ACKNOWLEDGEMENTS

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

March 2012

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I. Foreword

This year the Office of the United States Trade Representative (USTR) publishes its third annual *Report on Technical Barriers to Trade (TBT Report)*. This report was created to respond to the concerns of U.S. companies, farmers, ranchers, and manufacturers, which increasingly encounter non-tariff trade barriers in the form of product standards, testing requirements, and other technical requirements as they seek to sell products and services around the world. As tariff barriers to industrial and agricultural trade have fallen, standards-related measures of this kind have emerged as a key concern.

Governments, market participants, and other entities can use standards-related measures as an effective and efficient means of achieving legitimate commercial and policy objectives. But when standards-related measures are outdated, overly burdensome, discriminatory, or otherwise inappropriate, these measures can reduce competition, stifle innovation, and create unnecessary technical barriers to trade. These kinds of measures can pose a particular problem for small- and medium-sized enterprises (SMEs), which often do not have the resources to address these problems on their own. USTR is committed to identifying and combating unwarranted technical barriers to U.S. exports, many of which are detailed in this report. USTR's efforts to prevent and remove foreign technical barriers serve the President's goal of doubling U.S. exports by the end of 2014 through the National Export Initiative.

Since the last *TBT Report* was released, the United States has significantly advanced its efforts to resolve concerns with unjustifiable barriers to trade and to prevent their emergence. Indeed, in 2011 USTR secured several important additions to the arsenal of tools at its disposal to combat unnecessary trade barriers and made progress on the addition of others, including: passage of free trade agreements with Korea, Colombia, and Panama that strengthen our ability to ensure that the standards-related measures these trading partners adopt are transparent and serve legitimate objectives; the creation of new cooperation initiatives related to regulatory and standards issues in the WTO, APEC, U.S. FTAs, and other bilateral fora; and progress on the negotiation of a modernized Technical Barriers to Trade (TBT) chapter in the Trans-Pacific Partnership (TPP) that will build on and strengthen current TBT disciplines.

As part of the U.S. host year for APEC in 2011, USTR led several initiatives to promote the use of good regulatory practices across the Asia Pacific region and to prevent governments from creating standards-related barriers to trade in emerging technologies of critical importance to the United States – including in the areas of "smart grid," solar technologies, and commercial green buildings. At the APEC CEO Summit in Honolulu, President Obama highlighted the importance of these initiatives for regulatory convergence, which he said will permit countries "to all think about whether our regulations are as efficient, as effective as they can be, or where are they standing in the way of smart trade.[1]" USTR also took successful steps to eliminate or reduce potential foreign technical barriers to U.S. exports in 2011, for example, by working with Chile to ensure that diesel emissions standards in Chile continue to allow U.S.-manufactured commercial diesel trucks to be sold in the Chilean market.

[1] See http://www.whitehouse.gov/the-press-office/2011/11/12/remarks-president-obama-apec-ceo-business-summit-qa.

Again in 2012, USTR will engage vigorously with other agencies of the U.S. Government, as well as interested stakeholders, to press for tangible progress by U.S. trading partners in removing unwarranted or overly burdensome technical barriers. We will fully utilize our tool-kit of bilateral, regional and multilateral agreements and mechanisms in order to dismantle unjustifiable barriers to safe, high-quality U.S. industrial, consumer, and agricultural exports and strengthen the rules-based trading system. Recognizing that U.S. economic and employment recovery and growth continue to rely importantly on the strength of U.S. exports of goods, services, and agricultural products; we will be redoubling our efforts to ensure that the technical barriers that inhibit those exports are steadily diminished.

Ambassador Ron Kirk
U.S. Trade Representative
March 2012

II. Executive Summary

The *2012 Report on Technical Barriers to Trade (TBT Report)* is a specialized report focused on significant foreign trade barriers in the form of product standards, technical regulations and testing, certification, and other procedures involved in determining whether products conform to standards and technical regulations. These standards-related trade measures, known in World Trade Organization (WTO) parlance as "technical barriers to trade," play a critical role in shaping the flow of global trade.

Standards-related measures serve an important function in facilitating global trade, including by enabling greater access to international markets by SMEs. Standards-related measures also enable governments to pursue legitimate objectives such as protecting human health and the environment and preventing deceptive practices. But standards-related measures that are non-transparent, discriminatory, or otherwise unwarranted can act as significant barriers to U.S. trade. These kinds of measures can pose a particular problem for SMEs, which often do not have the resources to address these problems on their own.

This report is intended to describe and advance U.S. efforts to identify and eliminate such barriers. The report is comprised of the following key components:

- An overview of technical barriers to trade and the U.S. and international mechanisms for addressing them (Sections I-II);[2]

- An introduction to standards-related measures, including the genesis of this report and the growing importance of standards-related measures in global trade (Section III);

- An overview of standards-related trade obligations, in particular rules governing standards-related measures under the WTO Agreement on Technical Barriers to Trade (TBT Agreement) and U.S. free trade agreements (Section IV);

- A description of the U.S. legal framework for implementing its standards-related trade obligations (Section V);

- A discussion of standards, including the role of international standards in facilitating trade and fulfilling legitimate public policy objectives and federal agencies' participation in standards development (Section VI);

- An elaboration on conformity assessment procedures, including federal agencies' use of conformity assessment and the possibility for international systems of conformity assessment to facilitate trade (Section VII);

[2] For readers seeking a deeper understanding of the specific topics covered in this report, references and hyperlinks to additional information are provided throughout the report. To access official documents of the WTO (such as those identified by the document symbol "G/TBT/…") click on "simple search" and enter the document symbol at the WTO's document retrieval website: *http://docsonline.wto.org/gen_search.asp?searchmode=simple*.

