels with U.S. wheat at any port in China with expeditious delivery to buyers and processors without additional treatment.

In southern Chinese ports, U.S. winter wheat must discharge at one designated port and a cleaning fee is assessed. Although market values for U.S. winter wheat classes often are competitive with other origins, including Chinese domestic wheat, importers have limited purchases because of potential discharge issues and the additional costs and burden to re-ship wheat from the cleaning facility.

COLOMBIA

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. In 2009, the United States submitted comments to CAN on a proposed risk assessment, which stipulated that only live animals less than 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 nominally allowed live cattle imports from the United States, but at the same time imposed such restrictive requirements that they effectively prevented any such imports. In January 2011, USDA proposed a protocol to Colombia that covers trade in live cattle as well as provided further comments to Colombia regarding its requirements. The issue was discussed at the first meeting of the United States-Colombia Trade Promotion Agreement (CTPA) SPS Committee in November 2012. The United States will continue to urge Columbia

to open its market fully to cattle, U.S. beef and beef products based on science, the OIE guidelines, and the United States' negligible risk status.

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

COSTA RICA

Potatoes

In September 2013, Costa Rica banned the import of U.S. fresh potatoes allegedly due to excess soil in some shipments and the presence of zebra chip, a disease that causes striping of potatoes. To date, Costa Rica has not provided details of the zebra chip identification or testing methods. The United States requested this data since the potato shipments in question had followed the zebra chip protocol, and found free from zebra chip when returned to the United States and tested by a laboratory at Oregon State University. Moreover, according to industry experts, the shipments were destined for immediate processing into potato chips and posed no quarantine threat to Costa Rica, even if the pathogen had been present.

To further compound the unpredictability of exporting potatoes to Costa Rica, the Costa Rican government a week later rejected a newly arrived shipment for a pesticide residue violation. Pesticide records clearly show that not only was the pesticide in question not applied to the fields from which the potatoes originated, it had not been applied in the region for the last several years. U.S. embassy officials in Costa Rica stated they had never heard of a pesticide residue rejection of a shipment of U.S. produce in Costa Rica previously. The United States will continue to engage with the Government of Costa Rica to resolve these issues.

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. Ecuador and the other three CAN Member States (Bolivia, Colombia, and Peru) maintained that CAN rules prevented them from lifting their BSE-related restrictions.

USDA officials continued to raise this issue with the Ecuadorian authorities in 2013. In March 2014, these efforts resulted in a favorable answer from Ecuador in which it accepted the protocol proposed by USDA to open the market for U.S. beef and beef products. The United States will continue to urge Ecuador to open its market fully to U.S. cattle based on science, the OIE guidelines, and the United States' negligible risk status.

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

EGYPT

Food Safety

Dioxin

From February 10 thru August 30, 2013, Egypt implemented a requirement that 100 percent of all U.S.-origin beef liver and offal imports had to be sampled and tested for dioxin. This action came after a number of U.S.-origin beef liver shipments allegedly exceeded Egypt's permissible level for dioxin. Prior to this period, the government of Egypt's sampling and testing requirement was only five percent. Egypt subsequently reduced sampling and testing to 50 percent in August 2013 after the Ministry of Health's Food Safety High Committee revised its requirements based on a three month period of shipments that met Egypt's MRLs. The United States is concerned with the length of time needed for testing, the reliability and capability of the local testing laboratory, and the high costs associated with this testing. The mandatory testing program of beef livers and offals is disrupting trade and could potentially shut the United States out of the market. Egypt does not test domestic beef and beef products for dioxin.

Animal Growth Promotants

Egypt's Ministry of Industry and Foreign Trade Ministerial Decree 266 (2011) adopted the European Economic Commission Regulation 2377 (1990), which sets MRLs for veterinary medicinal products, including animal growth promotants, in foodstuffs of animal origin. Egypt's implementation of the EU's ban on utilization of animal growth promotants threatens to jeopardize the $217 million market for U.S. beef and variety meats. Throughout 2013, the United States worked with other trading partners to urge Egypt to rescind this decree. The United States will continue to engage with Egypt on this issue.

Plant Health

Seed Potatoes

Egypt is one of the last of the world's larger 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 and Land Reclamation (MALR) 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.

Cotton

On March 18, 2012, MALR signed Decree 438 lifting the import ban on cotton from all origins that was originally imposed on October 25, 2011, by Decree 1864. However, the March decree was abrogated on technicalities by a ruling in Administrative Court, and the Egyptian government continues to only permit cotton imports for utilization in the country's free trade zones as mandated in Decree 652 of November 22, 2011. In September 2012, CAPQ announced that Egypt would require inspection by CAPQ personnel prior to shipment. CAPQ informed USDA on November 13, 2013, that it is delaying the implementation of its decision due to the lack of availability of inspectors, but the requirement remains in force. The United States will continue to engage with Egypt to remove these burdensome requirements.

ETHIOPIA

Agricultural Biotechnology

In September 2009, Ethiopia established a biosafety law that may impose unduly burdensome documentation and testing requirements for agricultural biotechnology products. Ethiopia has since issued implementing regulations, which restrict the use of U.S. agricultural commodities derived from biotech. The restrictions include but are not limited to: requiring the applicant to use a qualified expert to undertake the risk assessment for each transaction; prohibiting the use of "may contain modified organisms" language for traded living modified organisms in shipments intended for direct use as food or feed, or for processing; and requiring a signed statement for all imports from the head of the competent national authority of the country of export to the effect that the competent national authority takes full responsibility for the completeness and accuracy of the information provided in the import application. 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 agricultural biotechnology trade issue.

EUROPEAN UNION

Agricultural Biotechnology

European Union (EU) measures governing the importation and use of GE products have resulted in substantial barriers to trade. EU policies restrict the importation and use of U.S. agricultural commodities derived from agricultural biotechnology. The EU's restrictions on GE products can

result in import prohibitions on U.S.-produced commodities and foods, as well as prohibitions on the cultivation of GE seeds.

These restrictions include but are not limited to:

- commercially infeasible traceability and labeling requirements for GE content in food products under EU Traceability and Labeling regulations;
- prohibitions on the importation of GE commodities by certain EU Member States;
- bans on cultivation of GE crops in certain EU Member States; and
- unnecessary and burdensome requirements related to planting of GE crops alongside non-GE crops (for example, requiring non-GE buffer zones around fields planted with GE varieties) in certain EU Member States.

Issues related to EU approval processes further inhibit trade in GE products. These include:

- delays in approvals of new GE traits despite positive assessments by the European Food Safety Authority (EFSA); and
- registration requirements for GE commodities.

Under EU law, each GE 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 GE product, EU biotechnology legislation provides that individual Member States may invoke their own bans under a so-called "safeguard clause."

EFSA undertakes the scientific assessment in the EU. EFSA assessments of GE products generally take longer than comparable scientific assessments in the United States and other countries. However, EFSA generally reaches the same scientific conclusion for a specific GE product as scientific authorities in the United States and other countries.

On June 8, 2013, the European Commission published Commission Implementing Regulation (EU) No 503/2013, which governs EFSA evaluations of GE traits. This regulation specifies the data and testing necessary for all applications, requiring certain tests, including feeding studies, irrespective of whether they are scientifically necessary and appropriate to the application or whether they go beyond or conflict with the approach to safety assessment outlined in the relevant Codex guidelines. The regulation is likely to increase the length of time that EFSA takes to evaluate applications.

If EFSA concludes that the GE product 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 28 EU Member States. Not once in over 12 years has an EU regulatory committee accepted a proposed measure to approve a new GE 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 GE 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, a 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 GE 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 Agreement obligations to consider biotech applications without undue delay with respect to 24 specific GE 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 Agreement 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 GE products. The United States continues to engage the European Commission in an effort to normalize trade in GE products.

As of December 31, 2013, 68 GE product applications (for import, cultivation, or renewal) were pending approval in the EU system. In the course of 2013, about 10 GE product applications for cultivation were withdrawn. The EU approved only five GE products in 2013 (two import, one renewal and two extensions of the scope of use), with an average processing time of 45 months. In addition, the EU has not approved for cultivation a single GE product of commercial significance to the United States in over 12 years, leading to the withdrawal of multiple pending requests.

EU delays in GE product approvals can block trade not only for the products subject to the delays, but also for approved varieties. Under the EU's implementation of its biotechnology legislation, the presence in U.S. grain or oilseed shipments of trace amounts of GE 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 July 2011, the EU implemented a "technical solution" to address the presence of trace amounts of EU-unapproved GE products in import shipments. The new rules only cover shipments of imported animal feed (thus excluding food for human consumption) and provide an impractically low tolerance level. The Commission has announced that it will assess the need to include food within the scope of the rules, but has yet to issue any proposals.

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, however, have continued to adopt new bans on products approved at the EU level. In most cases, the Commission asks 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 the Member State to lift its unjustified ban. However, the EU regulatory committees have blocked each such measure, just as the regulatory committees have failed to approve new GE 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 GE crops in its territory. The package included a new recommendation on the management of GE crops grown in proximity to conventional and organic crops (referred to as 'co-existence') and a proposed amendment to the governing EU legislation. The recommendation on co-existence took effect immediately. It provides Member States greater flexibility when developing national co-existence measures and allows them to define GE-crop-free areas. The legislative proposal, which is still under consideration and is subject to "co-decision" by the Member States and the European Parliament, would allow Member States to restrict or prohibit the cultivation of GE crops in all or part of their territories. The proposal does not require Member States to base any such restrictions on safety concerns, but allows them to take into account specific national or local issues, such as agronomic concerns related to segregating biotech and conventional crops, or political or economic motivations such as meeting market demand for non-biotech products.

In September 2013, the European Court of Justice (ECJ) ruled that the European Commission had failed to act on a petition to permit the cultivation of a biotech corn variety, known as 1507. The original application for approval for cultivation was submitted in July 2001. EFSA delivered positive safety assessments on six occasions between 2005 and 2012. Following legal action by the applicant, the Commission presented a draft Decision to approve 1507 corn for cultivation for a vote in the relevant regulatory committee in February 2009. However, there was no qualified majority in favor of the draft Decision to approve 1507 corn for cultivation. Under the relevant EU legislation, the Commission was required to submit, 'without delay', the draft Decision to the European Council for approval. This did not happen, however, until the applicant took further legal action, resulting in the September 2013 ECJ ruling. Following the ruling, the Commission finally forwarded the draft Decision to the Council in January 2014. The Council voted on the application, but did not reach a qualified majority; therefore, the decision has been returned to the Commission, which is required to take a decision on it.

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

Food Safety

Beef and Beef Products – Hormones

In May 2009, the United States signed a MOU with the EU to resolve on a provisional basis the WTO dispute between the United States and the EU 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. The MOU required the EU to maintain a duty-free TRQ of 20,000 metric tons (MT) in each of its first three years. It required the EU to increase the TRQ to 45,000 MT during the second phase of the MOU, which began in August 2012.

In October 2013, the United States and the EU agreed to extend the second phase of the MOU through July 2015. 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

The EU's failure to allow the use of PRTs that are used in the United States remains an issue. In December 2010, USDA requested the European Commission to approve the use of lactic acid as a PRT in the processing of beef carcasses and meat. EFSA which concluded that beef treated with lactic acid as a PRT is safe for human consumption. However, after considerable delay, the European Commission published a final regulation with an effective date of February 25, 2013, allowing the use of lactic acid on carcasses, but not meat cuts. The EU has not approved any other PRTs for use on beef.

