

# 2013 REPORT ON SANITARY AND PHYTOSANITARY MEASURES



UNITED STATES TRADE REPRESENTATIVE



# 2013 Report on Sanitary and Phytosanitary Measures



Ambassador Demetrios Marantis  
Office of the United States Trade Representative



## **ACKNOWLEDGEMENTS**

The Office of the United States Trade Representative (USTR) is responsible for the preparation of this report. In preparing the report, USTR solicited substantial information from U.S. embassies and from interested stakeholders. USTR gratefully acknowledges in particular the contributions of all U.S. government staff who contributed to the drafting and review of this report. Appreciation is extended to the Executive Branch agencies, including the Environmental Protection Agency, the Food and Drug Administration, and the Departments of Agriculture, Commerce, and State, for their important contributions and assistance. Finally, special thanks go to all U.S. Federal employees who work every day to resolve sanitary and phytosanitary trade barriers, helping to expand U.S. food and agricultural exports around the world.

March 2013



## 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
ASEAN	Association of Southeast Asian Nations
BAPHIQ	Taiwan's Bureau of Animal and Plant Health 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
CARICOM	Caribbean Community
COMESA	Common Market for Eastern and Southern Africa
Codex	Codex Alimentarius Commission
COFEPRIS	Federal Commission for the Protection against Sanitary Risk (Mexico)
CTPA	Colombia Trade Promotion Agreement
CU	Customs Union of the Russian Federation, Kazakhstan, and Belarus
EEC	European Economic Commission
EPA	U.S. Environmental Protection Agency
EFSA	European Food Safety Authority
EU	European Union
FAO	United Nations Food and Agriculture Organization
FAS	USDA's Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FMD	Foot and Mouth Disease
FSIS	USDA's Food Safety and Inspection Service
FTA	Free Trade Agreement
GE	Genetically Engineered
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
LL601	Liberty Link 601
LMO Act	Korea's Living Modified Organisms Act
LPAI	Low Pathogenic Avian Influenza
MAPA	Brazil's Ministry of Agriculture, Livestock and Food Supply
MARA	Turkey's Ministry of Agriculture and Rural Affairs

MOU	Memorandum of Understanding
MRL	Maximum Residue Limit
MT	Metric ton
NAFTA	North American Free Trade Agreement
NAPPO	North American Plant Protection Organization
NEI	National Export Initiative
NOAA	National Oceanic and Atmospheric Administration
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
RABESA	Regional Biotechnology Framework
SADC	South African Development Community
SCC	Somatic cell count
SENASICA	Services for the National Health for Food Safety and Food Quality (Mexico)
SPS	Sanitary and Phytosanitary
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
SPS Committee	WTO Committee on Sanitary and Phytosanitary Measures
SRM	Specified Risk Material
STDF	Standards and Trade Development Facility
TBT	Technical Barriers to Trade
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TIFA	Trade and Investment Framework Agreement
T&L	Traceability and Labeling
TPP	TransPacific Partnership
TPSC	Trade Policy Staff Committee
TRQ	Tariff Rate Quota
TWG	Trade Working Group
USAID	U.S. Agency for International Development
USDA	U.S. Department of Agriculture
USTR	Office of the U.S. Trade Representative
WHO	World Health Organization
WTO	World Trade Organization



## **FOREWORD**

The Office of the United States Trade Representative (USTR) is pleased to publish its fourth annual *Report on Sanitary and Phytosanitary Measures (SPS Report)*. This report was created to respond to the concerns of U.S. farmers, ranchers, manufacturers, and workers who confront 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 pests and diseases.

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

The United States achieved some important successes since the publication of last year's report in dismantling SPS barriers that blocked U.S. agricultural exports. For example, U.S. negotiators removed specific SPS barriers in El Salvador, Hong Kong, Japan, and Mexico for exports of U.S. beef; worked with Taiwan to implement a maximum residue limit (MRL) for beef containing ractopamine; successfully petitioned the European Union to allow the use of a pathogen reduction treatment on beef; resolved barriers for U.S. rough (paddy) rice and poultry products for export to Colombia; improved the import procedures for U.S. cherries entering Korea; and gained access for certain U.S. pears into China.

In 2013, USTR will continue to work with colleagues from across the U.S. Government, as well as interested stakeholders, to encourage other governments to remove their unwarranted SPS measures. As always, we will 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. ranch and farm products. We look forward to making further progress on behalf of America's farmers, ranchers, manufacturers, and workers, as well as families who depend on export-supported American jobs.

**Ambassador Demetrios Marantis**  
**Acting U.S. Trade Representative**  
**March 2013**



## TABLE OF CONTENTS

<b>I. EXECUTIVE SUMMARY .....</b>	<b>1</b>
<b>II. INTRODUCTION.....</b>	<b>3</b>
A. Genesis of This Report.....	3
B. SPS Measures – What They Are, Why They Are Needed, and When They Become Trade Barriers .....	4
C. The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures .....	5
D. Other SPS-Related International Agreements .....	9
E. International Standard Setting Bodies .....	10
F. U.S. Government Agencies.....	11
G. Sources of Information about SPS Trade Barriers.....	13
H. U.S. Government Engagement on Foreign SPS Trade Barriers .....	14
<b>III. MAJOR CROSS-CUTTING SPS ISSUES .....</b>	<b>19</b>
A. Export Certification Requirements .....	19
B. Biotechnology .....	21
C. Bovine Spongiform Encephalopathy .....	22
D. Avian Influenza.....	23
E. Maximum Residue Levels for Pesticides.....	24
<b>IV. COUNTRY REPORTS .....</b>	<b>27</b>
ARGENTINA .....	28
AUSTRALIA .....	29
BAHRAIN .....	31

BOLIVIA .....	31
BOSNIA AND HERZEGOVINA .....	32
BRAZIL .....	32
CHILE.....	33
CHINA.....	34
COLOMBIA .....	38
CROATIA.....	40
DOMINICAN REPUBLIC.....	40
ECUADOR .....	40
EGYPT.....	41
EL SALVADOR.....	42
ETHIOPIA .....	42
EUROPEAN UNION .....	43
INDIA .....	53
INDONESIA.....	55
ISRAEL.....	56
JAMAICA.....	57
JAPAN .....	57
KAZAKHSTAN .....	60
KENYA.....	62
KOREA.....	62
KUWAIT .....	64
KYRGYZSTAN .....	65

MACEDONIA .....	65
MALAYSIA .....	65
MEXICO.....	65
MOROCCO .....	68
NEW ZEALAND.....	68
NORWAY.....	68
PERU .....	69
PHILIPPINES .....	70
RUSSIA .....	70
SAUDI ARABIA .....	75
SERBIA .....	75
SINGAPORE .....	75
SOUTH AFRICA.....	76
SOUTH AFRICAN DEVELOPMENT COMMUNITY .....	77
SRI LANKA .....	77
SWITZERLAND .....	78
TAIWAN .....	78
THAILAND.....	81
TURKEY .....	82
UKRAINE.....	83
URUGUAY.....	84
VIETNAM .....	85

<b>V. TECHNICAL ASSISTANCE .....</b>	<b>89</b>
<b>APPENDIX .....</b>	<b>97</b>

## I. EXECUTIVE SUMMARY

The *2013 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) parlance as “sanitary and phytosanitary (SPS) measures,” play an increasingly critical role in shaping the flow of global trade. The United States strongly supports the right of governments through robust regulatory frameworks to protect their people, animals, and plants from health risks of this kind. This report focuses on SPS measures that appear to be unscientific, unduly burdensome, discriminatory, or otherwise unwarranted and create significant barriers to U.S. exports. Many of these measures can present particular challenges for small and medium sized enterprises 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 U.S. and international mechanisms for addressing them. In particular, section II covers the following topics: (1) the genesis of this report; (2) the growing importance of SPS measures in global trade; (3) rules governing SPS measures under the WTO’s *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement); (4) rules and mechanisms regarding SPS measures in U.S. free trade agreements (FTAs); (5) international standard setting in the SPS area; (6) the role of various U.S. Government agencies in addressing SPS-related trade issues; (7) sources of information about SPS trade barriers; and (8) U.S. trade policy mechanisms for considering and addressing SPS measures, including bilateral engagement and WTO dispute settlement.

Section III discusses important unwarranted SPS barriers that impede U.S. exports to multiple foreign markets. Among the most significant of these cross-cutting barriers are restrictions related to export certifications, 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, Bolivia, Bosnia and Herzegovina, Brazil, Chile, China, Colombia, Croatia, the Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, the European Union, India, Indonesia, Israel, Jamaica, Japan, Kazakhstan, Kenya, Korea, Kuwait, Kyrgyzstan, Macedonia, Malaysia, Mexico, Morocco, New Zealand, Norway, Peru, Philippines, Russia, Saudi Arabia, Serbia, Singapore, South Africa, the South African Development Community, Sri Lanka, Switzerland, Taiwan, Thailand, Turkey, Ukraine, Uruguay, 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 his 2012 State of the Union Address, President Obama called for the creation of an interagency trade enforcement unit charged with investigating unfair trading practices. 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, with a Director appointed by USTR and a Deputy Director appointed by the Secretary of Commerce, has assembled critical ITEC infrastructure and staff from a variety of agencies – including subject matter experts from the U.S. Department of Agriculture (USDA). ITEC significantly 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.

These annual reports have 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 workers, producers, businesses, consumers, and other stakeholders with regard to the actions this Administration is taking on their behalf.

First published in 2010, the *SPS Report* serves these goals. It is dedicated to describing significant and unwarranted SPS barriers in foreign countries. Many of these measures were previously addressed in the *National Trade Estimate Report on Foreign Trade Barriers (NTE Report)*.<sup>1</sup> 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 *2013 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 (*2013 Report on Technical Barriers to Trade, or TBT Report*) is being released in parallel with the *SPS Report*.

The *SPS Report* begins with an overview of SPS measures and the international trade rules that govern them. It then summarizes the manner in which the U.S. Government addresses 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 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

---

<sup>1</sup> 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.

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 U.S. poultry and beef exports, respectively, ignoring international science-based standards that establish appropriate measures for addressing those diseases.

Maintaining dependable export markets for U.S. agricultural producers is critical to this nation's economic health. Overall, U.S. farm exports totaled \$145.4 billion in 2012. According to USDA's Economic Research Service, each \$1 billion in U.S. agricultural exports supports approximately 6,800 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 therefore, that 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 WTO Members to take SPS measures necessary to protect human, animal, or plant life or health. An important question is how much protection a Member may seek against a particular risk when it adopts an SPS measure. Under the SPS Agreement, each Member is free to choose its own “appropriate level of sanitary or phytosanitary protection.”

### ***Science-Based Measures***

Once a WTO Member has established its appropriate level of protection, the SPS Agreement provides that the SPS measures it takes to achieve that level of protection must be based on scientific principles, must not be maintained without sufficient scientific evidence, and may be applied only to the extent necessary to protect human, animal, or plant life or health. In cases where relevant scientific evidence is insufficient, a government may provisionally adopt SPS measures on the basis of available information. In such circumstances, WTO Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the SPS measure accordingly within a reasonable period of time.

### ***Risk Assessment***

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

### ***Unjustifiable Discrimination and Disguised Restrictions on Trade***

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

### ***Harmonization***

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

The agenda for SPS Committee meetings varies, but several items appear regularly. Committee members routinely discuss matters related to how the SPS Agreement is being applied and implemented and specific trade concerns, such as 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 192 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 multilateral disciplines on SPS measures, the NAFTA contains a much more detailed SPS chapter than later U.S. 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 imported pests and diseases.