- A description of how the U.S. government identifies technical barriers to trade and the process of interagency and stakeholder consultation it employs to determine how to address them (Section VIII);

- An explanation of how the United States engages with its trading partners to address standards-related measures that act as barriers and prevent their creation through multilateral, regional, and bilateral channels, including the WTO's Committee on Technical Barriers to Trade (TBT Committee) and cooperative activities under the APEC Subcommittee on Standards and Conformance, among others (Section IX);

- A summary of current trends relating to standards-related measures (Section X); and

- An identification and description of significant standards-related trade barriers currently facing U.S. producers, along with U.S. government initiatives to eliminate or reduce the impact of these barriers (Section XI) in 19 countries – Argentina, Brazil, China, Chile Colombia, India, Indonesia, Japan, Kenya, Korea, Malaysia, Mexico, Russia, Saudi Arabia, South Africa, Taiwan, Thailand, Turkey, and Vietnam – as well as the Central American Customs Union (CACU), and the European Union (EU).

III. Introduction

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's system of multilateral trading rules. The President vowed an aggressive and transparent program of defending U.S. rights and benefits under the rules-based trading system as a key element in his vision to restore trade's role in leading economic growth and promoting higher living standards. The President has also recognized that non-tariff barriers have grown in significance for U.S. exporters seeking access to foreign markets. Two kinds of non-tariff measures pose a particular challenge to U.S. exports: sanitary and phytosanitary (SPS) measures and standards-related measures, the latter of which are also known as "technical barriers to trade" (TBT).

Accordingly, in 2009 Ambassador Kirk directed USTR to create a new *Report on Sanitary and Phytosanitary Measures (SPS Report)* and a *Report on Technical Barriers to Trade (TBT Report)*. He directed USTR staff to use these reports to promote understanding of the process of identifying non-tariff measures that act as significant barriers to U.S. exports; to provide a central focus for engagement by U.S. agencies in resolving trade concerns related to non-tariff barriers; and to document the actions underway to give greater transparency and confidence to American workers, producers, businesses, and other stakeholders regarding the actions this Administration is taking on their behalf.

The *TBT Report* is a specialized report dedicated to significant foreign barriers in the form of product standards, technical regulations, and conformity assessment procedures (standards-related measures). Prior to 2010, standards-related measures were addressed by the *National Trade Estimate Report on Foreign Trade Barriers (NTE Report)*.[3] By addressing significant foreign trade barriers in the form of standards-related measures, the *TBT 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 standards-related measures. A separate report addressing significant foreign trade barriers in the form of SPS measures (*2012 Report on Sanitary and Phytosanitary Measures*) is being released in parallel to this report.

The *TBT Report* includes country reports that identify specific standards-related trade barriers imposed by certain U.S. trading partners. The report also includes general information on standards-related measures, the processes and procedures the United States uses to implement these measures domestically, and the tools the United States uses to address standards-related measures when they act as unnecessary barriers to trade. This general information is provided

[3] 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 (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.

to assist the reader in understanding the issues and trade concerns described in the last two sections of the report, as well as the channels for resolving them. These last two sections review current trends relating to standards-related measures that can have a significant impact on trade and identify and describe significant standards-related trade barriers currently facing U.S. producers and businesses, along with U.S. government initiatives to eliminate or reduce these barriers.

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

Central Focus in 2011

During 2011, the United States succeeded in prompting its trading partners to reduce or eliminate a variety of trade restrictive technical barriers identified in last year's report. The United States also continued to intensify its efforts to help other governments to avoid imposing unnecessary standards-related measures, particularly with respect to innovative technologies and new areas of regulation, and assist them in strengthening their capacity building to promote good regulatory practices. In 2011, the United States also proposed new initiatives in key trade and economic forums, including in the WTO, in negotiations to conclude a broad-based Trans-Pacific Partnership (TPP) agreement, and in APEC, to encourage governments to eliminate and prevent unnecessary technical barriers to trade.

Overview of Standards-Related Measures

Today, standards-related measures play a critical role in shaping the flow of global trade. While tariffs still constitute an important source of distortions and economic costs, the relative role of tariffs in shaping global trade has declined due in large part to successful "rounds" of multilateral tariff reductions in the WTO and its predecessor, the General Agreement on Tariffs and Trade (GATT). Broadly speaking, standards-related measures are documents and procedures that set out specific technical or other requirements for products or processes as well as procedures to ensure that these requirements are met. Standards-related measures have gained prominence in international trade because of a desire to:

- ensure the connectivity and compatibility of inputs sourced in global markets;
- manage the flow of product-related information through complex and increasingly global supply chains;
- organize manufacturing or other production processes around replicable routines and procedures to yield greater product quality assurance;
- meet important regulatory and societal objectives, such as ensuring product safety, preventing deceptive practices, and protecting the environment; and

- promote more environmentally-sound or socially-conscious production methods.

Standards-related measures also play a vital role in enabling greater competition by helping ensure that producers and consumers can purchase components and end products from a wide variety of suppliers. These measures also enable more widespread access to technical innovations. Standards-related measures can offer particularly pronounced benefits to SMEs from this perspective. By establishing a common set of technical requirements that producers can rely on in manufacturing components and end products, uniform standards and product testing procedures can facilitate the diffusion of technology and innovation, contribute to increasing buyer-seller confidence, and assist SMEs to participate in global supply chains.

But when outdated, overly burdensome, discriminatory, or otherwise inappropriate standards-related measures are used, they can reduce competition, stifle innovation, and create unnecessary obstacles to trade. Even when standards-related measures are used appropriately, firms – particularly SMEs – can face significant challenges in accessing information about, and complying with, diverse and evolving technical requirements in major export markets. This is particularly the case when technical requirements change rapidly or differ markedly across markets.

Standards-related measures can be an effective and efficient means of achieving legitimate commercial and policy objectives. For policy makers, industry officials, and other stakeholders, the basic question is: how do we ensure that standards-related measures facilitate innovation, competition, consumer and environmental protection, and other public policy objectives – without creating unnecessary obstacles to trade? As supply chains grow increasingly complex, governments and other stakeholders must also address the question of how to better align standards and technical requirements across jurisdictions and markets to help producers comply with those requirements, and help goods flow across borders.