Milk and Milk Products

The EU limits the number of somatic cells permitted in raw milk, as measured by the somatic (non-reproductive) cell count (SCC). Exporters of dairy products to the EU must demonstrate that the milk used in the production of the exported products meets the EU's SCC requirements. The EU's SCC limit is burdensome for U.S. exporters since the FDA has established higher SCC levels than the EU permits. Moreover, the FDA considers the SCC level to be a quality rather than food safety criterion and, as such, believes that statements about SCC should not be required in health attestations contained in export certificates. The United States will continue to work with EU authorities to resolve this issue.

Poultry – Pathogen Reduction Treatments

In 1997, the EU began blocking imports of U.S. poultry products that had 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 the processing of 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 on their use that did not appear to be based on science. EU Member States rejected

the Commission's 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.

In June 2013, USDA submitted a new application to the EU for use of peroxyacetic acid as a PRT in poultry. EFSA officially validated the dossier in September 2013 and is expected to deliver a scientific assessment in early 2014.

MRLs

Since the establishment of the EU's harmonized pesticide MRL system in September 2008, the EU's process for setting import tolerances for pesticides has raised concerns. U.S. stakeholder groups have raised concerns that U.S. growers frequently cannot use newly-developed plant protection products, because no EU MRL has been established, or the EU MRL is set at a level that is too low.

In addition, U.S. stakeholders have raised concerns that it is unclear at what point in the tolerance-setting process agricultural or chemical industry stakeholders can provide technical data and usage information – information vital to the process. Publication of opinions from EFSA marks the first point at which the EU makes a proposed MRL publicly available. However, agricultural stakeholders are not provided an opportunity to comment on a proposed MRL until the proposal has been notified to the WTO, at which point the EU generally cannot make changes to the proposal.

U.S. stakeholders have also voiced concerns about costs associated with the EU's import tolerance application process, including the level of fees that the EU charges for filing an application for a tolerance. Moreover, the EU requires information that does not need to be generated to have a tolerance established in the United States. Many grower groups assert that they cannot afford to seek EU import tolerances due to these challenges. The United States will continue to advocate for the streamlining of the EU's system for the establishment of import tolerances for pesticides.

Ractopamine

On July 5, 2012, Codex adopted maximum residue levels for ractopamine, a new animal drug approved for use in feed that promotes feed efficiency in pigs and certain other livestock. The EU, however, maintains a ban on meat produced with ractopamine, despite U.S. government approval of ractopamine, establishment of the Codex maximum residue level for ractopamine, and scientific evidence indicating that ractopamine can be used safely. As a consequence of the EU's ban, U.S. pork exporters must participate in the burdensome *Pork for the EU Program* to verify that pork being shipped to the EU 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, pose a major impediment to U.S. pork exports to the EU, and only a small group of U.S. suppliers currently ship to the EU. The United States will continue to encourage the EU to implement the Codex standards or provide sufficient scientific evidence to support its ban on meat produced with ractopamine.

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 (VEA). 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.

Since that time, the U.S. Government has actively engaged with the European Commission on this issue and has provided the EU with information it has stated it needs to reach an equivalence determination and allow imports of U.S. molluscan shellfish to resume. The United States will continue its engagement with the EU to allow resumption of exports.

Animal Health

Animal By-Products: Tallow

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. The regulation effectively prohibited the importation of U.S. tallow that is not intended for human consumption. Between 2002 and 2007, the United States and the EU engaged in discussions resulting in an agreement with the EU to amend its regulation to allow the importation of U.S. tallow for some technical purposes. In the years 2007-2009, the EU stated that it had to wait until it replaced Regulation (EC) 1774/2002 to make those changes.

In 2009, the EU published Regulation (EC) 1069/2009, which began the process of replacing Regulation (EC) 1774/2002. Upon publication of Regulation (EC) 1069/2009, the EU stated that the changes related to tallow would not come into effect until new implementing regulations for Regulation (EC) 1069/2009 were implemented. In 2011, the EU published Regulation (EU) 142/2011, which took effect in March 2011 and revised the EU's requirements for importing tallow. While this regulation contained requirements for tallow intended for technical purposes that exceeded the recommendations of the OIE, the EU assured the United States that the EU would not apply the regulation in such a manner to block the importation of U.S. tallow intended for certain technical purposes. Consequently, U.S. industry began preparing to meet these new requirements. However, in 2012, the EU began applying the regulation in such a manner to effectively prohibit the importation of U.S. tallow. Later in 2012, the United States began discussions with the EU to try to re-open the market. The EU has worked on a draft regulatory change for tallow used for biodiesel manufacture. However the EU's requirement that U.S. tallow and its derivatives be treated as hazardous materials and subjected to costly additional

procedures within the European Union remains an obstacle to imports of U.S. tallow. The United States continues to press the EU to remove its unwarranted requirements and allow more market access for U.S. tallow.

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

Plant Health

Seeds

It is challenging to re-export to the EU seeds that were produced in another country and subsequently shipped to the United States if the re-exportation was not planned before the seeds left their country of production. This is because the EU requires the seeds to be accompanied by a phytosanitary certificate from the country of origin that includes EU-specific language, including citation to EU directives.

Wheat

Many EU countries, especially the UK and Greece, aggressively sample shipments of U.S. wheat to test for KB spores even though KB is only being found in a few counties in Arizona. In the nearly 20 years since KB was first found in the United States, KB has never emerged elsewhere in the world as a result of imports of U.S. wheat, and there has never been a confirmed case of KB contamination of a U.S. wheat shipment. Nonetheless, instead of looking for KB by inspecting shipments for bunted kernels, many EU countries test shipments for spores. These tests can produce false positives, resulting in lost shipments.

The EU, moreover, has to date refused to accept USDA's Federal Grain Inspection Service (FGIS) official sampling and testing requirements for vomitoxin (deoxynivalenol or DON) and ochratoxin in shipments of U.S. wheat for export as equivalent to the EU testing method for these mycotoxins. USDA is working with technical experts in the European Commission to garner EU recognition of FGIS sampling and testing methods for vomitoxin and ochratoxin in U.S. wheat exports. U.S. industry expects that EU recognition of these sampling and testing methods would significantly reduce testing burdens, and related costs, associated with the exportation of U.S. wheat to the EU.

EU Country Specific Issues

<u>Austria</u>

Agricultural Biotechnology

Since 1997, Austria has maintained a series of cultivation and import bans on GE agricultural products. The United States challenged several of these bans at the WTO, which found the challenged bans inconsistent with Austrian and EU obligations under the SPS Agreement. In May 2008, Austria lifted its import bans on the MON 810 and T25 GE 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) varieties. A cultivation ban on a GE starch potato was issued in April 2010.

Not only does Austria maintain cultivation bans at the federal level, but Austrian states also maintain bans. Moreover, Austria consistently votes against EU regulatory approval for new biotech crop varieties, regardless of the scientific evidence presented in the application dossier. See section III.B for an explanation of the agricultural biotechnology trade issue.

Bulgaria

Agricultural Biotechnology

In March 2010, Bulgaria issued a new biotechnology law, which prohibits the cultivation of GE crops in all protected regions, as well as surrounding areas. Protected regions are distributed throughout the country in a manner that results in the restrictions applying to the entirety of Bulgaria's territory, and accordingly the restrictions in effect serve to ban all biotech field trials and production. In addition, the law requires the Minister of Agriculture to invoke the EU's "safeguard clause" for a particular GE crop in Bulgaria whenever another EU Member State invokes the safeguard clause for that same crop. (See discussion above of the EU safeguard provisions.) Separately, in July 2010, Bulgaria enacted a prohibition on the use of GE products and ingredients in the production of foods for children and in baby food. The July 2010 regulation also banned distribution and sale of GE 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.

In April 2012, the European Commission (EC) notified Bulgaria that pursuant to EU requirements, it would need to revise its legislation to allow activities related to biotechnology when they do not pose health or environmental risks. In response, Bulgarian authorities announced proposed amendments to Bulgaria's biotechnology law on December 3, 2013. The amendments are open for public comment and are likely to enter into force in early 2014.

In 2013, Bulgaria also amended its Feed Act of November 2012. This action imposed further restrictions on trade in feed containing GE products and increased the fines for trading in illegal or improperly-labeled GE feed products. The amendments aimed to harmonize Bulgarian law with certain EU regulations in the area of feed safety and traceability.

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

Croatia

Agricultural Biotechnology

Croatia prohibits the importation of all foods that contain even trace amounts of GE agricultural products. This restriction makes it extremely burdensome and expensive to export U.S. food products to Croatia.

Although Croatia has become an EU Member State and has adopted the EU's biotech legislation, Croatia remains part of a group of EU member states that maintain more-stringent national biotech policies than the EU. Croatia regularly tests products for biotech events at the border and in the market. The testing is performed in accordance with Croatia's annual plans for Sanitary Inspection, which vary each year based on available resources.

Croatia's GE law bans the release of GE plants in areas that have been designated by the government of Croatia as having 'protected' status, as well as all areas within a certain distance of those 'protected' areas; in areas of organic farming; and in areas that are of importance to ecotourism. The law provides a legal tool for preventing the cultivation of GE plants in most of the country. Moreover, 14 out of Croatia's 20 counties have issued hortatory declarations that they are "GE free". To date, no permits have been granted for the deliberate release of GE plants in Croatia – either for field trials or commercial cultivation – and no food or feed products containing biotechnology have been approved for importation into Croatia.

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

France

Agricultural Biotechnology

Cultivation in France of MON 810 corn 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, invoking 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 left in place its ban on the cultivation of MON 810. While the French State Council lifted the ban November 2011, pursuant to the conclusions of the European Court of Justice, France re-initiated its national ban on the cultivation of MON 810 on March 18, 2012. The press revealed that the government of France reinitiated the ban without the advice of France's High Council on Biotechnology.

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

BPA Ban

In late 2012, France adopted legislation that bans the use of materials produced using Bisphenol-A (BPA) in packaging that touches food. The ban took effect in January 2013 with respect to packaging for food products designed for infants or pregnant and lactating women. Beginning in 2015, it will cover packaging for all foods; in the interim, food packaging containing BPA must bear a warning label advising against consumption of the packaged food by pregnant and lactating women and infants aged less than three years. If fully implemented, this measure is expected to severely limit U.S. exports of canned and many packaged foods, which can use packaging containing BPA. The U.S. Government has expressed its concerns about this issue to the office of the French Prime Minister and officials at France's Ministries of Health, Agriculture, Trade, and Finance. The U.S. Government has also discussed the issue with the European Commission.

Germany

Agricultural Biotechnology

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

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

Greece

Agricultural Biotechnology

Greece maintains a ban on all biotech cultivation as well as on the importation of several GE 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 a ban on cultivation. Greece now maintains its bans on MON 810 by invoking the "safeguard clause" under the EU regulations.

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

Hungary

Agricultural Biotechnology

In 2005, Hungary imposed a moratorium on the cultivation of GE crops, which was upheld by the EU Council of Ministers in February 2007 and again in 2009. In 2011, Hungary implemented new rules for the testing of seed for the presence of GE products. The new rules do not address any identifiable environmental or health risks, the testing methodologies used pursuant to the new rules 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 highlighted 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 laboratory. Seed imported from a third country requires testing by a Hungarian government laboratory. As the Hungarian laboratories 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.