The NAFTA encourages the three NAFTA Parties (the United States, Canada, and Mexico) to adopt international and regional standards, while at the same time explicitly recognizing each 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 inaugurated in 1995 include an SPS chapter.<sup>2</sup> While those chapters do not impose new or additional substantive rules or obligations, many of these agreements establish SPS committees that provide a forum for the parties' trade and regulatory authorities to resolve contentious bilateral or regional SPS issues, consult on SPS matters that are pending before relevant international organizations, and coordinate technical cooperation programs.

### **E. International Standard Setting Bodies**

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 avian influenza (LPAI) may be traded with minimal restrictions, and countries reporting highly pathogenic avian influenza (HPAI) may trade safely in poultry and poultry products under specified conditions. The guidelines, however, do not recommend any type of import bans on poultry commodities from countries with non-notifiable subtypes of AI.

More recently, on July 5, 2012, Codex adopted eight standards for the maximum residue levels for ractopamine in beef and pork. Ractopamine is a feed ingredient 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.

---

<sup>2</sup> 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.

#### *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 member of all other 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, Jordan, Mexico, South Africa, and the United Kingdom (UK). 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***

The Market Access and Compliance (MAC) unit at the U.S. Department of Commerce leads the Trade Agreements Compliance (TAC) Program, which supports the enforcement side of the National Export Initiative (NEI). Under the TAC Program, MAC coordinates U.S. Government efforts and resources to systematically monitor, investigate, and ensure that foreign governments comply with the over 250 international trade agreements to which the United States is party. The TAC Program represents the U.S. Government's focal point for identifying foreign trade barriers that obstruct U.S. exporter market access. Commerce works closely with its interagency colleagues to address SPS-related trade barriers, as well as all matters pending before the SPS Committee. In addition, to advance the NEI's advocacy efforts, the Department's 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 of Commerce 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. Additionally, MAC coordinates SPS-related work at the Department of Commerce including work done by the Manufacturing and Services (MAS) unit on issues concerning U.S. industry and manufacturers.

### ***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 2012 alone, the interagency group reviewed 908 SPS notifications by 50 WTO Members and provided comments to these trading partners on 119 proposed or in-force SPS measures.

Slightly more than 15 percent of the comments were on measures regarding processed products; nearly 45 percent of the comments addressed requirements for live animals and fish (and their products, including dairy products); and about 40 percent of the comments were for measures that introduced new standards or entry requirements for plants, bulk commodities (including U.S. agricultural products derived from modern biotechnology), and horticultural products. The leading recipients of U.S. Government comments included the Republic of Korea with 13 comments, the European Union with 9 comments, and China, Chinese Taipei, Colombia, and Qatar with 8 comments each.

As part of these submissions, the United States requested its trading partners to take a number of actions, including the following: change or reduce product certification requirements; modify requirements of a measure; repeal an import ban; rescind entry requirements; delay implementation of a measure; and reduce testing fees. The United States also requested its trading partners to adopt the international standards of Codex, the 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, one proceeding is suspended, and a sixth proceeding is currently underway. These proceedings are described below.

#### *European Communities – Hormones<sup>3</sup>*

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

---

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

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 – Varietal Testing*

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

#### *Japan – Apples*

In 2002, the United States challenged Japan's restrictions on imports of U.S. apples, which were based on concerns over the introduction of fire blight. The WTO 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.

#### *European Communities – Agricultural Biotechnology*

In 2003, the United States challenged the EU's *de facto* moratorium on approvals of U.S. agricultural products derived from modern biotechnology, such as certain corn and soybean varieties, as well as marketing prohibitions that individual EU Member States had imposed on 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, 2012, a large backlog of 72 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. The EU approved six products (five import and one renewal) in 2012, taking an average of 40 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.

*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.





### **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 maximum residue levels for pesticides. The individual country reports contained in section IV provide details on these barriers in specific markets.

Underlying these cross-cutting SPS trade barriers (and many of the other unwarranted SPS barriers described in section IV) is the disturbingly common failure by some U.S. trading partners to base their SPS measures on science, as the SPS Agreement requires. Unfortunately, some trading partners place other factors ahead of, or consider them together with, scientific principles when establishing or applying certain SPS measures. Some trading partners apply SPS measures with an eye toward protecting domestic 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 feed ingredient, where it is clear that certain trading partners consider factors other than science in imposing SPS measures.

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

#### **A. Export Certification Requirements**

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

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

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

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

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

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

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

In February 2010, the United States and Australia sponsored an APEC export certification roundtable in Australia.<sup>4</sup> Representatives of 20 of the 21 APEC Member Economies reached several conclusions and observations regarding the issuance and usage of official certificates in the APEC region, including avoiding redundancy in certifications and requiring attestations only when essential information is necessary to ensure food safety or fair practices in food trade. The representatives further discussed common challenges arising from certification requirements and options to address those challenges, the basis for requirements on export certificates, and common understandings and best practices in dealing with export certificates.

In April 2012, the United States and Australia sponsored a follow up export certification workshop for APEC Member Economies in the United States. Representatives of more than 100 APEC Member Economies and developing countries attended. The workshop built on the themes of the earlier roundtable, and the large attendance confirmed that export certification remains an important issue as well as a challenge for many countries.

---

<sup>4</sup> [http://fscf-ptin.apec.org/docs/events/export-certification-roundtable/ECR\\_event\\_report.pdf](http://fscf-ptin.apec.org/docs/events/export-certification-roundtable/ECR_event_report.pdf)

## B. Biotechnology

Over the past 16 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 28 in 2012. Modern enhancements allow farmers to use fewer and safer pesticides while improving crop yield. Crops produced using agricultural biotechnology that are consumed in the United States for food, feed, or fiber include alfalfa, canola, corn, cotton, papaya, soybeans, squash, and sweet corn. USDA's National Agricultural Statistics Service estimates that in 2012, 93 percent of soybean acreage, 88 percent of corn acreage, and 94 percent of cotton acreage in the United States were planted with biotech varieties. New GE crops will continue to be brought to market, leading to more acceptance of biotech crops on the one hand, and potentially more trade challenges on the other.

U.S. exports of biotech corn and soybeans, as well as other agricultural products that contain – or may contain – biotech-derived ingredients, face a multitude of trade barriers. The country-by-country section of the *SPS Report* includes numerous examples of unwarranted import bans and restrictions currently being applied to U.S. biotech products. In addition, some trading partners impose mandatory labeling requirements on foods derived from biotech products that create technical barriers to trade by wrongly implying that these foods are unsafe.<sup>5</sup> Some U.S. trading partners have continued to impose restrictions on these products even though repeated dietary risk assessments have shown no food safety concerns, and these biotech products have proven safety records.

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

---

<sup>5</sup> These labeling requirements are addressed in the *TBT Report*.

### **C. Bovine Spongiform Encephalopathy**

BSE is a transmissible, fatal neuro-degenerative brain disease of cattle. BSE was first diagnosed in the United Kingdom (UK) in 1986. At its peak in 1992, there were 37,316 reported cases of BSE, 99.9 percent of which were in the UK. As of January 2013, the OIE indicated that in 2012, the number of cases had decreased to 12 cases globally, two of which were outside of Europe. 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. It is important to note that 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 is the international organization responsible for improving animal health worldwide. The OIE classifies the BSE risk status of cattle populations in particular countries on the basis of a risk assessment and other criteria. The OIE has established three risk categories: negligible risk, controlled risk, and undetermined risk, with different recommendations for the safe trade in live cattle, beef and beef products from countries in each category. In May 2007, 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 “controlled risk” status.

OIE guidelines specify that that live cattle and specific beef and beef products from a controlled risk country can be safely traded provided that certain slaughter and processing conditions are met, and appropriate “specified risk materials” (SRMs) are removed from the carcass before shipment. SRMs are those tissues where the BSE agent is known to accumulate and can therefore pose a human health risk. From a human health perspective, the removal of these tissues from cattle over the designated age is the single most significant measure to ensure the production of safe beef and beef products. With respect to BSE, all cattle tissues that the OIE has not designated as SRMs are safe for human consumption.

#### *U.S. BSE-Related Controls*

The United States implemented an OIE-consistent feed ban in 1997, which prohibits feeding ruminants most mammalian protein. The U.S. feed ban was further strengthened in 2009 by prohibiting the use of the highest risk cattle tissues in all animal feed (not just ruminant feed). The presence of a ruminant-to-ruminant feed ban is the most important 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 SRM removal. As a result of these interlocking measures, beef and beef products produced in the United States are safe for consumption. On March 9, 2012, USDA issued a proposed rule to further align its BSE regulations to the OIE guidelines.

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

In December 2003, as a result of the first case of BSE detected in the United States, at least 100 countries closed their markets to all U.S. beef and beef products, causing substantial 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. In 2011, the volume of U.S. exports of beef and beef products recovered, as U.S. beef and beef product exports reached 1.3 million metric tons. However, in 2012 exports fell 12 percent to 1.1 million metric tons on tight supplies. Despite lower volumes, U.S. beef and beef products exports still reached a record \$5.51 billion in 2012 due to increased prices.

The increased value of sales is attributable to not only high prices but also favorable exchange rates and higher consumer demand for meat in countries with expanding economies. 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 is a virus that can infect wild birds and poultry. The OIE divides AI viral strains into two groups based on the ability of the particular virus to produce disease: LPAI and HPAI. LPAI naturally occurs in wild birds and can spread to domestic birds. In many cases, LPAI causes either no, or only minor, symptoms in infected birds. HPAI is more virulent than LPAI and can,

accordingly, spread 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 outbreak of HPAI in the United States. U.S. HPAI control policies are consistent with the relevant science-based standards, guidelines, and recommendations issued by the OIE.

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

Despite these measures, many countries have imposed unwarranted import bans on U.S. poultry products based on professed concerns over AI, often citing isolated LPAI outbreaks. For example, China currently bans imports of poultry and poultry products from two U.S. states, Arkansas and Virginia. 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 103 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.





## 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.<sup>6</sup>

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

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

The *SPS Report* provides more focused and structured reporting on country-specific issues than appeared in past years' *NTE Report*, which may have included SPS issues that USTR has not included in this report. Where possible, each listing sets out the United States' current understanding of the measure or practice, why it raises concerns, and how the United States is seeking to address it. The *SPS Report* is not simply a recounting of all outstanding issues that stakeholders have brought to USTR's attention this year or in the past. For purposes of this report, USTR included measures that represent significant and unwarranted SPS 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

---

<sup>6</sup> 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' risk status.

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

### **Animal Health**

#### *Pork*

Currently, U.S. pork does not have access into Argentina. Argentina will not accept U.S. pork unless it first completes an assessment of the risk posed by U.S. pork. In October 2012, the United States provided the necessary information regarding U.S. swine health and surveillance of swine diseases to Argentine authorities to complete a risk assessment process. That process is pending. Moreover, Argentina has indicated to the United States that if approved for import, U.S. pork must either be shipped frozen or tested for trichinosis. 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. The United States will continue to work with regulatory authorities in Argentina to resolve this trade concern.

#### *Poultry*

While U.S. exporters currently have access to Argentina's market for certain 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 Newcastle disease. Argentina indicated previously 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 in light of Argentina's determination that the U.S. poultry inspection system is not "equivalent" to the Argentine system. The United States has expressed concerns regarding both Argentina's poultry product limitations and failure thus far to grant equivalency to the United States. In technical discussions held in July 2012, Argentina stated that as soon as it publishes its revised poultry

regulations, the United States should reaffirm its interest in obtaining market access for poultry products in order for Argentina to resume its evaluation of the U.S. request for access. U.S. officials will continue to engage on the issue.