The rules, procedures, and opportunities for engagement that international, regional, and bilateral trade agreements establish serve as an important foundation for addressing many of these questions. The TBT Agreement is the principal agreement establishing multilateral rules governing standards-related measures. (Box 1 lays out definitions provided under the TBT Agreement for standards-related measures.) U.S. free trade agreements (FTAs) establish additional rules on these measures with specific trading partners. The TBT Agreement's rules are vital in setting the terms on which the United States engages with its trading partners on standards-related measures, and U.S. FTAs build on these rules in important ways. These agreements are described in more detail in Section IV below.

A broad and active agenda of U.S. engagement on many fronts is needed to ensure that foreign standards-related measures do not impose unwarranted barriers to trade. USTR leads Federal government policy deliberations on these measures through the interagency Trade Policy Staff Committee (TPSC). U.S. activities in the WTO are at the forefront of USTR's efforts to prevent and resolve trade concerns arising from standards-related measures. Coordinating with relevant agencies through the TPSC, USTR engages with other governments in many venues, including those established by U.S. FTAs and through regional and multilateral organizations, such as the WTO, APEC and the Organization for Economic Cooperation and Development (OECD). USTR also raises standards-related issues in bilateral dialogues with U.S. trading partners. These efforts are designed to ensure that U.S. trading partners adhere to internationally-agreed

rules governing these measures and to reduce or eliminate unnecessary measures of this kind that can create barriers for U.S. producers and businesses.

Box 1. Key Definitions in the WTO Agreement on Technical Barriers to Trade

Technical regulation

> Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking, or labeling requirements as they apply to a product, process, or production method.

Standard

> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking, or labeling requirements as they apply to a product, process, or production method.

Conformity assessment procedures

> Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.
>
> *Explanatory note:* Conformity assessment procedures include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation, and approval as well as their combinations.

Source: Annex 1 of the TBT Agreement.

Note: These definitions apply only with respect to products and related processes and production methods, not to services.

IV. Overview of Trade Obligations on Standards-Related Measures

TBT Agreement

The TBT Agreement is designed to ensure that standards-related measures serve legitimate objectives, are transparent, and do not create unnecessary obstacles to trade. The TBT Agreement contains a comprehensive set of obligations for WTO Members on the development and use of these measures. It establishes rules on developing, adopting, and applying voluntary product standards and mandatory technical regulations – as well as for the conformity assessment procedures (such as testing or certification) used to determine whether a particular product meets such standards or regulations. These rules help distinguish legitimate standards-related measures from protectionist measures, and ensure that testing and other conformity assessment procedures are fair and reasonable.

The TBT Agreement recognizes that WTO Members have the right to take standards-related measures necessary to protect human health, safety and the environment at the levels they consider appropriate and to achieve other legitimate objectives. At the same time, the TBT Agreement imposes a series of rules regarding the development and application of those measures. For example, the TBT Agreement requires governments to develop standards-related measures through transparent processes, and to base these measures on relevant international standards (where effective and appropriate). The TBT Agreement also prohibits measures that discriminate against imported products or create unnecessary obstacles to trade. The TBT Agreement sets out a *Code of Good Practice* for both governments and non-governmental standardizing bodies to guide the preparation, adoption, and application of voluntary standards. The Code is open to acceptance by any standardizing body located in the territory of any WTO Member. Box 2 outlines the key disciplines of the TBT Agreement.

Box 2. Key principles and provisions of the TBT Agreement

Non-discrimination: The Agreement states that "in respect of their technical regulations, products imported from the territory of any Member [shall] be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country." (Art. 2.1) The Agreement requires Members to ensure that "conformity assessment procedures are prepared, adopted and applied so as to grant TBT Agreement access for suppliers of like products originating in the territories of other Members under conditions no less favorable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation." (Art. 5.1.1) The Agreement also requires that Members ensure that related fees are equitable (Art. 5.2.5) and that they respect the confidentiality of information about the results of conformity assessment procedures for imported products in the same way they do for domestic products. (Art. 5.2.4)

Avoidance of unnecessary obstacles to trade: When preparing or applying a technical regulation, a Member must ensure that the regulation is not more trade-restrictive than necessary to fulfill the Member's legitimate objective. (Art. 2.2) The obligation to avoid unnecessary obstacles to trade applies also to conformity assessment procedures. They must not be stricter than necessary to provide adequate confidence that products conform with the applicable requirements. (Art. 5.1.2)

Better alignment of technical regulations, standards, and conformity assessment procedures: The Agreement calls on Members to use relevant international standards, or the relevant parts of them, as a basis for their technical regulations and to use relevant international recommendations and guides, or relevant portions of them, as the basis

for their conformity assessment procedures. The Agreement, however, does not require the use of relevant international standards, guides and recommendations if they would be ineffective or inappropriate to fulfill the Member's "legitimate objectives." (Arts. 2.4 and 5.4) In addition, Members should participate "within the limits of their resources" in the preparation by international standardization bodies, of international standards for products for which they either have adopted, or expect to adopt, technical regulation, and in the elaboration of international guides and recommendations for conformity assessment procedures. (Art.2.6 and 5.5)

Use of performance-based requirements: Whenever appropriate, product requirements should be set in terms of *performance* rather than design or descriptive characteristics. (Art. 2.8)

International systems of conformity assessment: Members shall, whenever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein. (Art. 9.1)

Acceptance of technical regulations as equivalent: Alongside harmonization, the Agreement encourages Members to accept technical regulations that other Members adopt as "equivalent" to their own if these regulations adequately fulfill the objectives of their own regulations. (Art. 2.7)