In 2012, Hungary adopted an amendment to its 1998 Act on Biotechnology. The amendment refines the rules that apply to non-commercial release of GE varieties for research purposes, expands the regulatory powers of the relevant Hungarian authorities, and mandates that administrative procedures for imports of GE food and feed align with EU rules.

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

Italy

Agricultural Biotechnology

Numerous actions attest to the fact that Italy is pursuing a GE-free strategy. Italy has one of the most anti-GE 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 GE crops by creating fragmented national and regional biotech authorities. Moreover, Italy has not established a national legal framework for the cultivation of GE products. Seed importers report that they are subject to criminal penalties for the adventitious (i.e., accidental or unintended) presence of GE seeds in commercial shipments of non-GE seeds.

In September 2012, the ECJ issued a decision concluding that Italy's additional national authorization procedures for GE crops are unlawful and that the cultivation of GE varieties cannot be made subject to a national authorization when their use has been authorized at the EU level. The ECJ was ruling on a case brought against the Italian Ministry of Agriculture, which had denied authorization to plant a GE corn variety pending the adoption of national coexistence measures.

On August 12, 2013, an Inter-Ministerial Decree was published in Italy's Official Gazette formally restricting the cultivation of GE crops in Italy, despite the findings in the ECJ's September 2012 decision that Italy's *de facto* ban on cultivation approvals was illegal and could only be imposed as an 'emergency measure' with supporting documentation. Furthermore, on September 24, 2013, EFSA concluded there was no evidence to support Italy's request to impose emergency measures banning biotech cultivation under Article 34 of Regulation No 1829/2003.

Latvia

Agricultural 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, 101 of the 110 municipalities in Latvia have banned the cultivation of GE 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 GE-free zones can be created on the basis of voluntary agreements among the "economic operators" in an area.

The United States has engaged the government of Latvia regarding its current policy and has requested further information about the basis for the current biotech cultivation bans.

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

Luxembourg

Agricultural 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 agricultural biotechnology trade issue.

Poland

Agricultural Biotechnology

Since 2006, Poland has not only opposed the approval of GE 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 GE 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 GE crops beginning in August 2008. On August 28, 2012, the Polish President signed an amendment to Poland's Feed Act delaying the implementation of a ban on the entry, production, manufacturing, marketing, and use of animal feed containing GE components until January 1, 2017. However, effective January 28, 2013, the Polish government banned the cultivation of EU-approved MON810 corn and a GE potato variety, the Amflora potato, through an amendment to the Polish Seed Act applying the EU safeguard clause.

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

Portugal

Agricultural Biotechnology

Portugal is the second largest EU producer of MON810 corn, after Spain. However, 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 to oppose Madeira's request by the legislated deadline. Madeira's authority for its ban on GE cultivation 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 GE crops in part or all of their territory. The net effect of the Madeira GE-free declaration is that no GE crops can be grown in Madeira. In June 2012, the Azores, another Autonomous region of Portugal, also declared itself a GE-free cultivation zone.

Portugal not only allows autonomous regions to declare themselves GE-free, it also allows municipalities to do so. To date, 30 out of Portugal's 308 municipalities have done so.

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

Romania

Food Safety

Eggs

Under the VEA, the EU agreed that egg products and shell eggs from the United States unconditionally meet the EU's appropriate level of sanitary protection. The VEA also states that the United States can certify establishments for export to all member states, including Romania. However, Romania has not recognized non-EU suppliers of fresh or processed eggs. Because there is no EU regulation listing the United States or U.S. suppliers as eligible to export to all EU Member States, Romania's failure to adopt a national regulation prevents U.S. access to the Romanian egg products market.

Animal Health

Supplementary Testing for Frozen Bovine Semen

In 2011, as part of a new surveillance program, the Romanian Veterinary Authority required samples to be collected from imported bovine semen for testing for Bovine Brucellosis. In September 2012, after several months of engagement by FAS Bucharest, the Romanian Veterinary Authority modified its Brucellosis testing requirement to apply only to new-to-market bulls originating from non-EU countries. This requirement continues to be applied with respect to bovine semen from the United States even though U.S. veterinary certificates attest that the donor animal is free from Bovine Brucellosis, and even though the requirement is not applied to bovine semen from animals of EU origin.

HONG KONG

Food Safety

Hong Kong is in the midst of a transition to a positive pesticide MRL list, which is scheduled to go into effect on August 1, 2014. The United States has submitted several rounds of comments to Hong Kong regarding the transition and has identified numerous U.S.-approved pesticides that were missing from Hong Kong's provisional positive MRL list. As a result of U.S. efforts, numerous MRLs for U.S.-approved pesticides have been included on Hong Kong's national MRL list, but there remain a significant number of U.S.-approved pesticides for which MRLs have not yet been established in Hong Kong. The United States will continue to engage with Hong Kong during this transition to determine what additional data is needed for Hong Kong to set MRLs for U.S.-approved pesticides, and will work with relevant authorities to obtain tolerances for the remaining U.S.-approved pesticides prior to Hong Kong's implementation date.

INDIA

Food Safety

Dairy Products

Since 2003, India has imposed unwarranted SPS requirements on U.S. dairy imports, which have precluded U.S. access to India's dairy market, one of the largest in the world. India has insisted on onerous certification requirements and refused to accept U.S. food safety and animal health standards as effective.

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, creating uncertainty for importers. India also restricts the importation of pork that has been fed ruminant-derived protein, which is inconsistent with OIE guidelines. Similarly, the animal health attestations that India requires for the exportation of pork to India are vague, and India requires extra inspections that do not appear to be consistent with international standards. India also prohibits imports from the United States of pork products obtained from animals raised outside the United States, notwithstanding the safety of those products. Further, import certificates are valid for only six months and must be obtained for each imported lot. The United States will continue to press India to lift its unwarranted restrictions and to revise its import certificates so as to clarify any legitimate requirements and be valid for a reasonable period of time.

India only allows imports of U.S. pork from plants that inspectors have certified are free of PRRS, trichinae, transmissible gastroenteritis, atrophic rhinitis, leptospirosis and anthrax for two years prior to slaughter. 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 these diseases in the United States to extremely low levels. The United States continues to discuss this issue with India.

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

Animal Health

Poultry, Swine, and Pet Food

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

To further address this matter, the United States requested WTO dispute settlement consultations with India regarding its import ban on March 6, 2012. The United States and India held consultations in Geneva in April 2012. The consultations did not lead to a resolution of the dispute. At the request of the United States, in 2012 the WTO Dispute Settlement Body established a panel to resolve the dispute. During 2013, the parties to the dispute filed written submissions, and the panel held two meetings with the parties. The panel is expected to issue its report on the U.S. claims against India in 2014.

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

Plant Health

Pulses

India requires that shipments of all pulses to India be fumigated with at methyl bromide (MB) at the port of origin. However, it is not feasible to fumigate pulses at U.S. ports due to the phase-out of MB in the United States. Additionally, it is difficult to fumigate pulses with MB in colder climates.

In August 2004, the United States asked India to permit the exportation of U.S. pea and pulse consignments to India without fumigation at the port of origin provided they are inspected and, if necessary, fumigated at the port of arrival. India has enacted, but not implemented a requirement that shipments of all pulses to India be fumigated at the point of origin, allowing MB fumigation on arrival, but has offered no permanent solution. The most recent extension expires on March 31, 2014. The United States continues to seek a permanent resolution to this issue.

Wheat and Barley

India maintains zero-tolerance standards for certain plant quarantine pests, such as weed seeds and ergot. These zero tolerance standards block U.S. wheat and barley exports to India. Bilateral discussions to resolve these issues continue.

INDONESIA

Food Safety

Beef and Pork

Indonesia does not recognize the equivalence of the U.S. inspection system for beef and pork. Instead, Indonesia requires U.S. meat establishments seeking to export to Indonesia to complete an extensive questionnaire that includes proprietary information. Indonesia's document-review process, moreover, has resulted in approval of only a limited number of U.S. establishments. Several U.S. beef and pork establishments submitted applications more than three years ago and still have not obtained approvals.

The United States has raised concerns about the establishment questionnaires and approval system with Indonesia repeatedly, including at the WTO SPS Committee and at meetings of the

United States-Indonesia Council on Trade and Investment, and will continue to raise concerns in WTO and bilateral fora.

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 Ministry of Agriculture. The law allows imports of these products only from facilities that Indonesian authorities have individually audited and approved. The law and associated implementing regulations, issued in 2011, impose overly stringent auditing and inspection requirements. To date, Indonesia has not notified Law 18/2009 to the WTO.

Following an audit of the U.S. food safety system as it applies to a dairy product in 2011, Indonesia agreed to a simplified questionnaire for U.S. dairy facilities seeking to pre-register for review and approval. The United States is continuing to work with Indonesia to further to improve the system under which U.S. establishments are made eligible to export dairy products to Indonesia.

IRAQ

Food Safety and Animal Health

On May 5, 2013, Iraq's Advisory Committee for Food Safety issued Decision 183, which declared U.S. beef ineligible for import due to BSE concerns. The United States has requested the Advisory Committee to rescind the decision and lift the ban on U.S. beef. The United States will continue to urge Iraq to open its market fully to U.S. beef based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

ISRAEL

Food Safety and Animal Health

Live Cattle, Beef, and Beef Products

Israel imposed BSE-related restrictions on the importation of live cattle, beef, and beef products from the United States in 2003, but dropped these restrictions in 2011. Although Israel rescinded the restrictions, U.S. exporters remain unable to ship live cattle, beef, and beef products to Israel, because Israel has not agreed with the United States on a protocol for the exportation of these products from the United States to Israel. In 2013, the United States and Israel had productive discussions on a protocol; however, the issue remains unresolved.

See section III.A for an explanation of the export certification trade issue, and 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 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. Israel has not conducted a PRA, and these pests have not been found in shipments from the United States. In 2012, Israel agreed to remove the cold treatment requirement for U.S. pears shipped in a firm state. Experts from USDA and Israel continue to work on an appropriate additional declaration to accompany the export certificates for pears. Regarding U.S. apples, originally Israel had approved four cold treatment methods, one of which was approved as an interim measure. Israel notified USDA in October 2013 that the one treatment that was approved as an interim measure would be unavailable until Israel receives, reviews, and accepts research data from cold treatment efficacy trials, which are currently underway. As a result, exporters to Israel must use one of remaining three methods of cold treatment to minimize the risks

Cherries

For nearly nine years, Israel has banned imports of U.S. sweet cherries, citing risks of various plant pests and diseases. U.S. officials are working with Israel to complete Israel's risk assessment on sweet cherries in an attempt to resolve this longstanding issue. During technical bilateral meetings in August 2010, Israel agreed to expedite its risk assessment for U.S. sweet cherries. To date, however, the issue remains unresolved.

JAMAICA

Animal Health

Pork

Jamaica currently bans imports of U.S. pork. However, during 2013, Jamaica completed a risk assessment on U.S. chilled and frozen pork, with favorable results. The United States and Jamaica are currently negotiating language for veterinary certificates that would enable the shipment of U.S. pork to Jamaica. Jamaica also continues to work with the United States on the U.S. request for a determination of the equivalence of the U.S. sanitary system for 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, allowing imports of some U.S. beef and beef products from animals aged 20 months or younger produced under a special program for Japan.