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

## **Plant Health**

### *Apples and Pears*

Argentina currently bans imports of U.S. apples and pears due to concerns about the efficacy of post-harvest treatments for *Erwinia amylovora* (the bacterium that causes the disease 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. Argentina is currently reviewing the information and developing pest risk assessment (PRA) for U.S. apples and pears. The United States continues to work with Argentine officials to open its market for U.S. apples and pears.

## **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. On March 1, 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, a country interested in exporting beef and beef products to Australia must request Food Standards Australia New Zealand, a regional food safety agency, to conduct an individual country risk assessment. On March 18, 2010, the Australian Minister for Agriculture, Fisheries and Forestry announced that Biosecurity Australia must conduct a separate import risk analysis for each exporting country to address animal quarantine issues. The United States submitted a completed BSE-related questionnaire in June 2010 and hosted a visit by an Australian official in July 2010 to discuss Australia's BSE evaluation process. Biosecurity Australia has not yet concluded its risk assessment for 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' 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 concerns, Australia also requires all solid waste from pork imports, regardless of whether the pork is cooked or uncooked, must be treated as a quarantine waste product. The new requirements have raised the costs of handling imported pork.

### *Poultry*

Australia bars imports of fresh, frozen, and cooked turkey meat from the United States. In 2009, the United States requested Australia to prioritize granting market access for U.S. cooked turkey meat. In 2012 Australia initiated an evaluation of U.S. cooked turkey meat to assess the existence of a virus that causes Infectious Bursal Disease. The United States will 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 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.

### *Stone Fruit*

Australia currently bans imports of U.S. stone fruit (peaches, nectarines, plums, and apricots) due to concerns about certain plant pests. In July 2010 Australia issued a final policy to allow market access for U.S. stone fruit from California, Idaho, Oregon and Washington with a systems approach for peach twig borer. However, in response to appeals from stakeholders, Australia subsequently prohibited access until a mitigation could be found for spotted wing drosophila (SWD). As a result, U.S. stone fruit exporters will not be able to ship U.S. stone fruit to

Australia until there is agreement on a mutually acceptable mitigation for SWD for stone fruit. The United States is engaged in an active dialogue with Australia on mitigation measures for SWD and is seeking to develop a preclearance program. This issue remains a top priority of the United States in its SPS engagement with Australia and is regularly addressed in bilateral discussions.

### *Table Grapes*

The United States has been working with Australia for over 20 years to achieve access to the Australian market for California table grapes. Australia first opened its market under limited conditions in 2002. The United States has worked through the United States-Australia FTA SPS Committee to remove other restrictions to expand access for U.S. table grapes in the Australian market. However, one Australian state, Western Australia, continues to deny market access for U.S. table grapes to its territory. Australia has indicated that it would complete a risk assessment to initiate the process to consider allowing California table grapes to gain access to Western Australia. The United States will continue discussions with Australia as it moves forward with this process.

## **BAHRAIN**

### **Food Safety**

#### *Pork*

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

## **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' 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, genetically engineered (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.

U.S. embassies in Belgrade, Sarajevo and Zagreb organized an agricultural biotechnology outreach program in Serbia, Croatia, and BiH in 2012. The goal was to advance U.S. agricultural biotechnology policy goals and promote acceptance of agricultural biotechnology in these countries. Using the GE HoneySweet plum, which is resistant to the plum pox, as an example of a crop from which these countries would benefit, the speakers countered misconceptions about agricultural biotechnology, fostered positive public opinions about agricultural biotechnology products, and shared advice for developing a more conducive policy environment for agricultural biotechnology products.

## **BRAZIL**

### **Food Safety**

#### *Live Cattle, Beef, and Beef Products*

Brazil bans imports of U.S. live cattle, beef, and beef products following the detection of a BSE-positive animal in the United States in 2003. In late 2008, Brazil promulgated a draft regulation that establishes sanitary requirements for the importation of ruminants and ruminant products from countries affected by BSE. Brazil continues to state that it has not completed its review of technical information provided by the United States. During high level discussions, Brazil indicated it was not willing to conform its import restriction to the OIE guidelines. U.S. officials pressed Brazilian officials for resolution of this matter on a number of occasions in 2012. The United States will continue to urge Brazil 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.

#### *Pork*

Brazil only allows imports of U.S. pork from plants that its inspectors have individually inspected and approved. This approach is burdensome on the industry and significantly limits the market access of companies willing and able to export to Brazil. Brazil has not explained

why a plant-by-plant inspection 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. These requirements are unwarranted as U.S. pork producers maintain stringent biosecurity protocols that serve to limit the incidence of trichinosis in the United States to extremely low levels.

In May 2009, the United States proposed a voluntary certification process, which Brazil rejected in October 2009. In August 2010, the United States held technical discussions with Brazil on U.S. risk management techniques for trichinosis. In October 2010, Brazil indicated that it was prepared to work with the United States on this issue. U.S. officials engaged on the matter with their Brazilian counterparts on a number of occasions in 2012. 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 MAPA 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. MAPA states that pest risk assessments might be required to address comments received. The United States will continue to engage Brazil on the issue.

## **CHILE**

### **Food Safety**

#### *Pork*

Chile requires pork produced in the United States to be shipped frozen or tested for trichinosis. Chile's requirements constitute a significant impediment to U.S. fresh and chilled pork exports to

Chile. The United States does not consider these requirements to be necessary given that U.S. producers maintain stringent biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. As an alternative, the United States proposed less trade restrictive risk mitigation measures to assure Chile that U.S. pork exports do not contain trichinae. The United States has raised this issue on the margins of the Trans-Pacific Partnership (TPP) SPS negotiations on numerous occasions 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 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' 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. The United States is still awaiting the results of the Maine audit.

This issue has been raised on the margins of the TPP SPS negotiations on numerous occasions. 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.

## **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 creates significant and unwarranted delays in China's approval of agricultural biotechnology



products, which could result in substantial disruptions in exports of certain U.S. agricultural products.

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, a feed additive that promotes feed efficiency in pigs and certain other livestock, despite U.S. government approval, establishment of a Codex standard, and scientific evidence indicating that ractopamine can be used safely. China has enforced this ban by barring imports from several U.S. facilities that previously shipped pork to China that contained trace amounts of ractopamine at concentrations below the U.S. MRL and the Codex MRL. 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.

During meetings in conjunction with the U.S.-China Strategic and Economic Dialogue in 2011, U.S. officials asked China to adopt an interim MRL while awaiting Codex's final adoption of an MRL. China's Ministry of Agriculture (MOA) declined this request, claiming that China needs to await a final decision by Codex. 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.

### *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.

In March 2010, USTR and USDA senior officials met with their Chinese counterparts in Beijing to restart beef market access negotiations based on full consistency with the OIE guidelines on BSE. Bilateral discussions on U.S. beef exports continued throughout 2010, including high-level meetings between USDA and USTR officials and their Chinese counterparts. During the first two weeks of January 2011, senior officials from USTR and USDA led a team of experts from both agencies and FDA for a meeting with their counterparts in Beijing. The talks were

beneficial both in assisting the two sides in understanding each other's positions on the key issues as well as in narrowing differences in a number of areas.

Both sides continued to engage at senior and technical levels throughout 2011 and 2012, including a visit by U.S. regulators to meet with their Chinese counterparts in December 2012, exchanges between working level officials, and discussions of the issue during the meetings of the Joint Commission for Commerce and Trade (JCCT). 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' 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*, 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 cannot be entirely eliminated from raw meat and poultry, and that proper storage, handling, and cooking of raw meat and poultry reduce significantly the risk of a number of food-borne diseases caused by these microbes. In 2009, China's regulatory authorities assured the United States that they were in the process of revising China's standards for *Salmonella* in poultry, but they have yet to do so. The United States continues to engage China on this issue.

### *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 equivalence 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. Due to the uncertainty of regulations in China, U.S. producers sharply reduced processed meat exports and are looking for clear guidance as to China's import requirements. The United States will continue to seek resolution of this issue with China.

## **Animal Health**

### *Animal Feed*

China's AQSIQ published in 2009 Decree No. 118, which is a measure regulating animal feed and feed additives, and indicated that it would begin verifying compliance with the measure in

early 2011. Such activities include: requiring foreign regulatory agencies to maintain a list of facilities approved to export feed products; requiring plant-by-plant audits; and requiring manufacturers to provide proprietary information to AQSIQ, including photographs of processing facilities. Many of the requirements appear to be unwarranted.

In 2011, the United States and China agreed that these verification requirements would not be applied until June 30, 2012, to give both countries the opportunity to discuss this issue further. As a result of those discussions, 121 U.S. animal feed facilities under the authority of APHIS were approved to export animal feed to China as of August 2012. To address China's new requirements for fishmeal under Decree No. 118, in 2012, the National Oceanic and Atmospheric Administration (NOAA) negotiated new certification requirements for fishmeal with China to retain market access for this commodity. Notwithstanding these negotiations, industry estimates that U.S. animal feed exports to China experienced a significant decline as a result of Decree No. 118.

### *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. However, since that time the United States and China have not yet reached agreement on the entry and certification requirements.

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

### *Poultry*

At the December 2012 JCCT meeting, China announced that it would lift its AI-related ban on poultry from Minnesota, although it continues to ban poultry and poultry products from Arkansas and Virginia (or transshipped through those states) based on reported detections of LPAI in those states. China's current AI-related import bans raise concerns that they are not science-based or consistent with OIE guidelines.

During bilateral meetings in 2012, including JCCT working group meetings, the United States and China agreed to hold further technical talks to address China's bans on imports from the remaining states.

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

## **Plant Health**

### *Apples*

Since 1995 China has only allowed imports of two varieties of U.S.-origin apples from three states (Idaho, Oregon, and Washington). 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. 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 Washington.

### *Potatoes*

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

### *Strawberries*

The United States is seeking to establish permanent market access to China for California strawberries. In 2008, AQSIQ allowed California strawberries to be imported for the Olympic and Paralympic Games in Beijing. At that time, Chinese authorities acknowledged that California strawberries were safe. However, USDA has since sought permanent access, and while China has not provided any scientific justifications for its delay, a decision on permanent access has not been granted.

## **COLOMBIA**

### **Food Safety**

#### *Poultry*

Colombia is in the process of establishing a new national policy for *Salmonella*, although the specifics of that new policy remain unclear. In April 2012, the United States and Colombia

established through an exchange of letters a protocol to address *Salmonella* regulatory concerns. The understanding states that Colombia recognizes the U.S. monitoring and control procedures for *Salmonella* and that Colombia will not reject poultry meat or poultry products for *Salmonella*-related reasons provided the shipment is accompanied by agreed-upon FSIS certification. As part of the letter exchange, the two countries further agreed to cooperate on the development of Colombia's national policy on *Salmonella*, and the United States continues to work with Colombia in addressing this matter.

## **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 Colombia to open its market fully to cattle, 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.