Mutual recognition of conformity assessment: The Agreement requires each Member to recognize "whenever possible" the results of conformity assessment procedures (*e.g.* test results or certifications), provided the Member is satisfied that those procedures offer an assurance of conformity that is equivalent as its own. (Art. 6.1) (Without such recognition, products might have to be tested twice, first by the exporting country and then by the importing country.) The Agreement recognizes that Members may need to consult in advance to arrive at a "mutually satisfactory understanding" regarding the competences of their respective conformity assessment bodies. (Art. 6.1) The Agreement also encourages Members to enter into negotiations to conclude agreements providing for the mutual recognition of each other's conformity assessment results (i.e., mutual recognition agreements or MRAs). (Art. 6.3)

Transparency: To help ensure transparency, the Agreement requires Members to publish a notice at an early stage and notify other Members through the WTO Secretariat when it proposes to adopt a technical regulation or conformity assessment procedure and to include in the notification a brief indication of the purpose of the proposed measure. These obligations apply whenever a relevant international standard, guide, or recommendation does not exist or the technical content of a proposed technical regulation or conformity assessment procedure is not in accordance with the technical content of relevant international standards, guides, or recommendations. In such circumstances, Members must allow "reasonable time" for other Members to comment on proposed technical regulations and conformity assessment procedures, which the TBT Committee has recommended to be "at least 60 days" (G/TBT/26), and take comments it receives from other Members into account. (Art. 2.9 and 5.6) The Agreement establishes a Code of Good Practice that is applicable to voluntary standards and obligates Members and standardizing bodies that have accepted it to publish every six months a work program containing the standards it is currently preparing and give interested parties at least 60 days to comment on a draft standard; once the standard is adopted it must be promptly published. (Annex 3) The Agreement also requires that all technical regulations and conformity assessment procedures be promptly published. (Art. 2.11 and 5.8) In addition, the Agreement requires each Member to establish an inquiry point to answer all reasonable questions from other Members and interested parties and to provide documents relating to technical regulations, standards, and conformity assessment procedures adopted or proposed within its territory. (Art. 10.1)

Technical assistance: The Agreement calls on Members to provide technical assistance to other Members. (Art. 11) Technical assistance can be provided to help developing country Members with such matters as preparing technical regulations, establishing national standardizing bodies, participating in international standardization bodies, and establishing bodies to assess conformity with technical regulations.

Enforcement and dispute settlement: The Agreement establishes the *Committee on Technical Barriers to Trade* as the major forum for WTO Members to consult on matters relating to the operation of the Agreement, including specific trade concerns about measures that Members have proposed or adopted. (Art. 13) The TBT Agreement provides for disputes under the Agreement to be resolved under the auspices of the WTO Dispute Settlement Body

and in accordance with the terms of the WTO's Dispute Settlement Understanding. (Art. 14)

Other: As noted above, the Agreement sets out a "Code of Good Practice" for preparing, adopting, and applying voluntary standards. (Annex 3) Standardizing bodies that Members establish at the central level of government must comply with the Code and Members must take reasonable measures to ensure that local government and private sector standardizing bodies within their territories also accept and comply with the Code. (Art. 4.1) The Code is open to acceptance by any standardizing body in the territory of a WTO Member, including private sector bodies as well as public sector bodies. The Code requires Members and other standardizing bodies that have accepted it to adhere to obligations similar to those for technical regulations, for example, to ensure that the standards they adopt do not create unnecessary obstacles to trade and are based on relevant international standards, except where ineffective or inappropriate.

Note: The OECD and WTO have also developed summaries of the TBT Agreement. See Trade Policy Working Paper No. 58, *Do Bilateral and Regional Approaches for Reducing Technical Barriers to Trade Converge Towards The Multilateral Trading System?* (OECD (TAD/TC/WP(2007)12/FINAL), WTO Trade Gateway, and TBT Committee reports and recommendations.

Access to information on product-related technical requirements is critical for facilitating trade. Producers, growers, manufacturers, and other supply chain participants need to know the requirements with which their products must comply in order to sell them in prospective markets. The TBT Agreement, therefore, requires every WTO Member to establish a national inquiry point that is able to answer reasonable questions from other Members and interested parties concerning its proposed or existing measures, and provide relevant documents, as appropriate. It also requires each WTO Member to ensure all standards-related measures that it adopts are promptly published or otherwise made publicly available.

The TBT Agreement requires WTO Members to provide other Members the opportunity to participate in the development of mandatory standards-related measures, which helps to ensure that standards-related measures do not become unnecessary obstacles to trade.[4] In particular, the TBT Agreement requires each Member to publish a notice in advance that it proposes to adopt a technical regulation or conformity assessment procedure.[5] It also requires each WTO Member to notify proposed technical regulations and conformity assessment procedures to the WTO so that other WTO Members may comment on them in writing. WTO Members are required, without discrimination, to take into account these written comments, plus the results of any requested discussions of those comments, when finalizing their measures.[6] In 2011 alone,

[4] Depending on the WTO Member's domestic processes, interested parties may participate directly in that Member's process for developing new standards-related measures, for example, by submitting written comments to the Member, or indirectly by working with their own governments to submit comments.

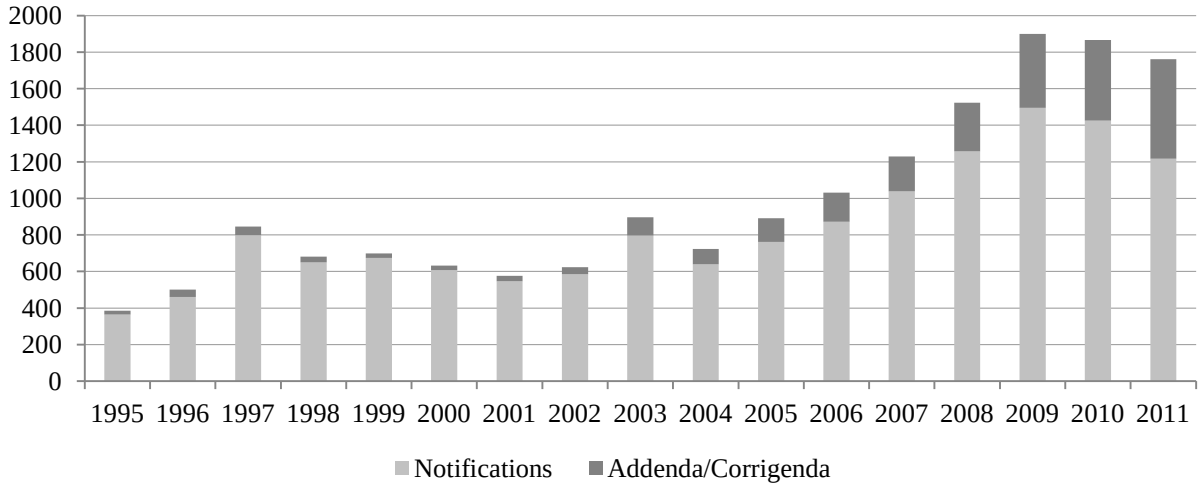
[5] Members typically do this by publishing a notice in an official journal of national circulation or on a government website that they propose to adopt a technical regulation or conformity assessment procedure or by publishing the full text of the draft measure.