In October 2012, Japan's Food Safety Commission (FSC) issued a final risk assessment regarding the importation of U.S. beef and beef products, which recommended that Japan: (1) raise the age limit for cattle from which U.S. beef and beef products destined for Japan can be produced from 20 months of age to 30 months, and (2) adopt a revised definition of SRM that is closely aligned with the international standards of the OIE.

Based on the FSC risk assessment, Japan entered into consultations with the United States with the aim of revising Japanese import requirements for U.S. beef and beef products. In January 2013, the United States and Japan agreed on new terms and conditions for the export of U.S. beef and beef products to Japan. Under these new terms, which entered into effect on February 1, 2013, Japan now permits the import of beef from cattle less than 30 months of age. In an accompanying letter exchange, Japan also confirmed that the FSC is conducting an ongoing BSE risk assessment, which will assess the possibility of raising the age limit above 30 months for beef and beef product imports from the United States, taking into account international standards. As a result of these actions, U.S. beef exports to Japan reached nearly $1.4 billion in 2013, a 35 percent increase from 2012. The United States continues to press Japan for full market access, including all products from animals of all ages, consistent with OIE guidelines.

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 Japan's 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. More than seven of the 46 additives remain unapproved. The United States understands that Japan is currently reviewing the remaining unapproved 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.

Gelatin and Collagen

Japan banned the importation of U.S.- ruminant-origin gelatin and collagen 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 were subsequently 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 undertake a risk assessment to pave the way for lifting the ban on U.S. ruminant-origin gelatin and collagen consistent with science and OIE guidelines.

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

Pre- and Post-Harvest Fungicides

Until 2013, Japan maintained a bifurcated approval process for fungicides applied both before and after harvest. Fungicides applied pre-harvest are classified under Japanese law as pesticides and, before 2013, had to be approved through the approval process for pesticides. Fungicides that are applied post-harvest are classified as food additives and, before 2013, had to be approved pursuant to the process used for approval of food additives. Accordingly, any fungicide used both pre- and post-harvest was required to undergo two separate risk assessments. The bifurcated approval process for fungicides applied both pre- and post-harvest was redundant and took as many as six years to complete. The requirement for dual risk assessments deterred registrants from pursuing approval for new and safe products. While significantly impacting U.S. exports, Japan's dual risk assessment requirement did not have a significant impact on domestic producers, as Japanese farmers do not generally apply fungicides after harvest.

Japan's pre-2013 policy appeared 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 the fall of 2013, Japan announced a new streamlined review process for agricultural chemicals, including fungicides, applied both as pesticides (pre-harvest application) and as food additives (post-harvest application). Under the revised system, in line with international norms, Japanese officials will conduct a single risk assessment focusing on the characteristics of the agricultural chemical itself instead of the time of application to the crop. The revised process is expected to significantly reduce the length of time taken by regulatory reviews. The United States will work with Japan during the implementation of the new review process.

Although Japan has stopped conducting bifurcated reviews of applications for approvals of fungicides, the United States remains concerned that Japan requires products treated with a post-harvest fungicide to be labeled at the point of sale with a statement indicating that they have been so treated. This unnecessary labeling requirement dampens demand for the products.

Maximum Residue Limits

Prior to 2013, Japan's refusal to accept an application for an import tolerance for a pesticide or fungicide until the agrochemical was approved for use in a major supplier country exacerbated the risk of disruptions in U.S. exports to Japan by causing a significant time lag between U.S. approval of a chemical and Japan's establishment of an import tolerance for that chemical. In May 2013, however, Japan announced that going forward, it would accept an import tolerance application for a pesticide or fungicide regardless of whether an MRL for the pesticide or fungicide has been set in the country that is the source of the application, as long as the core risk assessment is completed. With this change in policy, agrochemical companies submitting registration applications with U.S.-EPA became able to apply simultaneously for import tolerances in Japan.

In July 2009, the United States and Japan concluded an MOU on MRLs that changed the way in which MRL violations are handled. Pursuant to the MOU, Japan established a mechanism under its import and food monitoring policy for shippers to address violations quickly. While there has been improvement in how Japan handles MRL violations, the United States remains concerned that Japan's procedures still require industry-wide enhanced surveillance of shipments of a product after a single violation by a single shipper.

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

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. While the United States and Japan agreed to modifications of the protocol in 2012, which addressed some of the problematic requirements related to HPAI, Japan continues to impose LPAI-related restrictions that do not appear be consistent with OIE recommendations. The United States continues to press Japan to agree to a fully OIE-consistent revised protocol and to discontinue LPAI-based restrictions on these commodities.

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, Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) and USDA reached an agreement to allow limited imports of U.S. fresh potatoes from 13 states to produce potato chips. The agreement allowed shipments only to a single chipping facility in Japan and provided for a shipping period of just five months (February to June). In 2010, Japan added the state of Washington to the list of U.S. states eligible to ship chipping potatoes to Japan. In 2011, MAFF extended the eligible shipping period to include July. In 2012, the United States secured MAFF's approval of two additional U.S. states (Nevada and Montana) as eligible potato shipping states which significantly contributed to the increase om imports of U.S. fresh potatoes during that year.

In 2011, the Japanese government also approved a second potato processing facility to receive U.S. chipping potatoes. This plant was in the Kagoshima Port area, and its approval has doubled Japan's capacity to process U.S. chipping potatoes. However, Kagoshima does not have an international port and so currently U.S. potatoes must be transported on a feeder vessel. The U.S. potato industry and Japanese processors remain extremely interested in securing approval for the overland transportation of potatoes from an international port to the Kagoshima facility. At bilateral discussions in August 2013, Japan indicated that approval could occur for all

overland routes, and thus for shipment to all Japanese potato processing facilities, but this has not yet occurred. Approval for overland transportation of U.S. potatoes will reduce the cost of transporting them to Japanese processing facilities and will clear the way for the processing of potatoes at non-port processing facilities. The United States will continue to engage with the government of Japan on this issue.

KAZAKHSTAN

Systemic Issues

The entry into force of the Customs Union of Russia, Kazakhstan, and Belarus on January 1, 2010 (the "Customs Union" or CU) has complicated exports into and trade among the three countries, as they harmonize and revise their SPS measures.

The process of harmonizing and revising SPS measures between the Customs Union (CU) countries, which include Russia, Kazakhstan, and Belarus, is ongoing. On July 1, 2010, the CU implemented harmonized veterinary requirements stipulating that imports for all 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. Although CU inspection regulations allow the CU to accept guarantees provided by SPS authorities in non-CU countries that certify new establishments in lieu of inspection by CU authorities, implementation of this provision has lacked predictability and transparency, with CU countries often insisting, without providing any rationale, on inspecting a facility prior to its approval.

The United States worked with Russia and the CU authorities to remove products from the list of goods subject to veterinary control where no scientific basis supporting their inclusion was provided, to eliminate the requirement that the United States provide a list of all facilities that meet CU requirements for low risk goods subject to veterinary control and to streamline the approval of U.S. facilities. The CU countries have amended the CU agreements to align some of the CU's veterinary requirements with international standards, guidelines, and recommendations. However, both on paper and as implemented by CU countries, many CU requirements continue to appear inconsistent with international standards, guidelines and recommendations.

The U.S. Government continues to work with Kazakhstan to encourage improvements in the CU's SPS regime and to ensure that implementation of the CU's SPS measures does not disrupt trade. However, as a result of its adoption of CU requirements, Kazakhstan has begun to impose some measures that have the potential to restrain U.S. exports.

In addition to implementing CU import requirements, 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;
- 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).

Agricultural Biotechnology

The Kazakh draft law "On Seeds Farming" theoretically allows the field-testing of GE crops, although the draft law "On State Regulation of Genetic Engineering Activities" sets out an approval process for field tests. In the absence of an approval process, no field tests can occur. These draft laws have remained pending in the Kazakh Parliament since early 2011. The draft laws are expected to come up for discussion again in 2014. Some sources believe that it is likely the laws will only pass after Kazakhstan's WTO accession.

CU regulations covering GE products have recently come into force, regulating labeling of imports of GE products. As Kazakhstan continues to integrate into the CU, it is expected that the policies and views of the other CU countries will play a greater role in shaping the regulation of biotechnology in Kazakhstan.

See section III.B for an explanation of the agricultural 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 prevalence of trichinae to extremely low levels in commercial swine. The United States will continue to work with the regulatory authorities in Kazakhstan and the CU to resolve this trade concern.

Ractopamine

It appears that Kazakhstan imposed a *de facto* ban on imports of all U.S. beef, pork, turkey, processed products containing beef, pork, or turkey, raw materials for casings, and casings, effective February 2013, based on detections of ractopamine residues in various beef and pork shipments to Russia, another CU country. Kazakhstan has not notified the United States regarding its ractopamine-related import restrictions.

KENYA

Agricultural Biotechnology

Following a November 8, 2012, Kenyan Cabinet and Presidential decree, on November 21, 2012, the Kenyan Ministry of Public Health ordered public health officials to remove all foods, feed, and seeds derived from agricultural biotechnology from the market and to enforce a ban on agricultural biotechnology food and feed imports. U.S. officials are engaging with Kenya on the issue.

Food Safety

Poultry

Contrary to OIE guidelines, Kenya prevents the importation of live chicks from the United States, citing the presence of low pathogenic avian influenza in the United States. In addition, as with other meat products, the importation of poultry and poultry products, such as frozen chicken (whole bird and/or parts), eggs in shell for human consumption, and liquid or powdered egg products, requires a permit and a no-objection letter from Kenya's Department of Veterinary Services (DVS). Prior to issuing a no-objection a letter, the DVS may, depending on the country of origin of the products, conduct a risk assessment. Moreover, the DVS may deny import permits based on "local market needs."

Plant Health

Corn

Kenya imposes a MRL for aflatoxin on corn of 10 ppb. Kenya also limits the maximum moisture content of corn to 13.5 percent. Both the moisture and aflatoxin standards apply to locally-sourced and imported corn. The 10 ppb aflatoxin limit is not scientifically justifiable; the CODEX and U.S. standard is 20 ppb. Moreover, most U.S. corn has moisture content higher than 13.5 percent and therefore cannot be imported into Kenya. However, under special circumstances, such as food shortages, the Government of Kenya has allowed the importation of corn with a moisture content above 13.5 percent, provided that the corn is dried and milled immediately upon arrival to reduce the risk of aflatoxin contamination.

Peas and Beans

Kenya does not permit the importation of whole peas from the United States due the risk of *pseudomonas pisi* fungus, although it allows the importation of split peas. Kenya also prohibits the importation of U.S. beans due to the occurrence of *corynebacterium flaccumfasciens* bacteria in some parts of the United States. Kenya's prohibitions on the importation of U.S. beans and whole peas appear to lack a scientific basis.

In addition, Kenya restricts the importation of U.S. lentils due to the presence of darnel weed in the United States. Darnel weed, however, also exists in Kenya, calling into question the justification for Kenya's ban on U.S. lentils.

Wheat

Kenya maintained a long-standing prohibition on U.S. wheat exports due to flag smut. Although Kenya did not enforce the prohibition for some time, it began enforcing the prohibition in 2006. USDA subsequently worked with Kenyan officials, enabling them in 2007 to lift the ban except with respect to wheat shipped through Washington, Oregon, and Idaho. USDA continues to work with Kenya to allow wheat shipments from these States to enter Kenya.

Kenya's SPS restrictions also impact U.S. wheat exports from the Pacific Northwest to Uganda. USDA continues to work with Kenya to resolve this issue.