### *Pork*

Colombia requires pork produced in the United States to be shipped frozen or tested for trichinosis. Colombia's requirements constitute a significant impediment to U.S. fresh and chilled pork exports to Colombia. The United States does not consider these requirements to be necessary as U.S. producers maintain stringent biosecurity protocols that serve to limit the appearance of trichinae in the United States to extremely low levels. U.S. and Colombian regulatory authorities reached a framework understanding concerning access to Colombia for fresh/chilled pork in May 2012 and have worked subsequently to finalize the associated details. The status of this work was reviewed at the CTPA SPS Committee meeting held in November 2012, and U.S. officials are working to address the remaining issues.

## **CROATIA**

### **Agricultural Biotechnology**

Croatia prohibits the import of all food products that contain even trace amounts of food products derived from modern agricultural biotechnology. This restriction makes it extremely burdensome and expensive to export U.S. food products to Croatia. U.S. embassies in Belgrade, Sarajevo, and Zagreb organized an agricultural biotechnology outreach program in Serbia, Croatia, and Bosnia and Herzegovina in 2012. The goal was to advance U.S. agricultural biotechnology policy goals and promote acceptance of agricultural biotechnology in these countries. Using the GE HoneySweet plum, which is resistant to the plum pox, as an example of a crop from which these countries would benefit, the speakers countered misconceptions about agricultural biotechnology, fostered positive public opinions about GE products, and shared advice for developing a more conducive policy environment for GE products

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

## **DOMINICAN REPUBLIC**

### **Food Safety**

#### *Beef and Beef Products*

The Dominican Republic bans imports of U.S. beef and beef products from cattle 30 months of age and over due to concerns about BSE. On a number of occasions during 2012, USDA officials raised this issue with the Dominican Republic's Veterinary Services division. The United States will continue to urge the Dominican Republic 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.

## **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.

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

August 30, 2010, Ecuador published Regulation 20137, which proposed certain import requirements related to several animal diseases including BSE, Brucellosis, and foot-and-mouth disease (FMD) for U.S. live cattle, beef, and beef products. The United States will continue to urge Ecuador 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.

## **EGYPT**

### **Food Safety**

Egypt's Ministry of Industry and Foreign Trade Ministerial Decree 266 (2011) adopted the European Economic Commission (EEC) 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. The United States has requested that Egypt rescind this decree, and will be engaging at a technical level with Egypt on this issue.

### **Plant Health**

#### *Seed Potatoes*

Egypt is one of the last of the world's largest seed potato importers that bans imports of most varieties of U.S. seed potatoes due to phytosanitary concerns regarding *Ralstonia* (brown rot). The United States considers that the U.S. seed certification process effectively mitigates *Ralstonia*, and USDA has informed Egypt of that. Nevertheless, Egypt requires registered varieties to undergo mandatory field trials for three seasons, as well as compliance with a host of other plant quarantine conditions. The United States has urged Egypt to develop a mutually agreeable work plan for conducting the field trials to address their concerns and facilitate commercial shipments of U.S. seed potatoes to Egypt.

#### *Wheat*

In 2010, Egypt's Central Administration for Plant Quarantine (CAPQ) of the Ministry of Agriculture 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 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 and restore U.S. cotton exports.

## **EL SALVADOR**

### **Plant Health**

#### *Rice*

El Salvador has begun enforcing a regulation for rough rice from the United States that requests an additional declaration in the phytosanitary permit stating that shipments are free of weed seeds. The United States is working to resolve this barrier.

## **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 by 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. 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.

EU policies restrict the importation and use of U.S. agricultural commodities derived from agricultural biotechnology. These restrictions include but are not limited to:

- Delays in approvals of new GE traits despite positive assessments by the European Food Safety Authority (EFSA);
- Imposing commercially infeasible requirements on GE content in food products under EU Traceability and Labeling (T&L) regulations;
- Prohibitions on importation of GE commodities by certain EU Member States;
- Difficulties in applying for registration of GE commodities in the National Seed Catalog; and
- Application of unnecessary and burdensome coexistence requirements to planting of GE crops alongside non-GE crops by certain EU Member States.

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. 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. EFSA has never concluded that a GE variety in U.S. commercial production is unsafe. If EFSA concludes that the GE product is as safe as its conventional counterpart, the application proceeds to the comitology process. In 2012, the European Commission proposed to change its regulations governing the EFSA evaluation to specify the data and testing necessary for all applications. The Commission finalized this proposal in February 2013 despite U.S. government comments questioning the scientific basis for the regulation. The regulation requires certain tests, including feeding studies, irrespective of whether they are scientifically necessary and appropriate to the application and go beyond or conflict with the approach to safety assessment as outlined in the Codex plant

guideline. The new regulation risks further increasing the length of time EFSA needs to evaluate applications.

Under the comitology process, the European Commission first prepares an approval measure based on the scientific assessment. The Commission then submits the measure to a regulatory committee comprised of representatives from each of the 27 EU Member States. Not once in over 12 years has an EU regulatory committee accepted a proposed measure to approve a new 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 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 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.

At the end of 2012, 72 GE product applications (for import, renewal, and cultivation) were pending approval in the EU system. The EU approved only six GE products in 2012 (5 new products and one renewal of a previously approved product), with an average processing time of 40 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.

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 threshold 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 have continued to adopt new bans on products approved at the EU-level, however. 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 a Member State to lift an unjustified ban. However, the EU regulatory committees have blocked each such measure, just as the regulatory committees have failed to approve new 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 includes a new recommendation on the co-existence of GE crops with conventional and organic crops and a proposal amending the governing legislation. The recommendation on co-existence took immediate effect. It provides Member States greater flexibility when developing national co-existence measures and allows them to define 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 territory. The proposal does not require Member States to base any such restrictions on safety concerns, but allows them to take into account other societal concerns.

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

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

## **Food Safety**

### *Beef and Beef Products – Hormones*

In May 2009, the United States signed a memorandum of understanding (MOU) with the EU to resolve on a provisional basis their WTO dispute over U.S. beef raised with growth-promoting hormones. The MOU, which took effect in August 2009, provides additional duty-free access to the EU market for high-quality beef produced from cattle that have not been raised with growth-promoting hormones – 20,000 metric tons (MT) in each of the first three years, increasing to 45,000 MT beginning in the fourth year. The EU increased the quota to 48, 200 MT beginning in August 2012.

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 approve pathogen reduction treatments (PRTs) that are used in the United States is still an issue. In December 2010, USDA requested the Commission to approve the use of lactic acid as a pathogen reduction treatment (PRT) in processing of beef carcasses and meat. The European Commission subsequently requested EFSA do a risk assessment on the use of lactic acid as a beef PRT. In July 2011, EFSA issued its risk assessment, which concluded that beef treated with lactic acid as a PRT is safe for human consumption. After considerable delay, the European Commission published a final regulation allowing the use of lactic acid, which entered into effect on February 25, 2013.

### *Cherries*

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

### *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 that did not appear to be based on science. EU Member States rejected the Commission's flawed proposal, first at the regulatory committee level and then, in December 2008, at the ministerial level.

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

### *Ractopamine*

The EU currently maintains a ban on pork produced with ractopamine, a feed additive that promotes feed efficiency in pigs and certain other livestock, despite U.S. government approval, establishment of a Codex standard, and scientific evidence indicating that ractopamine can be used safely. As a consequence of this ban, U.S. pork exporters must participate in the burdensome *Pork for the EU Program* to verify that the pork has not been produced using ractopamine. In addition, U.S. pork shipments to the EU must undergo expensive laboratory testing to verify the absence of ractopamine residue. These requirements, which appear to lack scientific justification, pose a major impediment to U.S. pork exports to the EU, confining U.S. exports to a small group of U.S. suppliers. On July 5, 2012, Codex adopted standards for the maximum residue levels for ractopamine. The United States will continue to encourage the EU to implement the international standards or provide sufficient scientific evidence to support its unwarranted SPS trade barriers.

### *Seafood*

Prior to 2008, the EU authorized imports of U.S.-origin molluscan shellfish under the terms of the United States-European Community Veterinary Equivalence Agreement. In 2008, the Commission's Directorate General for Health and Consumers notified FDA that the import approval for U.S.-origin molluscan shellfish would expire at the end of 2009. Despite high-level U.S. Government engagement on the issue, the EU began barring imports of all U.S.-origin molluscan shellfish other than scallops in July 2010.

Since that time, the U.S. Government has actively engaged with the European Commission on this issue and has provided the EU sufficient evidence that U.S. molluscan shellfish are safe to consume. The United States considers that it has provided the EU the information it needs in order to reach an equivalence determination and allow imports of U.S. molluscan shellfish to resume.

## **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 import 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 tallow for some technical purposes. In the years 2007-2009 the EU stated that they had to wait until they had 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 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 did revise the 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 import of U.S. tallow intended for certain technical purposes. 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 import of U.S. tallow. Later in 2012, the United States began high level discussions with the EU to try to re-open the market. As a first step, the EU is preparing a draft amendment that could remove the effective prohibition on tallow intended for the manufacture of biodiesel, while retaining some costly requirements for U.S. producers. The United States continues to press the EU to remove those unwarranted requirements and allow more market access for U.S. tallow.

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

### *Milk*

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

## **EU Country Specific Issues**

### Austria

#### *Agricultural Biotechnology*

Since 1997, Austria has maintained a series of cultivation and import bans on agricultural products derived from GE. The United States challenged several of these bans at the WTO, which found them inconsistent with Austrian and EU obligations under the SPS Agreement. In May 2008, Austria lifted its import bans on the MON 810 corn (a pest-resistant corn variety) and T25 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) lines.

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. The combined restrictions cover the entire country and, in effect, ban all biotech field trials and production. In addition, the law requires the Minister of Agriculture to invoke a “safeguard clause” for a particular GE crop in Bulgaria whenever another Member State applies a safeguard clause for that same crop in its own territory. Separately, in July 2010, Bulgaria enacted a prohibition on the use of GE products and ingredients in the production of foods for children and in baby food. The new 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 and has asked Bulgaria to provide justifications for them.

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 and invoked the “safeguard” clause under EU regulations. In October 2008, EFSA found that France had presented no scientific basis to justify the safeguard measure. Nonetheless, France has left in place its ban on the cultivation of MON 810. 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 the 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 food contact surfaces for food products designed for infants or pregnant and lactating women, effective in January 2013, and for all foods beginning in 2015. In addition, the law requires the development of warning labels to be placed on all foods. 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. Currently, the U.S. Government is engaging with other stakeholders while considering options. The U.S. Government has expressed its concerns via a demarche to the French Prime Minister and French officials at the Ministries of Health, Agriculture, Trade and Finance, and has discussed the issue with the European Commission.

## Germany

### *Agricultural Biotechnology*

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

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

## Greece

### *Agricultural Biotechnology*

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

Hungary maintains three differing testing policies based on the origin of the seed. Seed produced in Hungary is subject to random testing for the presence of GE products, but no comprehensive testing and certification is required. Seed imported from another EU Member State is required to have a testing certificate from an accredited EU 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 in addition to the EU authority. 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 European Court of Justice (ECJ) issued a decision that Italy's additional national authorization procedures for GE crops are unlawful, concluding that the cultivation of such 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 a national coexistence measures.

## 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, 95 percent of the 109 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.

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

See section III.B for an explanation of the 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 Komorowski signed an amendment to the Feed Act pushing back the implementation of a ban on entry, prohibition of manufacturing, marketing, and use of animal feeding containing GE components till January 1, 2017. Current legislation envisaged that the ban was to be implemented on January 1, 2013. The signed amendment ensures access for imported feed with GE component to Poland until at least the end of 2016.