[6] The obligations described in this paragraph apply to measures that have a significant effect on trade and are not based on relevant international standards, guides, or recommendations or in circumstances where relevant international standards, guides, or recommendations do not exist. In many instances, however, Members, including the United States, notify proposed technical regulations and conformity assessment procedures regardless of whether they are based on relevant international standards.

WTO Members notified 1,217 new or amended technical regulations and conformity assessment procedures to the WTO. Box 3 shows the number of notifications yearly since 1995.[7]

Box 3. Number of TBT Notifications since 1995

Source: G/TBT/31



Article 13 of the TBT Agreement establishes a "Committee on Technical Barriers to Trade" to oversee the operation and implementation of the TBT Agreement. The TBT Committee is open to participation by all 153 WTO Members. The TBT Committee is one of over a dozen standing bodies (others include the Committees on Import Licensing, Antidumping Practices, and Rules of Origin, for example) that report to the WTO Council for Trade in Goods. The activities of the TBT Committee are described in detail below.

Operation of the TBT Agreement

The TBT Agreement sets out rules covering complex requirements developed and implemented by disparate bodies (central and local governmental agencies; inter-governmental entities; and non-governmental, national and international standardizing organizations). WTO Members' central government authorities have primary responsibility for ensuring compliance with the TBT Agreement, including by taking reasonable measures to ensure that local and non-governmental bodies, such as private sector standards developing organizations, adhere to the

[7] WTO Members notify new measures, as well as addenda and corrigenda to previously notified measures. An addendum alerts WTO Members that substantive or technical changes have been made to a measure that has been previously notified. A corrigendum conveys editorial or administrative corrections to a previous notification. Many Members also notify adopted technical regulations and conformity assessment procedures (regardless of whether or not they are based on relevant international standards).

relevant provisions. Further, each Member must inform the TBT Committee of the laws, policies, and procedures it has adopted to implement and administer the TBT Agreement.[8]

The quality and coherence of these laws, policies, and procedures – as well as how they are put into practice – influence the extent to which standards-related measures in any particular country are transparent, non-discriminatory, and avoid creating unnecessary obstacles to trade, as the TBT Agreement requires. In practice, sound mechanisms for internal coordination among a Member's trade, regulatory, and standards officials are critical to ensuring the Member effectively implements the TBT Agreement. When interested agencies and officials coordinate their efforts in developing standards-related measures, it makes it more likely that the government will consider alternative technical specifications that may lessen any potential adverse effects on trade while still fulfilling the measure's objective.

Further, when governments take account of how the products they propose to regulate are traded in global markets, it can actually make the measures they adopt more effective in fulfilling their objectives. The effectiveness of a WTO Member's internal coordination also often determines the extent to which it is able to resolve specific trade concerns raised by other Members. In some developing countries, ineffective internal coordination and a lack of established procedures for developing standards-related measures are a key concern. For these countries, technical assistance or cooperative efforts to improve internal coordination can be vital in helping U.S. exporters sell into these markets.

In discharging its responsibility in overseeing the TBT Agreement, the TBT Committee conducts triennial reviews of systemic issues affecting WTO Members' policies and procedures for implementing specific obligations.[9] In the course of these reviews, Members adopt specific recommendations and decisions, and lay out a forward-looking work program to strengthen the implementation and operation of the TBT Agreement. To advance their understanding of systemic issues, Members share experiences and participate in special events and regional workshops to explore topics in depth. In recent years, Committee events have covered good regulatory practice, conformity assessment, transparency, the role of international standards in development, and regulatory cooperation.

In addition to its triennial reviews and the related special events and workshops, the TBT Committee meets three times a year. At these meetings, Members may raise any specific trade concern regarding standards-related measures that other Members have proposed or adopted. The Committee's discussion of these concerns can help to clarify the technical aspects of the measures concerned, promote greater understanding of how the measures might affect trade, and perhaps even help to resolve the concerns. In 2011, WTO Members raised over 60 specific trade concerns in the TBT Committee, including, for example, concerns regarding measures relating to managing hazards arising from use of chemicals, labeling and other non-safety requirements relating to food products, and duplicative or redundant testing requirements on a wide variety of goods such as toys and medical devices. WTO Members have underscored the