KOREA

Agricultural Biotechnology

Korea's regulatory system for agricultural 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 biotechnology 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 implementing regulations, 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 product risk assessments may be redundant and lacking scientific justification. Korea's process may lead to delays in the approval of new products. In addition, the United States is concerned that the LMO Act, while nominally applying to all living GE organisms (*i.e.* plants and animals), was written solely with living modified plants in mind and thus does not readily apply to the trans-boundary movement of living GE animals.

In late 2012, Korea's National Assembly approved revisions to the LMO Act. However, the United States remains concerned that the revisions did not provide for a distinction between seed and food or feed processing, or revise the redundant risk assessment process. Korea is expected to revise the implementing regulations to the Act in 2014 to reflect the recent changes to the Act itself.

In 2013, Korea completed approval of five new single biotech events for food use and two new single events for feed use. The United States will continue to engage with Korea to avoid disruptions to exports of U.S. biotech products.

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

Food Safety

Beef and Beef Products

Prior to 2008, Korea restricted the importation of U.S. beef and beef products due to BSE-related concerns. Following a 2008 bilateral agreement to fully re-open Korea's market to U.S. beef and beef products, Korean beef importers and U.S. exporters have operated according to a voluntary,

commercial understanding that imports of U.S. beef and beef products will be from animals less than 30 months of age, as a transitional measure, until Korean consumer confidence improves. To date, this agreement has been operating smoothly. In 2013, the U.S. exported $609 million worth of beef (including variety meats) to Korea, an increase of five percent from the same period last year, making Korea the fifth-largest export market for U.S. beef.

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

Maximum Residue Limits

Korea is in the process of shifting to a new "positive list" system for listing MRLs. As part of this process, Korea is applying new MRLs. U.S. grain and fruit exporters face a significant challenge in continuing their trade with Korea during the transition period because of the uncertainty about which specific MRLs will be applied. The United States will continue to encourage Korea to maintain its current list of MRLs to allow sufficient time for a smooth transition to a new positive list system. The United States will also continue to seek guidance from Korea on how U.S. pesticide manufacturers and registrants can effectively respond to the Ministry of Food and Drug Safety's requests for information used in the establishment of MRLs for imports.

Korea has increased pesticide residue testing on U.S. commodities due to residue violations in U.S. shipments to other countries. After a single MRL violation by a U.S. export to either Korea or another country, Korea may impose restrictive import requirements on that product's grower, shipper, and importer, and may require that they make a certain number of compliant shipments to Korea before removing those requirements.

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

Potatoes

In August 2012, Korea prohibited the importation of fresh potatoes from the Pacific Northwest due to the presence of zebra chip in the region. Although Korea reopened its market to fresh chipping potatoes from the Pacific Northwest in September 2012, it continues to prohibit the importation of fresh table-stock potatoes from the Pacific Northwest. Korea does not have the insect that carries zebra chip from one potato plant to another, and the disease cannot be spread without this insect. Additionally, U.S. potatoes exported to Korea are treated with sprout inhibitor and are destined for consumption or processing – not propagation. Sprout-inhibited fresh potatoes destined for consumption or processing are not a phytosanitary threat.

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, but not Alabama. USDA provided information to the Kuwait Public Authority for Agriculture and Fishery Affairs enabling it to remove its ban on live cattle and beef from Oklahoma. However, the Municipality of Kuwait has refused to remove its ban on beef produced in Oklahoma. The United States will continue to urge Kuwait to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' negligible risk status for BSE.

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

KYRGYZSTAN

Food Safety

Poultry

In November 2013, Kyrgyzstan conducted an inspection of three U.S. poultry establishments without the knowledge of U.S. authorities. Kyrgyzstan subsequently restricted poultry imports from the United States to these three establishments without notifying the United States. The United States has protested the lack of a formal notification of Kyrgyzstan's intent to conduct inspections, restrict market access and the absence of any science-based justification for these restrictions. The United States has also urged Kyrgyzstan to lift its restrictions on poultry imports from the United States and to conduct an audit of the U.S. sanitary system for poultry in a manner consistent with international standards.

MACEDONIA

Food Safety

In what appears to be a consequence of Macedonia adopting EU certificate attestations, Macedonia stopped accepting the FSIS meat inspection system as equivalent to Macedonia's, and stopped accepting the standard FSIS export certificate. As a result, Macedonia also stopped accepting imports of U.S. pork. The U.S. government is working with the Government of Macedonia to agree on a pork export certificate that does not impose any non-scientific barriers to trade and that will allow the importation of U.S. pork to resume.

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

MALAYSIA

Agricultural Biotechnology

Although GE crops are not generally approved for planting in Malaysia, the Malaysian government recently allowed GE papaya trials. GE crop events are only supposed to be sold in the Malaysian market if they have been approved for food, feed, and processing. While Malaysia has approved a few corn and soybean GE events for release on the market, bulk shipments of corn and soybeans face the risk of rejection if a variety that has not yet been

approved is detected. Malaysia published new GE labeling guidelines last year that will be enforced starting in July 2014, including for processed food.

Food Safety

Pork

In June 2011, Malaysia's Department of Veterinary Services (DVS) stopped issuing import permits for frozen and chilled pork products from the United States. At that time, DVS instituted new requirements for the exportation of pork to Malaysia, which include a requirement that representatives of pork production companies submit a lengthy application for each facility that will be used to produce products for the Malaysian market, and that each such facility undergo an audit by DVS at the expense of the producer or the producer's government. Malaysia will only grant an import permit for the shipment of pork from a facility upon successful completion of these procedures. The United States has raised concerns over these requirements with Malaysia on multiple occasions and is actively working towards a resolution to regain access for U.S. pork exports. DVS has agreed to conduct a systems audit of the U.S. sanitary system for pork in early 2014 with the goal of moving towards reopening Malaysia's market to U.S. pork products.

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. However, through 2013, Mexico retained prohibitions on the importation of U.S. beef derived from animals over 30 months of age. Until 2012, Mexico also retained restrictions on the importation of U.S. weasand meat, ground beef, head meat, and small intestines from cattle under 30 months of age. However, in the fall of 2012, the United States and Mexico reached agreement to allow the importation of these products from the United States, provided they meet certain requirements.

Moreover, in response to the OIE's recognition last year of the negligible risk status of the United States with respect to BSE, Mexico notified the United States on September 27, 2013 that U.S. beef products would be authorized for importation into Mexico regardless of the age of the cattle from which they were derived, with the exception of traditional SRMs. The United States and Mexico are currently working to finalize a set of agreed veterinary certifications for the exportation to Mexico of U.S. beef derived from cattle over 30 months of age. In addition, the United States has submitted a proposal to Mexico to permit the exportation of U.S. live cattle to Mexico.

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

Dairy

Mexico refuses to allow the importation of unpasteurized commercial milk from the United States until it completes a risk assessment on the safety of U.S. unpasteurized commercial milk. However, Mexico has not initiated this risk assessment due to budgetary and personnel limitations. As a result, the United States is unable to send unpasteurized milk to Mexico for further processing. The United States will continue to urge Mexico to undertake the necessary risk assessment for this product.

Stone Fruit

U.S. peach, nectarine, and apricot growers encounter problems exporting to Mexico due to Mexico's requirements to control the oriental fruit moth and other pests considered to be quarantine pests by Mexico. The United States has worked to address these measures as they apply to growers in California, Georgia, South Carolina, and the Pacific Northwest.

California

Under the California Stone Fruit Work Plan, Mexico imposes a high level of direct 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 U.S. industry to pay for several 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 Mexican government oversight of U.S. producers through on-going bilateral discussions. 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 pilot project, based on 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 February 2011. In October 2011, due to interceptions of plum curculio, Mexico temporarily suspended shipments. As an alternative to the work plan, Mexico has proposed allowing importation of Georgia and South Carolina peaches using methyl bromide fumigation treatment under the direct oversight of Mexican inspectors. The industry is also interested in using irradiation treatment as a means of securing market access with reduced oversight by Mexico. A draft PRA and proposed Irradiation Operational Work Plan are under review by Mexico.

Pacific Northwest

USDA is awaiting a PRA from Mexico to address a request to allow peaches, nectarines, and plums from the Pacific Northwest to be shipped to Mexico. Mexico has stated that in the

absence of the PRA, it would accept peaches, nectarines, and plums 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 continue to have technical discussions on this issue.

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.A for an explanation of the export certification trade issue, 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.

NAMIBIA

Food Safety

Poultry

In February 2013, Namibian authorities' changed Namibia's import requirements for poultry and poultry products. U.S. export certificates must now attest that products are derived from chickens hatched and reared in the United States. While the Namibian market for U.S. poultry was quite small, all poultry products imported into Namibia, including those destined for the larger Angolan market, must meet these requirements. Since a common practice in the U.S. poultry industry is to import from Canada one day old chicks, USDA is not able to certify to these requirements. Therefore, currently U.S. poultry or poultry products are not exported to Namibia. In September 2013, USDA officials met with the Namibian Acting Chief Veterinarian Officer to start negotiating new import permit language to allow entry of U.S. poultry into Namibia. USDA is currently reviewing the latest import language requirements provided by Namibia during the September 2013 meeting.

NIGERIA

Food Safety

Meat and Meat Products

Nigeria continues to ban imports of all bovine animal meat and edible offal (fresh, chilled, frozen) as well as pork, sheep, goats and edible offal of horses, asses and mules. While BSE is the stated rationale, these bans apply to all countries, even those without BSE cases. Nigeria also bans the import of live and dead poultry (with the exception of day-old chicks) and poultry meat,

including fresh, frozen, and cooked poultry meat. While the stated rationale is to prevent the spread of AI, these bans were implemented during the 2006 AI outbreak and do not reflect current AI risk.

Import Certificates

Nigeria requires that all food, drug, cosmetic, and pesticide imports be accompanied by certificates from manufacturers and appropriate national authorities, regardless of origin. These certificates attest that the product is safe for human consumption (e.g., does not contain aflatoxin). However, Nigeria's limited capacity to review certificates, carry out inspections, and conduct testing has resulted in delays in the clearance of food imports.

NORWAY

Agricultural 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 agricultural 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

Agricultural Biotechnology

In December 2011, Peru adopted a ten-year moratorium on cultivation of biotech crops. The moratorium excluded products used in research in a confined environment, in pharmaceutical or veterinary products, or GE products used for food, feed or processing. A risk assessment must be performed for these excepted products, and 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 and to test for the presence of GE products in imported commodities could create uncertainty in the market and potentially disrupt U.S. exports. In November 2012, Peru published Implementing Regulations for the enforcement of the moratorium. The regulations do not provide necessary practical guidance for implementation, such as specifying the sampling size or procedures for testing of imported seeds. The regulations also include steep penalties for the presence of GE materials in imported seeds, even if inadvertent or in low levels. The United States continues to raise concerns with Peru in

multilateral and bilateral meetings and to ask Peru to formally notify the implementing regulations at the TBT Committee in Geneva, as required by the TBT Agreement.

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

Food Safety

Pork

Peru requires U.S. pork be shipped to its market frozen or be 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 has requested that Peru revise these requirements for fresh and chilled pork and provided evidence to Peru in May 2012 that supports this request. The United States raised the issue at the United States-Peru FTA SPS Committee meeting in June 2012. In March 2013, Peru requested the United States to complete a questionnaire so that it could initiate a risk assessment of pork shipments. The United States submitted the completed questionnaire in September 2013 and a response from Peru is pending. The United States will continue to engage 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. Prior to 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 are able to elaborate their own requirements regarding the importation of live cattle from the United States in accordance with the CAN risk assessment.