On December 21, 2012, President Komorowski signed into law amendments to the Law of the Seed that should bring Poland into compliance with EU legislation. On January 2, 2013, the Polish Council of Ministers, at the request of the Minister of Agriculture, re-authorized its 2008 framework position on agricultural biotechnology and permitted the Ministry to ban cultivation of GE crops by applying the EU safeguard clause. On January 28, 2013, the ban on GE crop cultivation entered into force along with the amended Law of the Seed.

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

## Portugal

### *Agricultural Biotechnology*

In May 2010, the Autonomous Region of Madeira (a Portuguese archipelago) became the first region of the EU to declare itself free of biotech cultivation after the European Commission failed to oppose Madeira's request by the legislated deadline. Madeira's authority for the ban was further codified when, in July 2010, the Commission announced new "co-existence" measures that authorize Member States to allow, restrict, or ban the cultivation of 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. The United States has raised this issue in bilateral meetings with Portugal.

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

## **INDIA**

### **Food Safety**

#### *Dairy Products*

Since 2003, India has imposed unwarranted SPS requirements on dairy imports, which have precluded U.S. access to India's dairy market, one of the largest in the world. For example, India requires the U.S. Government to certify that any U.S.-origin milk destined for India has been treated to ensure the destruction of *paratuberculosis*, whose presence, according to India, is linked to Crohn's Disease, a conclusion the United States disputes. The United States maintains that the presence of *paratuberculosis* in dairy products does not pose a human health risk, and India should not make elimination of this bacterium a condition for issuing an export certificate for U.S. dairy products.

In addition, despite repeated requests from the United States, India has not provided scientific evidence to substantiate its requirements regarding ruminant-origin materials in dairy cattle feed. India has also declined to take into account evidence that this feeding practice poses no safety concerns.

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 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 are vague, and India's demands for extra inspections 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 certificates must be obtained for each imported lot. The United States will continue to press India to lift the unwarranted restrictions and revise the import certificates 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 outbreaks in the United States. The United States has repeatedly raised concerns in the WTO SPS Committee about India's import bans, and has discussed these concerns with Indian officials numerous times, including at a high-level during the U.S.-India Trade Policy Forum. The United States and other trading partners have requested that India lift its ban.

In order to further address this matter, the United States requested WTO dispute settlement consultations with India regarding its import ban on March 6, 2012. Consultations were held in Geneva in May 2012. The consultations did not lead to a resolution of the dispute. A dispute settlement panel has been established, and the United States is continuing to pursue this matter.

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

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

## **Plant Health**

### *Wheat and Barley*

India maintains zero-tolerance standards for certain plant quarantine pests, such as weed seeds and ergot, which block U.S. wheat and barley exports. Bilateral discussions to resolve these issues continue. India has agreed to collaborate further by exchanging ergot strains and testing them on barley under controlled conditions.

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

## **INDONESIA**

### **Food Safety**

#### *Beef and Pork*

Indonesia continues not to recognize the equivalence of the U.S. inspection system for both beef and pork, and instead requires U.S. meat plants to complete an extensive questionnaire that includes proprietary information. In addition, Indonesia's document review process has resulted in approval of only a limited number of U.S. plants. Several U.S. beef and pork establishments submitted applications more than two years ago and still have not obtained approvals.

Following the April 2012 finding of a dairy cow with atypical BSE in the United States, Indonesia modified its import requirements to only permit access for boneless beef from cattle less than 30 months of age based on unwarranted BSE concerns. These BSE-related restrictions, combined with Indonesia's restrictive import licensing scheme, have resulted in the virtual closure of the market to U.S. beef.

The United States has raised these concerns with Indonesia repeatedly, including at the U.S.-Indonesia Trade and Investment Framework and at the WTO SPS Committee.

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

#### *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 the Indonesian authorities have individually audited and approved. Indonesia issued implementing regulations in November 2011 that impose overly stringent requirements concerning animal health and food safety. To date, Indonesia has not notified the WTO of Law 18/2009.

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

## **ISRAEL**

### **Food Safety and Animal Health**

#### *Live Cattle, Beef, and Beef Products*

In 2003, Israel restricted U.S. exports of live cattle, beef, and beef products following the detection of a BSE-positive animal in the United States. These restrictions do not appear to be consistent with OIE guidelines. Although Israel's 2011 policy on BSE permits imports of U.S. cattle, small ruminants, and associated breeding material, the United States and Israel have not agreed on a protocol for the import of live cattle, beef, and beef products from the United States. In 2012, the United States and Israel began re-engaging on this issue and have made significant progress with regard to export certificates.

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. Israel granted the United States an exemption from this requirement until September 1, 2012. During that time, USDA officials worked with industry and state officials on implementing the cold treatment requirement. During bilateral meetings held in December 2012, Israeli officials approved three cold treatment processes, and approved of an additional cold treatment process for fruit from the eastern United States until July 15, 2013, pending the outcome of ongoing APHIS cold treatment research on apple maggot eggs. The United States and Israel also reached agreement that pears shipped under commercial conditions would not be regulated for apple maggot eggs.

#### *Cherries*

For nearly nine years, Israel has banned imports of U.S. sweet cherries, citing risks from 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 the risk assessment for U.S. sweet cherries. During bilateral meetings held in December 2012, Israel indicated that it is close to completing its risk assessment.

## **JAMAICA**

### **Animal Health**

#### *Pork*

Jamaica currently bans imports of U.S. pork due to concerns regarding pseudorabies disease virus. Jamaica continues to work with the United States to complete a risk assessment and the U.S. request for an equivalence determination. This issue was raised at the March 2012 U.S.-Caribbean Community (CARICOM) Trade and Investment Council meeting. The United States will continue to engage with Jamaica to open its market to U.S. pork.

## **JAPAN**

### **Food Safety**

#### *Beef and Beef Products*

In December 2003, Japan banned U.S. beef and beef products following the detection of a BSE-positive animal in the United States. In July 2006, Japan partially reopened its market to allow imports of some U.S. beef and beef products from animals aged 20 months or younger produced under a special program for Japan. However, additional conditions imposed by Japan, including certain border measures, are restrictive and have made it difficult for the United States to regain a level of trade that approaches historic levels of exports to the Japanese market.

In December 2011, as the first step of a process to reassess its BSE-related trade restrictions and at the request of Japan's Ministry of Health, Labor and Welfare, the Japanese Food Safety Commission (FSC) initiated a risk assessment to examine raising the maximum age of the cattle from which U.S. beef can be exported to Japan, as well as revising the definition of specified risk materials (SRMs). In October 2012, the FSC issued its final risk assessment, which recommended that Japan: (1) raise the age limit for cattle from which U.S. beef and beef products can be exported to Japan from 20 months of age to 30 months, and (2) adopt a revised definition of SRMs 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, among other steps. It is estimated that these important changes will result in hundreds of millions of dollars in additional exports of U.S. beef to Japan in the coming years. The two governments also agreed to regular and *ad hoc* consultations to review progress under the agreement and address any issues that may arise. In an accompanying letter exchange, Japan also confirmed its ongoing BSE risk assessment by the FSC, which includes a consideration of raising the age limit above

30 months for beef and beef product imports from the United States, taking into account international standards.

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

#### *Food Additives*

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

In 2002 Japan created a list of 46 food additives that would be subject to an expedited approval process. More than 10 of the 46 additives remain unapproved. The United States understands that Japan is currently reviewing the remaining additives. The United States has urged Japan to complete work on the reviews and to develop a meaningfully expedited process for reviewing all future requests for food additive approvals. U.S. officials have also requested Japan to use such an expedited review process for additional, globally-used additives.

#### *Gelatin*

Japan banned the importation of U.S.-origin ruminant 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 have been amended to allow for their importation, no modification has been made to the prohibition on ruminant-origin gelatin for human consumption. This import ban appears to be inconsistent with OIE guidelines. The United States will continue to press Japan to lift the ban on gelatin and collagen, including from bovines of more than 30 months of age, consistent with science and OIE guidelines.

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

#### *Pre and Post Harvest Fungicides*

Japan's food safety regulations require a risk assessment for the pre-harvest application of a fungicide. However, Japan classifies fungicides that are applied post-harvest as food additives and requires them to undergo a separate risk assessment. As a result, registrants of fungicides that may be used both pre- and post-harvest must ensure that two risk assessments are performed, a process that is redundant and that can take as long six years to complete. The requirement for dual risk assessments deters registrants from pursuing approval for new and safe products. Japan's dual risk assessment requirement does not have a significant impact on domestic producers, as Japanese farmers do not generally apply fungicides after harvest.

Japan's policy appears to be inconsistent with Codex standards and widely accepted procedures among countries with robust pesticide regulatory systems. Countries assessing the risk posed by



a fungicide generally perform a single risk assessment, which takes into account the manner in which the fungicide is applied and focuses on the characteristics of the residue and the amount of residue present, regardless of the time of application to the crop.

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

### *Maximum Residue Limits*

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

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

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

## **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 to be consistent with OIE recommendations. The United States continues to press Japan to agree to a fully OIE-consistent revised protocol and 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 limited shipments to a single chipping facility and provided for a shipping period of just five months (February to June).

Once the agreement was implemented, USDA began working steadily with MAFF to expand access for U.S. potatoes. This work has resulted in a \$5 million per year increase in exports. In 2010, an additional state (Washington) was added to the list of states eligible to ship chipping potatoes to Japan. In June 2011, MAFF approved a second chipping facility to process U.S. potatoes. In July 2011, MAFF extended the eligible shipping period to include July. During 2012 USDA continued to negotiate with Japan for increased access for U.S. potatoes.

### *New Cherry Varieties*

U.S. cherries can currently be exported to Japan subject to either fumigation treatment or a systems approach of phytosanitary safeguards. Japan does not maintain varietal restrictions for cherries imported in accordance with systems approach safeguards. However, with regard to fumigation treatments, Japan only approves imports of new fresh cherry varieties based on individual fumigation trials. This burdensome process, which involves testing the efficacy of fumigation treatments for each separate variety, restricts the entry of new cherry varieties into the Japanese market. The United States is urging Japan to accept fresh sweet cherries as a single commodity under a single fumigation protocol, which would mean that all varieties may be imported without the need for separate testing. The United States continues to urge rapid resolution of this concern.

## **KAZAKHSTAN**

### **Systemic Issues**

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

Kazakhstan signed the Agreement of the Customs Union on Sanitary Measures and the Agreement of the Customs Union on Veterinary and Sanitary Measures on December 11, 2009. Since April 2010, Russia, Belarus, and Kazakhstan have concluded many additional agreements that harmonize SPS measures. These agreements create a unified list of goods subject to veterinary, phytosanitary, and sanitary-epidemiological control at the customs border and within the territory of the CU, set unified veterinary and sanitary epidemiological and hygienic requirements for those goods, and establish a single form of documentation used to confirm the safety of those goods. On July 1, 2010, the CU implemented harmonized veterinary

requirements, which stipulate that imports of all veterinary-controlled products are eligible for entry only if they are from facilities on a common list approved by all three Customs Union parties. The CU's SPS measures have the potential to restrain U.S. exports.

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

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

During 2011, the CU amended several of its SPS agreements, including aligning certain SPS requirements with international standards. The U.S. Government is working with Kazakhstan to encourage improvements in the CU's SPS regime and to ensure that implementation of the CU's SPS measures is not trade disruptive. In February 2013, APHIS sent a delegation to Moscow to negotiate several live animal and germplasm export certificates with the CU countries, including Kazakhstan. This will be followed by other U.S. delegations in 2013 to discuss certificates for the export of meat, dairy, and animal by-products.