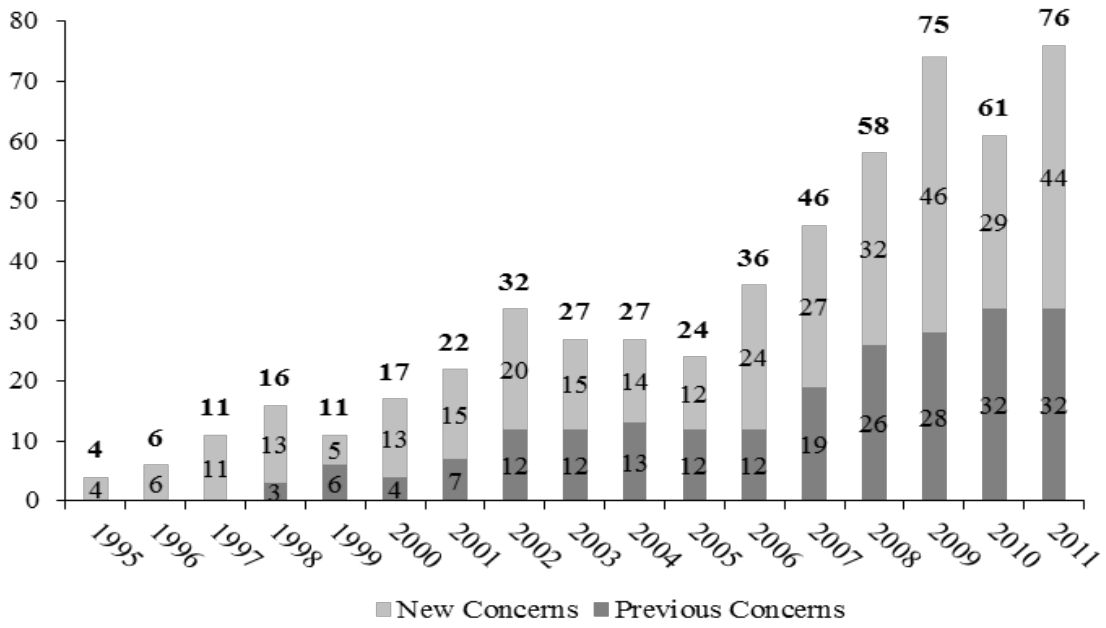
[8] See G/TBT/GEN/1/Rev.11 for a list of Members' submissions on the measures they have taken to implement and administer the TBT Agreement.

[9] The Committee's work on the outcome of the most recent triennial review is discussed in Section V.

importance of the Committee's regular discussions of specific trade concerns, and agreed that the Committee's work has helped to clarify and resolve trade issues between WTO Members.[10]

Box 4 shows the number of specific trade concerns WTO Members have raised in the TBT Committee since 1995. The general rise in concerns raised over the past few years reflects several factors – including an increase in the number of proposed measures that WTO Members have notified to the WTO, a heightened focus on standards-related activities, increased concern that these measures may be used as a form of disguised protectionism, and an increasing perception that discussions in the TBT Committee, as well as bilateral discussions on the margins of Committee meetings, can lead to results in addressing trade concerns. For a full accounting of the concerns raised in the Committee since 1995, see G/TBT/31.

Box 4. Number of specific trade concerns raised per year in the TBT Committee



(Source: WTO, G/TBT/31)

In 2011, the Committee also conducted a final formal review of how well China has implemented the TBT commitments it undertook when it joined the WTO in 2001. (China's membership agreement included a "Transitional Review Mechanism" requiring eight annual reviews on a range of subjects, including TBT, with a final review after 10 years.) Several members of the Committee, including the United States, raised concerns regarding the implementation of China's commitments, particularly with respect to issues relating to lack of

[10] See the discussion of the Operation of the Committee in the "*Fifth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade under Article 15.4*" G/TBT/26.

both transparency and the use of good practices in China's standardization and regulatory systems, and expressed serious concerns with China's compulsory certification system.[11]

Also in 2011, the Committee agreed to test a proposed way to streamline the discussion of specific trade concerns during its meetings and avoid unnecessary repetition. While addressing specific trade concerns is core to the Committee's responsibility in monitoring how well WTO Members are implementing the TBT Agreement, some exchanges on unresolved issues have become repetitive, leaving less time for the Committee to address the systemic issues needed to prevent and resolve trade issues.

Standards-Related Provisions in U.S. Free Trade Agreements[12]

In U.S. FTAs, the parties reaffirm their commitment to the TBT Agreement, and agree to strengthen its key provisions. U.S. FTAs build on the disciplines in the TBT Agreement in important ways, including by providing for greater transparency, establishing mechanisms for more in-depth consultation on specific trade concerns, and facilitating cooperation and coordination with FTA partners on systemic issues. As a result, the U.S. approach to standards-related measures in its FTAs is commonly referred to as "TBT plus."[13] U.S. FTAs, for example, require governments to publish the full text of their proposed standards-related measures, rather than simply publish a notice that it proposes to adopt the measure. In addition, U.S. FTAs provide interested parties, as well governments, the opportunity to comment on proposed measures. These provisions enable the United States and other FTA partners to engage and monitor each other's proposed measures more closely.

U.S. FTAs also contain substantive obligations that go beyond those in the TBT Agreement. For example, U.S. FTAs require FTA partners to accredit or otherwise recognize U.S. testing and certification bodies under no less favorable terms than FTA partners accord their own testing and certification bodies. Recent U.S. FTAs, as well as the earlier NAFTA, also build in mechanisms (such as special committees) for closer and more enduring engagement and cooperation on standards-related measures. These mechanisms can prevent specific trade concerns from arising and assist the FTA governments in resolving emerging problems.

By enhancing understanding of each Party's respective rulemaking processes and standards and conformance infrastructure, these consultative mechanisms can enable early identification of potential trade problems and provide opportunities for the FTA partners to discuss technical

[11] See G/TBT/M/55 pages 64-71 for the minutes of the TBT Committee's discussions under China's final TRM.

[12] This section describes TBT provisions of U.S. FTAs with Australia, Bahrain, Central America and the Dominican Republic, Chile, Morocco, Oman, and Peru, all of which were concluded in 2003 or later. Pending FTAs with Panama and Colombia, as well as the recently implemented U.S. FTA with Korea, contain similar TBT provisions. In addition to these FTAs, the NAFTA also includes provisions that go beyond those contained in the TBT Agreement, for example, with respect to transparency, cooperation with trading partners regarding standards-related measures, and national treatment for testing and certification bodies. The U.S. FTA with Singapore also includes TBT provisions that seek to enhance the parties' cooperation on standards-related measures.