USDA provided updated information to Peru in May 2012 to support the U.S. request for market access, and the U.S. officials subsequently raised the issue with Peruvian counterparts the June 2012 meeting of the United States-Peru FTA SPS Committee. In September 2013, the United States answered questions from Peru in a new proposal addressing BSE and other disease concerns and is awaiting a response from Peru. The United States will continue to engage with Peru to re-open its market for U.S. live cattle based on science, the OIE guidelines, and the negligible risk status of the United States.

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

PHILIPPINES

Food Safety

Meat Handling Regulations

The Philippines maintains a two-tiered system for regulating the handling of frozen and freshly slaughtered meat for sale in local "wet" markets. This system imposes excessively-high requirements 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. Despite numerous requests from the United States, the Philippines has not shared a risk assessment to support its treatment of frozen and freshly slaughtered meat. The United States has raised concerns with the Philippine government on numerous occasions and will continue to press the Philippines to address this issue.

SPS Import Clearance

The Philippines Department of Agriculture requires importers to obtain an SPS permit prior to shipment for any agricultural product and transmit the permit to the exporter. This requirement adds costs, complicates the timing of exports, and prevents the transshipment of products to the Philippines originally intended for other markets. It also prevents an exporter from reselling product if the importer refuses to accept delivery or abandons the shipment. The United States will continue to engage with the Philippines to address this issue.

RUSSIA

Systemic Issues

Russia is 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). Russia must also comply with its commitments on SPS matters contained in its protocol of accession to the WTO.

The process of harmonizing and revising SPS measures among the CU countries, Russia, Kazakhstan and Belarus, is ongoing. On July 1, 2010, the CU implemented harmonized veterinary requirements stipulating that imports for all 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 and CU authorities 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 low risk goods subject to veterinary control, and to streamline the approval of U.S. facilities. The CU countries have amended the CU agreements to align some of the veterinary requirements with international standards, recommendations, and guidelines. However, much of this work remains ongoing.

U.S. exporters also 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, Russia requires phytosanitary attestations for shipments of certain processed agricultural products, such as corn gluten, 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 will continue to engage with Russia to modify these requirements and to supply 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 CU now has competence for establishment inspections and approvals. The United States worked with Russia and CU authorities 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. However, implementation of this regulation has lacked predictability and transparency, because CU countries often continue to insist on conducting their own inspections prior to approval of an establishment, without providing any rationale. The United States will work closely with Russia to revise CU inspection regulations and to improve its implementation.

Veterinary Certificates

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

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

Agricultural Biotechnology

Although Russia has established a system for the approval of GE 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 and labeling of GE products. The United States has encouraged Russia to address these specific concerns, as well as to promote

greater cooperation on agricultural biotechnology generally. In September 2013, Russia passed Resolution No. 839, which approved framework rules for the registration of genetically engineered organisms for release into the environment and authorized the development of procedures for such registration by July 1, 2014. Resolution No. 839 will not have any immediate effect on the cultivation of biotech crops in Russia, but creates an approval process to make such cultivation possible in the future.

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

Food Safety

Pathogen Tolerances

Russia maintains a zero tolerance for all food products, including raw meat and poultry, for *Salmonella*, *Listeria, coliforms*, and colony forming units of aerobic and anaerobic bacteria. Such a policy is unwarranted with regard to raw products, because it is generally accepted by food safety experts and scientists that these pathogens are often closely associated with raw meat and poultry product and cannot be removed from the product.

Veterinary Drugs

Russia maintains a zero tolerance policy 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 veterinary drugs approved in the United States. Findings of veterinary drug residues during Russian border inspection of U.S. products have resulted in trade disruptions, including the unwarranted de-listings of U.S. beef, pork, and poultry facilities.

Ractopamine

In 2012, Russia began enforcing a zero tolerance standard for residues of ractopamine, a feed additive that promotes feed efficiency in pigs, cattle and turkey, despite U.S. government approval of use of this additive, establishment of a Codex standard, and scientific evidence indicating that ractopamine can be used safely. Based on the presence of ractopamine in various beef and pork shipments, Russia banned all U.S. beef, pork, processed products containing beef or pork, turkey, raw materials for casings, and casings, effective on February 11, 2013. The United States will continue to work with the Russian veterinary service to restore market access for these U.S. meat products.

Beef and Beef Products

Currently, U.S. producers may export deboned 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 the CU veterinary requirements, the United States will continue negotiations with Russia and its CU partners of a new sanitary 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 to 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 fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible 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.

Milk and Milk Products

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 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 continues to work with Russia and its CU partners to conclude a certificate to 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. 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, in cooperation with industry stakeholders, reviewed Russia's risk assessment for tetracyclines and provided comments to Russia. The United States will 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 exports of U.S. fresh and chilled pork 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 in commercial swine. 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 chicken using chlorine as a PRT, 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. The United States will continue to work with regulatory authorities in Russia to resolve this trade concern.

Animal Health

Pet Food and Animal Feed

Russia prohibits the use of most U.S. ruminant-origin ingredients in pet foods and animal feeds and has in place other restrictions and requirements that are impeding market access.

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

SAUDI ARABIA

Beef and Beef Products

In May 2012, the Saudi Food and Drug Authority (SFDA) banned the importation of U.S. beef and beef products due to the detection of a dairy cow with atypical BSE in California in April 2012. The confirmed case of BSE was the first in the United States since 2006, and only the fourth in U.S. history. The dairy cow was 10 years of age and the meat never entered the food supply. Nevertheless, the Saudi government has stated that the ban will remain in place until SFDA and the Saudi Ministry of Agriculture have evaluated the risks and ensured the safety of imports of U.S. beef and beef products. The United States is seeking the removal of the ban in accordance with applicable SFDA procedures and has provided SFDA with technical information regarding the case. The United States has asked for a report prepared by SFDA determining whether audits of U.S. facilities must be performed and, if so, the details and costs of any such audits. The United States will continue to engage SFDA to resolve the issue and allow U.S. beef exports to Saudi Arabia's market to resume.

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

SENEGAL

Animal Health

Since 2005, Senegal has maintained a ban on imports of poultry meat and poultry products from all countries purportedly to prevent the introduction of HPAI. Senegal did not notify the ban to the WTO and has not provided a scientific justification for the measure, despite numerous requests from the United States. The United States will continue to work with Senegal to lift the ban with respect to U.S. poultry meat and poultry products and ensure that Senegal's measures are based on science and international standards.

SERBIA

Agricultural Biotechnology

Serbia does not currently permit imports of food products that contain trace amounts of agricultural biotechnology, but it has indicated it may amend its biotechnology law to be less restrictive in connection with its WTO accession process.

SINGAPORE

Food Safety

Beef and Beef Products

Singapore prohibits the importation of all U.S. beef and beef products, except for deboned beef from animals under 30 months of age due to BSE concerns. The United States will continue to engage Singapore to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

Beef, Pork and Poultry Pathogen Reduction Treatments

Prior to 2012, Singapore prohibited the use of all PRTs in the production of beef, pork and poultry products, which added significantly to the cost of exporting such products. Based on documentation provided by the United States regarding the safety of certain PRTs, Singapore now allows the use of eight PRTs that have risk-assessments completed by the Joint FAO/WHO Expert Committee on Food Additives. The United States will continue to work with Singapore to approve additional PRTs.

Singapore also requires U.S. pork to be frozen or tested for trichinosis. The United States does not consider these requirements to be necessary since most U.S. producers maintain stringent biosecurity protocols that limit the presence of trichinae in the United States to extremely low levels in commercial swine. 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 will continue to urge South Africa to open its

market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' BSE negligible risk status.

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

Animal Health

Pork

South Africa imposes stringent time and temperature requirements on pork and pork products due to concerns for pseudorabies and trichinae, including a 20-day freezing requirement on U.S. pork to prevent the transmission of pseudorabies. In 1989, the United States started a voluntary eradication program for pseudorabies and, in 2004, the United States achieved the successful eradication of pseudorabies in commercial herds throughout all 50 states. The United States does not consider requirements due to trichinae concerns to be necessary since most U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low levels in commercial swine. The United States will continue to work with South Africa to obtain elimination of the current freezing requirement for pseudorabies and trichinae.

SOUTH AFRICAN DEVELOPMENT COMMUNITY

Agricultural Biotechnology

South African Development Community (SADC) Member States[6] 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 agricultural 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. In November, 2012, the United States held meetings with officials from SADC Member States regarding agricultural biotechnology and other innovative technologies.

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

[6] 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.

SRI LANKA

Agricultural 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 GE. Further, Sri Lanka requires all commodity imports to be accompanied by a certification that the commodity is "non-GE." The United States will continue to engage Sri Lanka on these issues.

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

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 will continue to urge Sri Lanka to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' negligible risk status.

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

SWITZERLAND

Agricultural 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 agricultural biotechnology crops, which was subsequently extended by an act of Parliament until November 2013. The Swiss Parliament is currently considering a possible extension of the moratorium until the end of 2017. 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 agricultural 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 United States will continue to urge Taiwan to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' risk status.

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

Beta-agonists

In September 2012, Taiwan adopted and implemented an MRL for ractopamine in beef muscle cuts consistent with the Codex standard. However, Taiwan continues to delay the implementation of MRLs for ractopamine in other cattle derived products and for swine that it notified to the WTO in 2007. Taiwan's lack of progress in adopting additional MRLs for pork has raised a significant concern because it forced 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 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. The United States continues to encourage Taiwan to implement the remaining proposed MRLs for ractopamine without further delay.

Taiwan currently maintains an unwarranted zero-tolerance policy for zilpaterol, a beta-agonist, in beef and has provided no risk assessment or science to support its policy. In October 2012, a sample of beef taken at the retail level by local health authorities tested positive for zilpaterol. Immediately after this incident was made public, U.S. beef importers with border inspection zilpaterol violations on record were subjected to unannounced inspections by local authorities, including product sampling. The United States will continue to raise its concerns about excessive inspection and testing.

Maximum Residue Limits for Pesticides

Taiwan's slow and cumbersome process for adopting MRLs for pesticides 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, potatoes, almonds, peaches and nectarines) 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 ingredients (except milk, hide-derived gelatin and collagen, and dicalcium phosphate), as well as many non-ruminant-origin ingredients, intended for use in animal feeds and pet foods due to BSE-related concerns. Prohibited ingredients include protein-free tallow, bovine blood, bovine bone-derived gelatin, and all rendered meals regardless of species of origin (except hydrolyzed feather meal). Additionally, U.S.-origin pet foods containing animal-origin ingredients other than those originating from milk, fish, hide-derived gelatin, dicalcium phosphate and/or collagen, exported to Taiwan must originate from U.S. facilities that have been inspected and approved by Taiwan's Bureau of Animal and Plant Health Inspection and Quarantine. The approval process is lengthy, taking a minimum of 18 months to two years, and requires the facilities to submit extensive applications.

The Taiwan Council of Agriculture (COA) has proposed to amend the requirements for importation of dog and cat food. The U.S. submitted comments on September 10, 2013, for COA's review. In the proposed rule, Taiwan appears to be moving toward allowing the use of OIE safe-to-trade items in dog and cat food although some restrictions due to BSE concerns may still remain. APHIS is requesting to approve the facilities which would like to export dog and cat food to Taiwan.