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

### **Agricultural Biotechnology**

Kazakhstan currently is considering a draft law to regulate the development and testing of agricultural biotechnology products in Kazakhstan. While the current draft law provides for the review and registration of agricultural biotechnology events for import and cultivation in Kazakhstan, it also includes rigid timelines for notification and supplementary data submissions and lacks clarity with respect to liability and the protection of confidential business information. The draft law also establishes a ban on the use of agricultural biotechnology products in food for children. The United States has requested Kazakhstan to provide a risk assessment supporting the draft law, but Kazakhstan has not done so. The United States has urged Kazakhstan, if it approves and implements the law, to consider an interim system for agricultural biotechnology approvals to avoid disrupting imports of products currently sold in Kazakhstan. In 2012, as a part of the CU with Russia and Belarus, Kazakhstan notified to the WTO a new measure on food labeling that includes a provision on labeling of agricultural biotechnology ingredients. The United States commented on the highly restrictive regulation. The United States also partially

funded and organized an outreach program in Kazakhstan on agricultural biotechnology regulations in November 2012.

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

## **Food Safety**

### *Live Cattle*

On January 17, 2013, Kazakhstan placed a temporary ban on imports of all U.S. cattle due to bluetongue, a non-contagious, insect-borne viral disease rarely found in cattle, following detection in a shipment of cattle in December 2012. No official notification was received by the United States, nor any timeline provided for a review of the U.S. system or an approvals process, and all import permits have been suspended. The United States and Kazakhstan met in January 13, 2013, to discuss the issue, and as a result a team of U.S experts traveled to Kazakhstan the week of January 28, 2013, for technical discussions concerning regulatory oversight. On March 14, 2013, Kazakhstan announced that it was re-opening the market to U.S. cattle.

### *Pork*

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

## **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 Kenya on the 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 the product risk assessments may be redundant and lacking scientific justification. The process may also lead to delays in the approval of new products. The United States is also concerned about Korea's narrow scope of definition for "adventitious presence." In addition, the United States is concerned that the LMO Act, while nominally applying to all living modified 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 modified animals. In late 2012, Korea's National Assembly approved revisions to the LMO Act. The implementing regulations to the Act are expected to be revised in 2013 to reflect the recent changes to the Act itself. The United States is in the process of reviewing the revised Act to determine if the revisions address U.S. concerns. The U.S. and Korean governments will continue to work together to address these concerns.

Korea completed approvals for five new GE plants in 2012. U.S. concerns continue, however, with regard to the lack of predictability in Korea's agricultural biotechnology review process. The United States will continue to engage with Korea to avoid significant 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*

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. In 2012, the U.S. exported \$582 million worth of beef (including variety meats) to Korea, making Korea the fourth-largest export market for U.S. beef. The United States will continue to urge Korea to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' risk status.

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

### *Maximum Residue Limits*

Korea has a national MRL list and uses a unique and complicated deferral approval process using Codex and other systems when no national MRLs are established. Korea has increased pesticide residue testing on U.S. commodities due to residue violations occurring in other countries. After a single MRL violation by a U.S. export (including one detected by authorities of another country), Korea imposes restrictive requirements on that product's grower, shipper, and importer, and requires that they must make a certain number of compliant shipments before the sanctions are removed.

The United States will continue to encourage Korea to maintain the current list of MRLs based on the most current available scientific data, or until Korea completes the appropriate risk assessments. The United States will also continue to seek guidance from Korea on how U.S. pesticide manufacturers and registrants may submit to the Korea Food and Drug Administration relevant information and requests for the establishment of import MRLs for pesticides.

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

### *Cherries*

Korea requires U.S. cherries to undergo fumigation with methyl bromide before shipping. Replacing the fumigation requirement with alternative mitigation measures would address Korea's phytosanitary concerns while increasing the shelf life of the cherries, thus allowing shipment by ocean vessel rather than air freight and substantially reducing transportation costs. The United States has been engaged with Korean quarantine officials since 2008 to agree on an alternative mitigation measure to methyl bromide. Korea sent inspectors to California, Washington, Oregon, and Idaho to evaluate the step-by-step process used by U.S. producers to ensure that various pests are controlled during the growing season. This gave Korean officials a better understanding of the U.S. system and ensured that trade continued while both sides work to find an alternative mitigation measure to methyl bromide fumigation. The United States will continue to work with Korea on this issue.

## **KUWAIT**

### **Food Safety**

#### *Beef and Beef Products*

In 2006, following the detection of a BSE-positive cow in Alabama, two government offices in Kuwait – the Kuwait Public Authority for Agriculture and Fishery Affairs and the Municipality of Kuwait – banned all live cattle and beef from Oklahoma, not Alabama. USDA has worked to rectify the situation, and was able to convince both offices to remove the ban on live cattle and beef from Oklahoma. However, the Municipality of Kuwait has refused to remove the ban on beef produced in Oklahoma, despite the continued engagement of USDA. 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' risk status.

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

## **KYRGYZSTAN**

### **Food Safety**

#### *Pork*

Kyrgyzstan maintains a ban on U.S pork exports from several U.S. states due to concerns regarding the H1N1 virus. Kyrgyzstan instituted the H1N1-related ban on U.S. pork even though there is no evidence to indicate that the virus can be conveyed to humans through the consumption of pork. The OIE, FAO, and WTO each issued statements shortly after the H1N1 outbreak calling on countries not to institute import bans on pork on this basis.

## **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, and stopped accepting the FSIS export certificate without additional attestations. 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 will allow trade to resume.

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

## **MALAYSIA**

### **Food Safety**

In June 2011, Malaysia's Department of Veterinary Services (DVS) stopped issuing import permits for the United States for frozen and chilled pork products and instituted new requirements, which include requiring pork facilities to complete a lengthy application and to submit to an audit by DVS at the expense of the producer or the producer's government. Only upon successful completion of these procedures will an import permit be granted. 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, including a possible systems-based audit of U.S. pork facilities in 2013.

## **MEXICO**

### **Food Safety**

#### *Live Cattle, Beef, and Beef Products*

In March 2004, Mexico became one of the first major markets previously closed to U.S. beef and beef products due to BSE concerns to reopen its market when it announced that it would accept

imports of U.S. deboned beef from cattle less than 30 months of age. Mexico currently allows the importation of all U.S. beef derived from animals less than 30 months of age. All cattle and products derived from cattle over 30 months are banned.

In October 2008, the United States and Mexico reached an agreement allowing imports into Mexico of U.S. breeding cattle born after 1999. In the fall of 2012, the United States and Mexico reached agreement on the requirements for the exportation of weasand meat, ground beef, head meat, and small intestines. The new procedures have expanded access for the U.S. livestock sector. The United States will continue to press Mexico to open fully its market to all U.S. live cattle, 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.

## **Plant Health**

### *Potatoes*

Mexico prohibits the shipment of U.S. fresh potatoes beyond a 26 kilometer zone along the U.S.-Mexico border. In 2003, the United States and Mexico concluded the Table Stock Potato Access Agreement, which provided a process for allowing U.S. potatoes access to the whole of Mexico over a three-year period. Since then, however, Mexico has refused to move forward with further implementation of the 2003 agreement, citing pest detections in shipments over the intervening years. Over that same period, APHIS and U.S. potato producers have taken steps to address Mexico's concerns, which have resulted in significant drops in pest interceptions.

In December 2010, the U.S. and Mexican Secretaries of Agriculture agreed to explore alternative approaches to resolve this issue, including third-party mediation. Subsequently, Mexico and the United States agreed to mediate this issue under the auspices of the North American Plant Protection Organization (NAPPO). The NAPPO decision was released in September 2011. In that report, the Mediation Panel identified six pests in their analysis which should be considered quarantine pests by Mexico for the pathway "potato for consumption." The NAPPO report and recommendations were agreed to by both the United States and Mexico.

On September 4, 2012, Mexico published an executive order and on November 20, 2012, Mexico proposed new draft regulations for the importation of potatoes. These draft regulations appear to be inconsistent with the panel's report and if implemented would further restrict market access for U.S. potatoes. For example, the draft regulations list 83 quarantine pests, far more than the six identified in the NAPPO report and recommendations. The United States has submitted formal comments to Mexico, expressing its concerns that the proposed regulations are not based on science, nor consistent with the 2003 Table Stock Potato Access Agreement, the report and recommendations of the NAPPO Mediation Panel, and the International Plant Protection Convention's requirements regarding phytosanitary measures. The United States will continue to press Mexico for a science-based solution.



## *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 Mexico inspector direct oversight. The industry is also interested in market access under irradiation treatment and 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 met in January 2011 to discuss the issue and committed to engage in further discussion. Mexico is in the process of completing the PRA and, in that regard, conducted a site visit in November 2011.

## **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. At the December 2012 United States-Morocco Joint Committee meeting, the United States and Morocco agreed that work on resolving these longstanding issues would continue through ongoing engagement between the technical experts.

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.

## **NEW ZEALAND**

### **Animal Health**

#### *Pork*

New Zealand restricts imports of fresh pork from the United States in consumer-ready form due to concern about PRRS. In April 2009, after several years of consultation and analysis, New Zealand issued four new Import Health Standards (IHS) for pig meat, pig meat products, and by-products from the United States, Canada, the EU, and Mexico. The new standards allow imports of chilled and frozen pork, but the chilled products are to be in 3 kilogram or less consumer ready packs. The domestic pork industry opposed the new standards in the courts on the grounds that the IHS process was not followed properly and the scientific evidence for the new standards was not strong enough. On March 18, 2013, the New Zealand Court of Appeals dismissed the New Zealand Pork Industry Board's appeal. The United States continues to engage with New Zealand on this issue.

## **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 imports and production of GE products, except for GE products used in research in a confined environment, in pharmaceutical or veterinary products, or 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. As a result, U.S. exports of conventional seeds to Peru (valued at over \$7 million in 2011) have stopped. The United States continues to raise concerns with Peru in bilateral meetings.

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

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

## **PHILIPPINES**

### **Plant Health**

#### *Market Access for U.S. Vegetables*

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

## **RUSSIA**

### **Systemic Issues**

On August 22, 2012, Russia became a Member of the WTO. 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 in its protocol of accession.

The entry into force of the CU between Russia, Kazakhstan, and Belarus has complicated exporting into and trade among the three countries as they harmonize and revise their SPS measures. For example, on July 1, 2010, the CU implemented harmonized veterinary requirements stipulating that imports for all controlled products subject to veterinary control are eligible for entry only if they are produced in facilities on a list approved by all three CU countries. The United States worked with Russia to remove products from the list of goods subject to veterinary control where no scientific basis supporting their inclusion was apparent, to eliminate the requirement that the United States provide a list of all facilities that meet CU requirements for goods subject to veterinary control, and to streamline the approval of U.S. facilities. In 2011, the CU countries amended the CU agreements to align some of the veterinary requirements with international standards, recommendations, and guidelines, but much of this work remains uncompleted. In addition, the CU issued new decisions in preparation for Russia's accession to the WTO governing risk assessments and equivalence, harmonization with international standards, and inspection of facilities.