[13] For a discussion of agreements that promote divergence from multilateral approaches (or "TBT minus") see Trade Policy Working Paper No. 58, *Do Bilateral and Regional Approaches for Reducing Technical Barriers to Trade Converge Towards The Multilateral Trading System?* (OECD (TAD/TC/WP(2007)12/FINAL).

alternatives before a measure is finalized.[14] The provisions in U.S. FTAs that provide for more timely and robust consultations, enhance the notifications process, and provide for direct bilateral engagement on notified measures are particularly important in this regard. These consultative mechanisms can provide a channel for peer-to-peer capacity building activities with FTA partners whose standards and conformance infrastructure is underdeveloped or is otherwise in need of improvement.

Like the TBT Agreement, the TBT provisions of U.S. FTAs recognize that FTA partners should not be prevented from taking measures necessary to protect public health and safety or the environment. At the same time, U.S. FTAs lay out ways in which FTA partners can reduce the impact on their bilateral trade stemming from differing regulatory regimes. Several U.S. FTAs also contain provisions designed to encourage FTA partners to accept each other's regulations as equivalent to their own, where appropriate.

Lastly, recent U.S. FTAs provide strong support for the *U.S. Standards Strategy* – which establishes a framework for developing voluntary product standards – by formally recognizing the TBT Committee's *2000 Decision on Principles for the Development of International Standards.*[15] The U.S. experience with the *2000 Committee Decision* is described at length in G/TBT/W/305. These issues are discussed in more detail in Section V below.

In 2011, the United States advanced work towards concluding the broad outlines of an agreement with eight Asia Pacific trading partners through the Trans-Pacific Partnership (TPP) negotiations. As these negotiations continue towards conclusion in 2012, the United States is pursuing an active agenda with regard to TBT and standards-related issues, aiming to identify further opportunities to "raise the bar" in this area through effective TPP provisions. Further details on the TPP are provided in Section (IX) below.

[14] See, for example, G/TBT/W/317 for a discussion of the cooperative standards-related work on automobiles, chemicals, food, energy, and other issues under the NAFTA.

[15] Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement, contained in document G/TBT/1/Rev.10.

Box 5. Key Standards-Related Provisions in U.S. Free Trade Agreements

The United States has concluded FTAs with a number of countries. While each agreement is unique, many of these free trade agreements share common provisions relating to standards-related measures. This box summarizes standards-related provisions common to U.S. FTAs with Australia, Bahrain, Central America and the Dominican Republic, Chile, Korea, Morocco, Oman, and Peru. Pending FTAs with Panama and Colombia contain these provisions as well.

Affirmation of the TBT Agreement: The FTAs reaffirm the parties' obligations under the TBT Agreement and use the TBT Agreement's definitions of key terms, such as technical regulation, standard, and conformity assessment procedures.

International standards: The FTAs require FTA partners to apply the principles of the *2000 Committee Decision* in determining whether an international standard, guide, or recommendation exists.

Conformity assessment procedures: The FTAs recognize the variety of mechanisms that exist for facilitating acceptance of each other's conformity assessment procedures, and they list specific examples of those mechanisms. The agreements also call for FTA partners to intensify their exchange of information regarding these mechanisms; require an FTA partner to explain when it will not accept, or negotiate agreements to accept, another partner's conformity assessment results; call for FTA partners to recognize conformity assessment bodies in another partner's territory on a national treatment basis; and require FTA partners to explain any refusal to recognize another party's conformity assessment body.

Transparency: The FTAs state that each party shall permit persons from the other party to participate in the development of standards-related measures on terms no less favorable than those it accords to its own persons. They also enhance TBT Agreement transparency provisions by requiring that proposals be notified directly to the other Party; that objectives be included when notifying proposals; that interested parties as well as the FTA partner be provided a meaningful opportunity to comment and to have their comments taken into account in finalizing the measure; that 60 days be allowed for comment, where possible; that proposals be published or otherwise made available; that responses be provided to significant comments received at the time a final measure is published; and that additional information be provided about the objectives when requested.

Cooperation: The FTAs provide for FTA partners to intensify their joint work on technical regulations, standards, and conformity assessment bodies. They also urge participating governments to identify bilateral initiatives for specific issues or sectors.

Information Exchange: The FTAs call on each FTA partner to provide information or explanations regarding proposed measures within a reasonable period following a request from another FTA partner.

Administration: Each FTA creates its own committee or subcommittee to monitor application of the agreement's provisions, address specific issues that arise under the agreement, enhance cooperation, and exchange information on pertinent developments.

Note: For more information, see http://www.ustr.gov/trade-agreements/free-trade-agreements.

V. U.S. Statutory and Administrative Framework for Implementing Standards-Related Trade Obligations

The United States maintains a robust system to support implementation of its trade obligations on standards-related measures through strong central management of its regulatory regime, an effective interagency trade policy mechanism, and public consultation. The legal framework for implementing U.S. obligations under the TBT Agreement and standards-related provisions in U.S. FTAs includes the *Administrative Procedure Act of 1946* (APA), and the *Trade Agreements Act of 1979* (TAA).[16] The APA establishes a process of public participation in rulemakings by U.S. agencies through a system of notice and comment. The TAA prohibits Federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade and directs them to consider the use of international standards in rulemaking.

The TAA establishes USTR as the lead agency within the Federal government for coordinating and developing international trade policy related to standards-related activities, as well as in discussions and negotiations with foreign countries on standards-related matters. In carrying out this responsibility, USTR is required to inform and consult with Federal agencies having expertise in the matters under discussion and negotiation. The TAA also directs the Secretaries of Commerce and Agriculture to keep abreast of international standards activities, to identify those activities that may substantially affect U.S. commerce, and to inform, consult, and coordinate with USTR with respect to international standards-related activities.