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

THAILAND

Animal Health

Animal-Derived Products

Thailand bans the importation of most ruminant-origin products (including essentially BSE-risk free commodities, such as blood), and many non-ruminant origin commodities intended for use in pet foods or for livestock feed due to BSE-related concerns. Thailand also requires inspection and approval of U.S. manufacturing facilities that produce certain animal-derived products as a condition for approval for importation.

Food Safety

Beef and Beef Products

Thailand restricts 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 less than 30 months of age. In 2012, Thailand published new rules that largely align its BSE-related requirements with OIE guidelines. In August 2013, a team from the Thai Department of Livestock and Development conducted an audit of the U.S. beef production system as a step towards reopening the market fully to U.S. beef, but the results of that audit are still pending. The United States will continue to urge Thailand to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' negligible BSE risk status.

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

Ractopamine

In 2012, after the Codex established MRLs for ractopamine in cattle and pig tissues, Thailand indicated it would lift its ban on imports of pork from countries that allow the use of ractopamine. However, Thailand has not yet established MRLs for ractopamine in pork, which in effect continues to prevent imports of U.S. product. The United States has encouraged Thailand to act quickly to establish domestic MRLs.

Import Fees

Thailand imposes food safety inspection fees in the form of import permit fees on all shipments of uncooked meat. Current fees are $160 per ton for red meat (beef, buffalo, goat, lamb, and pork) and offals, and $320 per ton for poultry meat. Equivalent fees for domestic meat inspections, however, are significantly lower at $5 per ton for beef, $21 per ton for poultry, $16 per ton for pork, and zero for offals. The domestic fees are levied in the form of slaughtering or slaughterhouse fees. The United States will continue to press Thailand to eliminate or equalize the fees and ensure that the import fees are commensurate with the services provided and the costs incurred.

TURKEY

Agricultural Biotechnology

In 2010, Turkey implemented a new, overarching Biosafety Law, which immediately negated the approvals of agricultural biotechnology products granted under Turkey's previous biotechnology regulation and effectively stopped all trade in products derived from agricultural biotechnology (primarily soy and corn products). Turkey indicated that it intended to follow EU practices in implementing the Biosafety Law and limit its review of agricultural biotechnology products, at least initially, to those already approved in the EU.

In October 2010, Turkey's Biosafety Board began an expedited review of three agricultural biotechnology soybean products 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 agricultural biotechnology 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 agricultural biotechnology corn products for feed use. In February 2012, the Board approved three additional corn products, but rejected six others. In December 2013, Turkey repealed the approvals for two biotech corn traits. The United States has submitted comments to Turkey on the Biosafety Board's decisions and will continue to work with Turkey to obtain approvals for additional U.S. biotech products.

Biotech developers have been reluctant to submit their products for approval under Turkey's Biosafety Law, 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 Turkey's Ministry of Food, Agriculture and Livestock (MinFAL) to discuss these concerns, but these discussions have failed to resolve the industry's concerns.

In April 2011, MinFAL issued instructions to all port officials to begin testing imports for the presence of agricultural biotechnology products, including corn, soy, cotton, canola, sugar beets, potato, and tomato. As a result, imports of U.S. cotton were blocked until importers agreed to certify that cotton imports do not contain living modified organisms. Turkey does not accept pre-export testing, which places the risk on the exporter if the import is blocked as a result of the detection of an unapproved biotechnology product.

In September 2011, Turkey adopted a measure that allows for up to 0.1 percent presence in animal feed of agricultural biotechnology 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 percent threshold and to extend the provision to food products.

Turkey's policy on low level presence led to the indictment of two importers for the import of U.S. rice in April 2013 that tested positive for biotech traits, one of which was later confirmed to be 0.04 percent soybean that is approved for feed use only. In August 2013, Turkey added U.S. wheat products to the list of one hundred percent required testing due to the reported detection of

an unapproved biotech event in Oregon. The two repealed corn traits (discussed above) were added to the list of unapproved traits port officials test for at import. Turkey conducts a positive/negative test, and if positive, tests for each of the unapproved traits.

The United States has repeatedly raised concerns about specific provisions of the 2010 Biosafety Law and its implementing regulations with Turkish officials, including most recently at the May 2013 meeting under the bilateral Economic Partnership Commission. 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 agricultural biotechnology trade issue.

Food Safety

Meat

Turkey prohibits imports of red meat from the United States. 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. However, Turkey's proposed import conditions appear to deviate from OIE guidelines for BSE. In September 2010, Turkey allowed the imports of sheep and goats for breeding and production, and in March 2012 the United States and Turkey agreed upon language to finalize the export of breeding and fattening cattle to Turkey. The United States continues to work with Turkey to allow the export of live cattle for slaughter. The United States will continue to urge Turkey to open its market fully to U.S. live cattle for slaughtering, beef, and beef products based on science, the OIE guidelines, and the United States' negligible risk status.

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

Dioxin Certification

In June 2013, Turkey began to require dioxin-free certification for imports of animal feed and pet food products. This new requirement negates Turkey's 2006agreement that imports from the United States did not require such certifications. Turkey has not provided any evidence that products from the United States contain dioxins or violate Turkish requirements.

Food Additives

On June 30, 2013, Turkey published a regulation restricting the use of monosodium glutamate and six other food additives in "traditional" meat products. These products are listed in an annex to the regulation and are broadly-defined to include virtually all meat products. The U.S. government will continue to engage Turkey on this issue both bilaterally and in multilateral fora.

UKRAINE

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 most U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low levels in commercial swine. 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. In November 2013, Uruguay formally accepted the OIE May 2013 recognition of the United States as having negligible risk for BSE and agreed not to impose BSE conditions on U.S imports. However, access for cattle and beef and beef products is pending bilateral agreement on certificate conditions. The United States will continue to work with Uruguay to open its market fully to U.S. live cattle, beef, and beef products based on science, the OIE guidelines, and the United States' negligible BSE risk status.

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

Animal Health

Poultry

Uruguay currently bans imports of U.S. fresh and frozen poultry due to concerns over AI and END, but the United States and Uruguay have been working towards the resolution of the issue. In October 2007, the United States and Uruguay reached an agreement that permitted imports of U.S. turkey to resume.

In December 2011, Uruguay completed its END evaluation of the United States and recognized the United States as free of END and HPAI. In September 2013, as a next step towards access, Uruguay conducted an audit of the U.S. poultry system. The United States continues to work with Uruguay on this issue to pave the way for U.S. poultry producers to export fresh and frozen poultry to Uruguay.

Plant Health

Potatoes

Uruguay represents an important market for U.S. seed potatoes. In 2012, U.S. and Uruguayan technical agencies implemented an optional pre-sampling protocol for exporters of U.S. seed potatoes. Under this protocol, shipments are pre-screened to facilitate the agricultural inspection process at the Uruguayan ports-of-entry, which reduces the chances that U.S. shipments are delayed or rejected due to plant pest and disease concerns. Nevertheless, Uruguay's tolerance level for a fungus that causes powdery scab remains a concern for U.S. exporters because it appears to be set at an inappropriately low level. The United States will continue to work with Uruguay to address outstanding concerns relating to Uruguay's existing tolerance levels.

VENEZUELA

Food Safety

Live Cattle, Beef, and Beef Products

Venezuela 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 urges Venezuela to open its market fully to U.S. live cattle, beef, and beef products based on science, the OIE guidelines, and the United States' negligible BSE risk status.

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.

In April 2012, Vietnam issued Decree 38, an implementing regulation for its comprehensive Food Safety Law. Decree 38 is broad in scope, covering regulations for a wide variety of horticultural, seafood, and meat products and applies to foreign suppliers and domestic producers. The United States is concerned with Decree 38's lack of transparency and its onerous conformity assessment procedure. The United States has raised this issue bilaterally with

Vietnam on several occasions, including on the margins of TPP meetings and the WTO SPS Committee.

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 will continue to urge Vietnam to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' negligible BSE risk status.

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

Offal Products

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. In September, 2013 Vietnam indicated that its market was open fully to imports of red and white offal. In February 2014, MARD agreed with the United States on the terms and conditions necessary to resume trade. The United States will monitor implementation closely.

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, including proprietary information, in order for foods produced in those facilities to remain eligible for exportation to Vietnam. 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, timely 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.

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 reduces food safety risks of products imported to the United States and opens new export markets for U.S. food and agricultural products.

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 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 APEC, and the Standards and Trade Development Facility (STDF) to improve the risk assessment capabilities of all Members. The STDF is a global partnership that supports developing countries in building their capacity to implement international SPS standards, guidelines, and recommendations as a means to improve their human, animal, and plant health status and ability to gain or maintain access to markets.

Trade Capacity Building

U.S. trade capacity building efforts in the SPS area seek to foster a clear understanding of key SPS provisions in multilateral and bilateral trade agreements. Programs focus on the key requirement that SPS measures be supported by science, the fundamentals of risk assessment, and the most effective way to build and administer SPS regulatory programs. Forms of assistance include conducting regional trade capacity building workshops, conferences, hands-on training programs, mentorships, and site visits to U.S. research facilities.

The United States administers a number of programs to build expertise in foreign countries regarding agricultural biotechnology, food safety, animal health, and plant health. Fostering a cadre of specialists who support 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. USDA and FDA implement many of these technical assistance activities in partnership with other U.S. government agencies, international organizations, U.S. universities, agri-businesses, and private consultants. This technical assistance not only increases developing country partners' capacity to access the benefits of increased agricultural trade, but also builds

understanding of the U.S. SPS regulatory system, provides the United States with key partners within ministries of agriculture, health, and trade, and allows the United States to promote the adoption of SPS measures that are harmonized with science-based international SPS standards. Harmonization with international standards reduces potential risks posed by imports from our partner countries to American consumers and American agriculture and allows for increased U.S. agricultural exports.

In response to new obligations under the U.S. Food Safety Modernization Act and an interest in preventing problems in the global food safety supply chain, FDA is working with new and existing partners to broaden the reach of food safety technical assistance and capacity building. One such example is its partnership with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to provide food safety technical assistance. In 2011, JIFSAN created the International Food Safety Training Laboratory (IFSTL) to increase laboratory capacity and deliver laboratory-based training to scientists suitable for monitoring food safety compliance. JIFSAN also offers an integrated training program on food safety risk analysis principles that covers risk assessment, risk management, and risk communication. In addition, JIFSAN conducts numerous food safety training programs on good agricultural practices, good aquaculture practices, food safety inspections, and commercially sterilized processed foods. JIFSAN works collaboratively with a local organization (*e.g.*, a government agency or trade group) to host these training programs and arrange associated site visits. Since 2000, 60 such programs have been offered in 22 different countries. Building on these efforts, JIFSAN and FDA explored ways to leverage existing resources through the development of in-country partnerships to increase the cadre of in-country trainers. These efforts led to the development of the JIFSAN Collaborative Food Safety Training Initiative. There are currently five such initiatives currently being established in different countries. Support for these activities is part of a long-term capacity-building program by the United States aimed at strengthening the safety of imports and the food safety systems of other countries, including the testing methods foreign government laboratories use to meet U.S. and international standards.

In fiscal year 2013, FDA coordinated and organized 53 visits for 607 foreign nationals from governments, 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 utilize SPS measures to enhance their food safety systems and 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 enhance food safety systems globally, prevent problems in the global supply chain, 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 2013.