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

In November 2006, the United States and Russia signed bilateral agreements to address SPS issues related to: trade in pork, beef and beef by-products, biotech agricultural products, and certifications for U.S. pork and poultry establishments that export products to Russia. However, there have been implementation problems with several of these agreements. For example, under the November 2006 U.S.-Russia agreement on inspection of meat and poultry establishments, Russia agreed to grant U.S. regulatory officials the authority to certify new U.S. establishments and U.S. establishments that have remedied a deficiency. In accordance with the agreement, Russia also agreed to specific deadlines for responding to requests to list facilities that U.S. authorities had inspected and determined to be in compliance with the requirements to export to Russia. In practice, however, Russia has not consistently recognized the authority of U.S. regulatory officials to certify additional U.S. facilities, and there have been delays in responding to U.S. requests to update the list of approved U.S. facilities.

The CU now has competence for plant inspections, and consequently, the United States is currently seeking an agreement with the CU countries regarding inspections for meat and poultry plants. The United States worked closely with Russia to negotiate a new CU inspection

regulation that allows the CU to accept guarantees provided by SPS authorities in third countries that certify new establishments.

#### *Veterinary Certificates*

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

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

### **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, labeling of GE products, and the lack of an approval system for the cultivation of GE crops. The United States continues to engage Russia to address these specific concerns, as well as to promote greater cooperation on agricultural biotechnology generally. Russia has indicated that it expects to adopt additional biosafety regulations, including an approval system for the cultivation of GE crops, by 2014.

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

### **Food Safety**

#### *Pathogen Tolerances*

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

#### *Veterinary Drugs*

Russia maintains 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 drugs 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 in pork and beef, a feed additive that promotes feed efficiency in pigs and certain other livestock, 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. On December 7, 2012, Russia requested that all pork and beef shipments from countries that use ractopamine in the production of pork and beef verify that product exported to Russia contains zero residue of ractopamine or is sourced from animals that are not fed ractopamine. Based on the presence of ractopamine in various beef and pork, 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 has requested Russia to suspend these measures and adopt the Codex standards for ractopamine. The United States will continue to work with Russia to allow imports of these products to resume.

### *Beef and Beef Products*

Currently, U.S. producers may export boneless and bone-in beef to Russia from cattle under the age of 30 months and that meet the requirements set out in the U.S.-Russia Bilateral Agreement on Trade in Beef. Following the completion of consultations regarding the CU veterinary requirements, the United States began 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' risk status.

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

### *Dairy*

Russia has effectively banned the importation of U.S. dairy products since September 2010, when Rosselkhoz nadzor (Russia's Federal Service for Veterinary and Phytosanitary Surveillance) instructed customs officials to allow shipments only from exporters on Rosselkhoz nadzor-approved lists. During WTO accession negotiations, the United States successfully obtained a commitment from Russia that it would no longer require any foreign producer to be included on Rosselkhoz nadzor lists to be eligible to export dairy products. In 2012, the United States began negotiations with Russia and the CU on a new certificate that would reopen the Russian market to U.S. dairy products. The United States will continue to work with Russia and its CU partners to conclude a new certificate.

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 continues to press Russia to ensure that its measures on this subject are based on science.

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

### *Poultry*

On January 1, 2010, Russia banned the importation and sale of 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.

## **Animal Health**

### *Grains and Oilseeds*

Exports to Russia of U.S. grain and oilseed products for use in animal feed are severely limited due to Russia's requirement for producers to provide veterinary certificates warranting that their products are free of animal diseases. As part of its WTO accession commitments, Russia removed the veterinary certificates requirement for animal feeds of plant origin.

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

### *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.

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

## **SERBIA**

### **Agricultural Biotechnology**

Serbia does not currently permit imports of food products that contain trace amounts of agricultural biotechnology, but it has indicated that it will amend its biotechnology law to be less restrictive within the next six months to facilitate the country's WTO accession process.

In 2012, U.S. embassies in Belgrade, Sarajevo and Zagreb conducted an agricultural biotechnology outreach program in Serbia, Croatia, and Bosnia and Herzegovina to promote acceptance of agricultural biotechnology in the region, including by addressing misconceptions about agricultural biotechnology and sharing advice for developing a more conducive policy environment for agricultural biotechnology products. The program used the GE HoneySweet plum, which is resistant to the plum pox, as an example of a crop from which these countries would benefit.

## **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. For the past several years, Singapore has informed the United States that it is in the process of performing a risk assessment of U.S. beef and beef products. The United States will continue to urge Singapore 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.

### *Pork*

Prior to 2012, Singapore prohibited the use of all PRTs in the production of pork and pork products, which added significantly to the cost of exporting pork. 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 U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low levels. The United States will continue to work with regulatory authorities in Singapore to resolve this trade concern.

## **SOUTH AFRICA**

### **Food Safety**

#### *Beef and Beef Products*

In June 2010, South Africa opened its market to U.S. deboned beef from cattle of all ages, but continues to ban the importation of all other beef cuts and beef products, as well as other U.S. ruminant animals and products. The United States 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' 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 in commercial herds throughout all 50 states. The United States does not consider requirements due to trichinae concerns to be necessary since U.S. producers maintain stringent biosecurity protocols that limit the appearance of trichinae in the United States to extremely low

levels. The United States will continue to work with South Africa to obtain elimination of the current freezing requirement for pseudorabies and trichinae.

## **Plant Health**

### *California Table Grapes*

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

## **SOUTH AFRICAN DEVELOPMENT COMMUNITY**

### **Agricultural Biotechnology**

South African Development Community (SADC) Member States,<sup>7</sup> 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 regarding agricultural biotechnology and other innovative technologies.

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

## **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

---

<sup>7</sup> 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.

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’ 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. This moratorium has been extended by an act of Parliament until November 2013. U.S. officials will continue to urge their Swiss counterparts to address the cumbersome aspects of its regulatory review system and remove the moratorium on cultivation.

See section III.B for an explanation of the 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.

#### *Ractopamine*

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 trade concern by forcing U.S. pork producers to ship pork products selectively sourced from animals not treated with ractopamine. Since 2007, U.S. officials have raised this issue 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.

#### *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, and corn) due to the detection of pesticide or other crop protection compound residue levels that are within U.S. or Codex standards, but for which Taiwan has not yet established MRLs.

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

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

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

## **Animal Health**

### *Animal and Pet Feed*

Taiwan bans the importation of all ruminant-origin 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.

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

## **Plant Health**

### *Apples*

Under the current export work plan for the shipment of U.S. apples to Taiwan, the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) imposes a strict "three strikes" penalty structure for codling moth (CM) detections, where Taiwan will bar all imports of U.S. apples for the remainder of a shipping season if there are three confirmed detections of live CMs. APHIS and BAPHIQ have met on numerous occasions to discuss this issue and the work plan has been modified to include a 2-week grace period following each CM detection. This means that any CM detections that occur within the 2-week grace period do not count as an additional "strike." However, each year the U.S. apple trade is faced with the possibility that the fourth largest market for U.S. apples may suddenly close, creating significant uncertainty among U.S. producers. U.S. apple exports to Taiwan totaled \$85.0 million in calendar year 2012, about eight percent of total U.S. apple exports.

In October 2006, APHIS provided Taiwan with research demonstrating that the risk associated with CM transmission and establishment in Taiwan via U.S.-origin apples is extremely low. This research document was used in discussions with Taiwan counterparts in 2011 as additional modifications to the current "three strikes" penalty structure were negotiated. APHIS will continue discussions with BAPHIQ on the technical aspects of codling moth risk and modifications to the penalty structure of the work plan to eliminate the threat of market closure in 2013.

### *Potatoes*

Taiwan currently limits imports of fresh potatoes from the United States to those grown in Alaska, California, Idaho, Oregon, and Washington. These restrictions exclude major producing states, including Colorado. In 2002, the United States requested that Taiwan add Colorado to the

list of eligible states. In January 2013, Taiwan promulgated new regulations that should allow the importation of table stock potatoes from Colorado sometime in 2013.

## **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 under 30 months of age. In 2012, Thailand published new rules that bring it largely in line with OIE BSE guidelines. 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' 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. Thai officials indicated they will establish domestic MRLs by December 2013. The United States has encouraged Thailand to act quickly in this regard

#### *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. 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 equalize the fees and ensure that the import fees are commensurate with the services provided.

## **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 has indicated that it intends 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 food use. In February 2012, the Board approved three additional corn products, but rejected six others. Imports of U.S. corn will not resume until all petitioned products are approved, since all seed varieties are planted in the United States and consignments may contain any of these corn products due to the commodity handling system of the United States. The United States has submitted comments to Turkey on the Biosafety Board's decisions and will continue to work with Turkey to obtain approvals for additional U.S. biotech products.

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

In September 2011, Turkey adopted a measure that allows for up to 0.1percent 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 0.1percent threshold and to extend the provision to food products.

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

Under the Biosafety Law, MARA has pressed agricultural biotechnology developers to apply for approval of their products. However, developers have been reluctant to do so because a number of essential details of the approval process remain unclear, including what may constitute a failure of compliance and, in situations of noncompliance, what level and kind of penalties will



apply. In September 2011, U.S. and Turkish industry representatives began a dialogue with MARA to discuss these concerns, but these discussions have failed to resolve the industry's concerns.

The United States has repeatedly raised concerns about specific provisions of the 2010 Biosafety Law and its implementing regulations with Turkish officials, including at the June 2012 meeting under the bilateral Framework for Strategic Economic and Commercial Cooperation. In addition, the U.S. government and the U.S. agricultural industry have held a number of consultations with the Turkish government and Turkish industry, most recently in July 2012, about agricultural biotechnology and the agricultural biotechnology-derived products affected by this law and implementing regulations. The United States will continue to engage Turkey on this issue both bilaterally and in multilateral fora.

See section III.B for an explanation of the 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' risk status.

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

## **UKRAINE**

### **Agricultural Biotechnology**

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

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

In 2012, Ukraine revised further its biosafety legislation and notified seven biotechnology regulations to the WTO. The United States submitted comments on these regulations, which raise concerns regarding the monitoring and routine detection testing of GE products. Currently, the Ukrainian government ignores the illegal planting of agricultural biotechnology soy, rapeseed, and corn.

The United States continues to work with Ukraine to establish a functioning and predictable agricultural biotechnology regulatory framework.

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

## **Food Safety**

### *Pork*

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

## **URUGUAY**

### **Food Safety**

#### *Live Cattle, Beef, and Beef Products*

Uruguay continues to ban imports of all U.S. live cattle, beef, and beef products following the detection of a BSE-positive animal in the United States in 2003. The United States will continue to urge 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' risk status.

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

## **Animal Health**

### *Poultry*

Uruguay currently bans imports of many U.S. poultry products due to concerns over AI and Newcastle's disease. In October 2007, the United States and Uruguay reached an agreement that permitted imports of U.S. turkey to resume. The U.S. acceptance of this agreement, however, was premised on the understanding that the two countries would complete negotiations to provide market access for all poultry and poultry products, consistent with science and the relevant OIE guidelines. The United States has raised the issue with Uruguay repeatedly, including at the October 2011 Trade and Investment Council meeting.

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

## **Plant Health**

### *Potatoes*

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 inappropriately low. The United States will continue to work with Uruguay to address outstanding concerns relating to Uruguay's existing tolerance levels.

## **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, and will continue to seek a successful resolution.

## **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' risk status.

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

### *Offals*

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

The United States raised this issue at the June 2011 WTO SPS Committee meeting and was joined by numerous other WTO Members. In response, Vietnam indicated it would conduct a risk assessment to justify the remaining ban, but to date it has not shared any such risk assessment. The United States continues to engage with Vietnam on this issue.