Regional Activities

In 2013, USDA held regional workshops in Asia, Africa, Latin America, and the Caribbean for developing country delegates to various Codex committees. These workshops provided delegates with an opportunity to learn about the Codex process and improved understanding and support from many developing countries for science-based decisions in Codex committees. With greater participation of developing countries in international meetings, Codex decisions will better reflect the views of all of its members, while protecting consumers and facilitating trade.

USDA also is working with the STDF, the Association of Southeast Asian Nations, the African Union, Inter-American Institute for Cooperation on Agriculture IICA, and others to coordinate global pesticide residue field trials. These global partnerships are an outcome of USDA's continuing program of providing technical assistance to developing countries in conducting pesticide field trials. The goal of these partnerships is to promote common pesticide MRLs to facilitate trade. Working with other countries to promote the use of common MRLs serves to minimize detention or rejection of U.S. exports at foreign ports of entry for residue violations, because there will be fewer instances when U.S. MRLs differ (either because the levels are different, or because those pesticides are not registered in the export market country) from those of its export markets.

In the past year, USDA cooperated with the Federal Bureau of Investigation and U.S. university partners to conduct Food Defense International Awareness workshops in Brazil and Honduras. Food defense is the protection of the food supply from intentional contamination. These workshops provided a forum for representatives of government, industry, and law enforcement to discuss the challenges posed by the intentional contamination of the food supply and find cost-effective ways to address these challenges. They also provide a forum to discuss any new government regulations to help ensure that these regulations are based on scientific evidence and are harmonized among countries so as to cause the least amount of disruption to trade.

USDA also sponsored participants from various countries to attend U.S.-based courses in veterinary epidemiology, risk analysis, plant disease diagnostics, animal diseases, laboratory diagnostic networks, and building sound regulatory frameworks. USDA held these courses in various locations in the United States, including Fort Collins, Colorado; Raleigh, North Carolina; Washington, DC; Plum Island, New York; and Ames, Iowa. Key SPS officials from developing countries attended the courses where they were able to increase their knowledge and receive a more in-depth understanding of the rationale and science behind the U.S. SPS regulatory system. This improved understanding promotes increased trust in the U.S. regulatory system on the part of key officials in other countries, helping to facilitate the export of U.S. food and agricultural products.

USDA sponsored 19 Cochran Fellows from Brazil, Dominica, Egypt, Guatemala, Honduras, Iraq, Jordan, Liberia, Malaysia, Paraguay, and Trinidad and Tobago to attend the FSIS Meat and Poultry Inspection Seminar for International Government Officials. This training familiarized foreign government officials with inspection regulations and procedures used by USDA to ensure that the nation's meat, poultry, and egg products are safe, wholesome, and properly labeled. The seminar covered a range of issues, including Hazard Analysis and Critical Control Points and pathogen reduction; animal production; import and export policies and procedures;

the roles of FDA, state, and local inspection agencies; and field visits to import and export locations, and processing and slaughter plants. In addition to providing training to the Fellows, this program demonstrates the safety of U.S. products and facilitates port of entry procedures for U.S. exports.

Additionally, USDA provided food safety training to 10 Cochran Fellows from Algeria, Costa Rica, Ghana, Moldova, Nicaragua, Nigeria, and Ukraine at Michigan State University in East Lansing, Michigan. The training program focused on emerging food safety issues and concepts, U.S. and international food safety regulatory systems, food safety policy development, risk analysis, and food safety program implementation. By addressing food safety issues that present unjustified barriers to trade and that are increasingly tied to global trade agreements, this USDA program promoted U.S. exports to these countries and helped build an international food safety resource network.

Africa

USDA in cooperation with the U.S. Agency for International Development (USAID) continues to support three 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 establishing and maintaining science-based regulatory systems consistent with international standards.

An example of this support occurred when USDA collaborated with the OIE to provide technical information regarding the regulation of veterinary biologics in the United States to an assembled group of African government veterinary officials. This seminar occurred in Kenya and provided participants with information on the OIE activities linked to veterinary products, the responsibilities of OIE delegates and their national veterinary officials, the rights and obligations of OIE Members in trade, and on several other issues relevant for the production and use of veterinary products.

In May 2013, in support of the U.S. Government's Feed the Future Initiative, inter-disciplinary teams composed of technical experts from USDA, FDA and USAID, and specializing in food safety, animal and plant health, agricultural economics, and capacity building, reviewed SPS systems in East and West Africa offering recommendations to increase overall food security, including recommendations to improve the safety of domestic food supplies and opportunities for agricultural trade.

On July 1, 2013, President Obama launched Trade Africa, which seeks to increase U.S.-Africa trade and investment and support regional economic integration within Africa. Trade Africa's initial focus is on the member states of the East African Community (EAC), which includes Burundi, Kenya, Rwanda, Tanzania, and Uganda. Building on the existing U.S.-EAC Trade and Investment Partnership, Trade Africa contains a number of complementary, but distinct components, in part to build SPS capacity in the EAC.

Asia Pacific Economic Cooperation

Food Safety Cooperation Forum and Partnership Training Institute Network

Trade in food and agricultural products in the Asia Pacific is vital to U.S. interests, yet concerns about food safety in the region spiked in recent years following a series of high-profile food safety incidents. These prompted APEC economies to agree to strengthen food safety standards and practices in the region and encourage adherence to international science-based standards to facilitate trade in the region and enhance food safety. The SCSC established the Food Safety Cooperation Forum (FSCF) in 2007 with the goal of improving food safety regulatory systems in APEC economies in line with WTO Members' rights and obligations under both the SPS and TBT Agreements. In 2008, APEC economies called for increased capacity building to improve technical competence and understanding of food safety management among stakeholders in the food supply chain through the public-private partnership initiative, the Partnership Training Institute Network (PTIN). Since 2007, over $6 million of public and private sector funds have been contributed for FSCF and PTIN activities. The FSCF and PTIN have identified priority capacity building needs and delivered over 30 programs in key areas (supply chain management, food safety incident management, laboratory competency, risk analysis, food safety regulatory systems) since their inception.

2013 marked the first year of implementation of an APEC multiyear project: Building Convergence in Food Safety Standards and Regulatory Systems for 2013-2015. In April 2013 the project kicked off with a workshop led by Indonesia on best practices for small and medium sized enterprises, the development of an incident management network for the region, and meetings of the FSCF and PTIN Steering Groups. The FSCF agreed to endorse new work on FSCF Regulatory Cooperation Roadmaps on Export Certificates and MRLs at this meeting. Also in 2013, the PTIN conducted two laboratory capacity building needs assessment pilot projects with Chile and China. For Chile, this project included training on the detection of salmonella in seafood and the detection of veterinary drug residues. In addition to the two pilot projects, USDA, in partnership with JIFSAN, sponsored a regional workshop on laboratory capacity building priority setting for APEC member economies in College Park, Maryland in December 2013.

The PTIN also continued to work closely with the World Bank through the newly established Global Food Safety Partnership (GFSP) which includes an initial three year plan of close collaboration in food safety capacity building. The GFSP rolled out APEC PTIN modules on supply chain management in China, Vietnam, and Malaysia in May/June 2013 and an APEC PTIN module on aquaculture was delivered by the GFSP in Indonesia in June 2013.
Food safety efforts are an integral part of overall food security. In 2014, collaboration between APEC food security activities, taking place in the Public-Private Partnership on Food Security, and food safety efforts under way in the FSCF and PTIN, will be strengthened with a planned joint summit proposed for September 2014 in Beijing to identify joint goals for moving towards a safe and secure food region in APEC by 2020.

China

For the past six years, USDA and EPA's Office of Pesticide Programs have worked together to provide technical assistance to China's Institute for the Control of Agri-Chemicals, Ministry of Agriculture (ICAMA). These technical exchanges have resulted in the initiation of work sharing by ICAMA and EPA of six pesticides that are approved for use in China and the United States, but that are scheduled for re-evaluation. As a result of this collaboration, ICAMA and EPA signed a Letter of Intent to cooperate on Good Laboratory Practices (GLPs) for the conduct of pesticide studies to support registration of products. This multi-year cooperation between the United States and China benefits both countries by creating stability for exporters of agricultural commodities and pesticide chemicals, increasing confidence in the quality of science and decision-making for regulatory decisions, and enhancing the protection of public health and the environment of both countries.

Global Food Safety Partnership

In 2013, the United States pledged additional technical support for the GFSP. The GFSP evolved from a cooperation initiative between The World Bank Group and the FSCF into a global partnership. The GFSP is an innovative public-private partnership, dedicated to improving food safety through capacity building in low and medium income countries to improve public health, facilitate trade, accelerate economic growth, and alleviate rural poverty. The GFSP has received a total of $2.6 million in donations from the United States, the Netherlands, Denmark, and Canada and aims to raise an additional $45-50 million to further carry out its work. The GFSP will help enhance U.S. efforts to increase the trade in safe food by supporting food safety systems assessments and coordinating technical training and the sharing best practices. These efforts, in turn, will facilitate the implementation of international standards and the use science and risk-based approaches to food safety regulation. These programs will also help 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.

Latin America and the Caribbean

Since 2005, the United States has assisted the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR) countries in developing their institutional capacities to implement science-based regulatory systems consistent with international standards. The CAFTA-DR Trade Capacity Building Program includes SPS-related activities. Under this program, USDA 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. USDA bases its SPS assistance to CAFTA-DR countries 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.

In FY 2013, USDA focused its efforts on increasing the capacity of other CAFTA-DR Parties to harmonize SPS standards regionally, establishing MRLs for pesticides, and meeting anticipated requirements for export to the United States. USDA conducted regional SPS workshops and pesticide laboratory training, that helped lead to the establishment of an expert working group to

address issues related to MRLs for specialty crops, and adopting common microbiological residue standards among Central American Customs Union countries. In addition, USDA's work at the local level on plant pest diagnostic and management helped the region adhere to U.S. import requirements. This harmonization and training support improves trade flows within the region, and an increasingly integrated Central American market will assist in growing U.S. exports through reduced trade barriers.

USDA's Cochran Fellowship Program sponsored 13 Fellows from Argentina, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Panama, and Paraguay to attend FSIS Meat and Poultry Inspection training in Puerto Rico. The Fellows learned about U.S. inspection procedures and regulations used to ensure meat, poultry, and egg products are safe, wholesome, and properly labeled. The training helped create an understanding of U.S. regulations in foreign inspection offices with the goal of facilitating U.S. exports to the region.

Russia and Eastern Europe

In 2013, USDA collaborated with the U.S. Department of State and the U.S. Department of Defense to provide animal health technical assistance to Armenia, Georgia, Kazakhstan, and Ukraine. This technical assistance focused on the diagnosis, detection, and response to highly infectious animal diseases to help these partner countries control diseases of economic importance. The technical assistance also allows the United States to address foreign animal diseases, such as African swine fever, which could be very damaging to U.S. livestock herds if ever introduced in the United States. In addition, the training builds trust and credibility with foreign partners regarding the U.S. animal health system.

APPENDIX

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

Almond Board of California
American Potato Trade Alliance American Seed Trade Association
California Avocado Commission California Cherry Board
California Table Grape Commission
Distilled Spirits Council of the United States Grocery Manufacturers Association
National Grain and Feed Association
National Potato Council
Northwest Horticultural Council
U.S. Hop Industry Plant Protection Committee
U.S. Meat Export Federation
U.S. Wheat Associates

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