### *Products of Animal Origin*

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

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

*Products of Plant Origin*

In July 2011, Vietnam began enforcing new regulations on imported goods of plant origin. The United States has raised concerns regarding exporter registration requirements, sampling rates, and the coverage of MRLs. The United States will continue to work with Vietnam to address its concerns.



## **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. 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 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 international 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,

agribusinesses, 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 U.S. with key partners within ministries of agriculture, health, and trade, and allows the U.S. 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 to prevent 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. For laboratory capacity, JIFSAN created the International Food Safety Training Laboratory (IFSTL) in 2011 to deliver laboratory-based training to scientists suitable for monitoring food safety compliance. Additionally, JIFSAN conducts numerous food safety training programs on good agricultural practices, good aquaculture practices, risk assessment and commercially sterilized processed foods to the international community. Support for these activities is part of a long-term capacity-building program aimed at strengthening the safety of imports and strengthening 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 2012, FDA coordinated and organized 84 visits for 381 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 2012.

## **Regional Activities**

In 2012, 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, 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 FDA, the U.S. Department of State, the Federal Bureau of Investigation, and U.S. university partners to conduct Food Defense International Awareness workshops in Argentina, Chile, Costa Rica, Guatemala, Israel, Jordan, Korea, and Turkey. Food defense is the protection of the food supply from intentional contamination. These workshops provided a forum for representatives of government and industry 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 invited and sponsored participants from various countries to attend U.S.-based courses in veterinary epidemiology, risk analysis, plant disease diagnostics, animal diseases, and laboratory diagnostic networks. USDA held these courses in various locations in the United States, including Fort Collins, Colorado; Plum Island, New York; Washington, DC; Ames, Iowa; and Madison, Wisconsin. 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 nineteen 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 ten Cochran Fellows from Algeria, Costa Rica, Ghana, Moldova, Nicaragua, Nigeria, and Ukraine at Michigan State University in 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.

USDA sponsored and participated in five regional meetings, two each in Asia and Latin America and one in Africa, to provide information in advance of the 6<sup>th</sup> Conference of the Parties/Meeting of the Parties to the Cartagena Protocol on Biosafety (Protocol), which was held in fall 2012 in India. The regional meetings helped result in several key successes at the Protocol meetings including: 1) prevention of the adoption of a flawed risk assessment guidance document; 2) agreement that outcomes from two technical expert groups, one on risk assessment and the other on socio-economic considerations, will be brought back to the next Meeting of the Parties for consideration of next steps by all Parties; and 3) a call for Parties to notify their biosafety regulatory frameworks to the Biosafety Clearing-House.

### *Africa*

USDA in cooperation with the U.S. Agency for International Development (USAID) continues to support four resident SPS advisors and coordinators stationed in Sub-Saharan Africa to cover the East, West, and Southern Africa regions. These SPS advisors and coordinators directly supported government SPS agencies in their respective regions to develop institutional capacity for 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 support of science-based regulatory frameworks in Africa, USDA also provided financial support to the Common Market for Eastern and Southern Africa's (COMESA) regional workshop in Zambia in May 2012 and later attended the drafting session at which the COMESA Regional Biotechnology Framework (RABESA) was completed. The workshop helped solidify endorsement of the final draft of the RABESA by the delegates. This draft will be presented at the 2013 COMESA Joint Ministerial meeting for ratification by the COMESA Ministers of Agriculture, Environment and Natural Resources. This Framework should assist agricultural development and trade of GE products on a regional basis throughout East Africa.

### *Asia Pacific Economic Cooperation*

In November 2011, the United States pledged technical support for a new Global Food Safety Partnership (GFSP) between APEC and the World Bank. The GFSP is structured as a

collaborative, multi-stakeholder forum supported by a multi-donor trust fund (MDTF). The objective of the trust fund is to support training programs designed to enhance food safety and facilitate global food trade. A public-private partnership encompassing government institutions, private enterprises, producers, and other stakeholders is a fundamental component of the GFSP. The MDTF began with initial funding of \$1 million by industry, which is expected to eventually grow to \$15-20 million. The APEC region will serve as a pilot program for the work plan of the GFSP. The program will eventually be expanded globally to World Bank eligible economies. The GFSP will enhance U.S. efforts to facilitate the trade in safe food in the APEC region by coordinating technical training and sharing best practices so as to increase the capacity of APEC economies to implement international standards and use science and risk-based approaches to food safety regulation. These programs will also enable more growers, producers, and food safety officials to understand and use preventive controls, resulting in safer food for consumers and fewer safety incidents in food trade.

Within the APEC Subcommittee on Standards and Conformance's Food Safety Cooperation Forum's Partnership Training Institute Network, USDA sponsored an Export Certification Workshop in Greenbelt, Maryland in April 2012. The event provided a forum for government and industry representatives from APEC member economies to discuss common issues and concerns related to export certificates. Discussions included a focus on Codex guidance and use of Codex model certificates, criteria for determining when a food or agricultural certificate should or should not be required, appropriate use of export certificate attestations, and increased use of electronic certificates. Also under the auspices of APEC, USDA sponsored sub-regional "Laboratory Competency Strengthening Workshops" in Kuala Lumpur, Malaysia; Lima, Peru; and Hanoi, Vietnam. The sub-regional trainings focused on analytical methods, validation, adaptation to local conditions, import-export trade facilitation methods, regulatory requirements, Codex principles, and good laboratory practices.

### ***Latin America and the Caribbean***

Since 2005, USDA 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 2012, 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, pesticide laboratory training, pest risk assessment training, and fruit fly data collection 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. This harmonization support

improves trade flows within the region, and an increasingly integrated Central American market will assist in growing U.S. exports.

USDA's Cochran Fellowship Program sponsored thirteen 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.

In 2012, USDA's Cochran Fellowship Program and FSIS collaborated to train two government officials from Barbados, and St. Vincent and the Grenadines on food safety testing methods. The purpose of the seminar was to familiarize foreign government laboratory officials with testing methods and procedures used by FSIS to ensure that meat, poultry, and egg products are safe and wholesome. The training course was conducted at the FSIS Eastern Laboratory in Athens, Georgia, and covered many food testing issues, including general requirements for laboratory competence and methods for detecting major pathogens. This training helps to protect Latin American, Caribbean, and U.S. consumers from food safety risks.

### ***Russia and Eastern Europe***

USDA collaborates with the U.S. Department of State and the U.S. Department of Defense to provide animal health technical assistance to the countries of Armenia, Georgia, Kazakhstan, and Ukraine. USDA has focused this technical assistance 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. For example, the technical assistance provided to Kazakhstan regarding brucellosis, a highly contagious, infectious animal disease, promoted understanding of the use of vaccines in the United States and how this helped prevent the introduction of brucellosis in the United States. This assistance promotes the alignment of science-based systems and international standards to prevent disruptions in trade.

### **Country-Specific Activities**

#### ***Bangladesh***

In 2012, USDA's Norman E. Borlaug Agricultural Science and Technology Fellowship Program sponsored a Fellow from Bangladesh studying food safety systems at the University of Nebraska-Lincoln. Over the twelve-week training period, the Borlaug Fellow became familiar with predictive modeling systems typically used in the United States and how these models can be used effectively for risk assessment in agricultural supply chains. This training provided the Fellow with improved skills, and knowledge of U.S. food safety models and technologies, which will lead to improved food safety in Bangladesh and promote U.S. exports.

## *China*

For the past five years, USDA has worked closely with EPA's Office of Pesticide Programs to provide technical assistance to China's Institute for the Control of Agri-Chemicals (ICAMA). These technical exchanges have resulted in a joint review by ICAMA and EPA of six chemicals that are approved for use in China and the United States, but are scheduled for re-evaluation. This cooperation between the United States and China benefits both countries and creates stability for exporters, as the chemicals available to U.S. farmers increasingly will be approved for use in China.

In November 2012, a team from Kansas State University travelled to China through the U.S.-China Scientific Exchange Program to research factors affecting the control of PRRS in China. The goal of this exchange was to collaborate with Chinese researchers on efforts to minimize the global threat of Highly Pathogenic PRRS, a disease with the potential to threaten U.S. production and exports of U.S. pork to China.

## *Colombia*

USDA initiated an SPS technical assistance project with Colombia in 2012. Initial technical assistance focused on strengthening Colombia's pesticide registration process, but USDA expects to expand the project in 2013 to include strengthening Colombia's plant health system in addition to providing technical assistance to develop and strengthen Colombia's pesticide regulations. This project is an important platform for engaging with the Colombian government as the United States and Colombia implement the United States – Colombia Trade Promotion Agreement. This project promotes the use of the safer pesticides used by American producers and the reduction of food contamination, thus protecting public health.

## *Mexico*

In 2012, the United States provided SPS-related training to representatives from the Mexican government, industry, and academia on topics including animal vaccine development for beef (anaplasmosis) and poultry (avian influenza); agricultural biotechnology; laboratory analysis (emphasizing work with exotic Newcastle disease as well as general analytical methods and general validation and fitness for purpose); plant health risk analysis; meat and poultry product inspection; food defense, such as the molecular identification of the rice bacterial blight disease; and the diagnosis and control of paratuberculosis in dairy cattle, a disease that reduces milk production.

In addition, FDA expanded laboratory cooperation with SENASICA and COFEPRIS laboratories in 2012, and continued participation in exchanges of information and methodologies for sampling, particularly with regard to microbiology and pesticide residues.

### *Peru*

USDA collaborated with FDA, EPA, and various U.S. university partners to provide SPS capacity building to officials from Peru's government and agricultural universities. This technical assistance focused on risk analysis, inspection and surveillance, laboratory diagnostics, SPS regulation development, and university curriculum development. This program aims to improve Peru's ability to prevent contamination of its food supply and protect its agricultural sector from the spread of animal and plant diseases, and is part of the ongoing provision of technical assistance to Peru under the United States – Peru Trade Promotion Agreement. The training also aims to harmonize Peru's SPS regulations with international standards to facilitate trade. An example of this occurred this past year when Peru updated its Pest Risk Assessment Protocols and Inspection Regulations.

### *Vietnam*

USDA sponsored seven Cochran Fellows from Vietnam to attend a Food Safety Systems training program conducted by North Carolina State University in August 2012. The training program was designed to inform Fellows of the science behind the U.S. food safety system for raw and processed plant products. The training included discussions on the alignment of science-based systems and international standards and visits to fruit production areas, vegetable processing facilities, and extension offices in North Carolina. The Fellows also met with APHIS, EPA, and Grain Inspection, Packers & Stockyards Administration. The goal of this training was to provide the Fellows with a greater understanding of the U.S. regulatory system and increase U.S. exports of fruits and vegetables to Vietnam.

## **APPENDIX**

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

Almond Board of California  
American Feed Industry Association  
American Forest and Paper Association  
American Potato Trade Alliance  
American Soybean Association  
California Grape and Tree Fruit League  
California Table Grape Commission  
Distilled Spirits Council of the United States  
Grocery Manufacturers Association  
Herbalife International of America  
National Cattlemen's Beef Association  
National Confectioners Association  
National Fisheries Institute  
National Milk Producers Federation & U.S. Dairy Export Council  
National Pork Producers Council  
National Potato Council  
National Renderers Association  
North American Export Grain Association  
Northwest Horticultural Council  
U.S. Hop Industry Plant Protection Committee  
U.S. Meat Export Federation  
U.S. Wheat Associates  
USA Rice Federation  
Yum! Restaurants International

**OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE  
EXECUTIVE OFFICE OF THE PRESIDENT  
WASHINGTON, D.C. 20508**