The APA provides the foundation for transparency and accountability in developing Federal regulations. The APA requires agencies to undertake a notice and comment process open to all members of the public, both foreign and domestic, for all rulemakings, and to take these comments into account in the final rule.[17] In accordance with the APA, agencies publish proposed technical regulations and conformity assessment procedures and solicit public comment in the *Federal Register*. To fulfill WTO obligations to notify proposed technical regulations and conformity assessment procedures, the National Institute of Standards and Technology (NIST) in the Department of Commerce serves as the U.S. notification authority. NIST officials review the *Federal Register* and other materials on a daily basis and notify the WTO of technical regulations and conformity assessment procedures that agencies propose to adopt. NIST also serves as the U.S. Inquiry Point for purposes of the TBT Agreement.

The foundation for central regulatory review is *Executive Order 12866 – Regulatory Planning and Review* (E.O. 12866) and the implementing guidance of the Office and Management and Budget (OMB) *Circular A-4*. E.O. 12866 lays out the philosophy, principles, and actions that

[16] The standards-related provisions of the TAA are codified at United States Code, Title 19, Chapter 13, Subchapter II, Technical Barriers to Trade (Standards).

[17] The term "rule" refers to "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy…." 5 U.S.C. § 551(4). "Rule making" means the "agency process for formulating, amending, or repealing a rule…." 5 U.S.C. § 551(5). These definitions include rules or rulemakings regarding technical regulations and conformity assessment procedures. The APA makes exceptions for urgent matters, allowing Federal agencies to omit notice and comment, for example, where they find that notice and public procedures are impracticable or contrary to the public interest. 5 U.S.C. § 553(b)(3).

guide federal agencies in planning, developing, and reviewing Federal regulations. E.O. 12866 and Circular A-4 are the primary basis on which good regulatory practice (GRP) has been integrated into the Federal regulatory structure. These practices ensure openness, transparency, and accountability in the regulatory process, and, as a result, help ensure that the United States fulfills key TBT Agreement and U.S. FTA obligations. GRP,[18] such as that embodied in E.O. 12866 and *OMB Circular A-4,* enables government agencies to achieve their public policy objectives efficiently and effectively. GRP is also critical in reducing the possibility that governments will adopt standards-related measures that create unnecessary obstacles to trade.

Under the procedures spelled out in E.O. 12866, prior to adopting any significant regulatory action (*e.g.*, a proposed technical regulation) federal agencies must submit it for review to OMB. Significant regulatory actions are defined as those with an estimated annual impact on the U.S. economy of at least $100 million. OMB reviews federal agencies' proposed regulatory actions and consults with USTR and other agencies as needed. This review is designed to ensure, *inter alia*, that proposed regulatory actions are not duplicative or inconsistent with other planned or existing Federal regulatory actions, are consistent with U.S. international trade obligations, and take into account the trade impact of proposed regulatory actions. At the conclusion of this process, OMB provides guidance to the pertinent agency to ensure that its regulatory actions are consistent with applicable law, Presidential priorities, and E.O. 12866's regulatory principles.

On January 18, 2011, President Obama issued *Executive Order 13563 - Improving Regulation and Regulatory Review* (EO 15363), which reaffirmed and supplemented E.O. 12866. E.O. 13563 states that "[the U.S.] regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation….It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative." E.O. 13563 sets out certain regulatory principles, as well as new requirements designed to promote public participation, improve regulatory integration and innovation, increase flexibility, ensure scientific integrity, and increase retrospective analysis of existing rules.

In addition to the statutes and policies outlined above, the *National Technology Transfer and Advancement Act* (NTTAA) and OMB's implementing guidance to Federal agencies, *OMB Circular A-119*, require Federal agencies to use[19] voluntary consensus standards[20] in their

[18] For a discussion of good regulatory practices from the perspective of APEC and the OECD, see:
APEC, "*Information Notes on Good Practice for Technical Regulation*," September 2000.
OECD, *Cutting Red Tape: National Strategies for Administrative Simplification*. Paris, 2006.
OECD, *Background Document on Oversight Bodies for Regulatory Reform*. Paris: OECD, 2007.
OECD, *Regulatory Impact Analyses: Best Practices in OECD Countries.* Paris: OECD, 1997.
OECD, *Regulatory Performance: Ex post Evaluation of Regulatory Policies*. Paris: OECD, 2003.
OECD and APEC, *APEC-OECD Integrated Checklist on Regulatory Reform*. Mexico City, 2005.

[19] Circular A-119 defines "use" as the inclusion of a standard in whole, in part, or by reference in a regulation.

[20] Circular A-119 states that the following attributes define bodies that develop voluntary consensus standards: openness, balance of interests, due process, an appeals process, and consensus.

regulatory activities wherever possible and to avoid using "government-unique" standards.[21] The purpose is to discourage Federal agencies from developing their own standards where suitable voluntary consensus standards already exist. Voluntary consensus standards can often effectively achieve an agency's regulatory objectives. The NTTAA and the TAA are complementary: The NTTAA directs Federal agencies to look to voluntary consensus standards to meet their regulatory objectives, while the TAA directs them to consider using relevant international standards. As elaborated in Section V, international standards are those that recognized bodies, either intergovernmental or non-governmental, develop in accordance with principles such as openness, transparency, and consensus.

For additional information on the laws, policies, and interagency processes through which the United States implements the TBT Agreement, see G/TBT/2/Add.2, G/TBT/W/285, and G/TBT/W/315. See also the *Report on the Use of Voluntary Standards in Support of Regulation in the United States* presented to the High Level Regulatory Cooperation Forum of the United States – European Union Transatlantic Economic Council (TEC) in October 2009. For additional information on the relationship between technical barriers to trade and GRP, see G/TBT/W/287 and USITC Working Paper No ID-24, *The Role of Good Regulatory Practice in Reducing Technical Barriers to Trade*.

[21] Circular A-119 defines "government-unique standards" as standards developed by the government for its own uses.

VI. Standards

Voluntary standards serve a variety of functions and their use supports world trade, for example by promoting the connectivity and compatibility of inputs sourced in global markets. The TBT Agreement has a specific definition of "standard" – a document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods for which compliance is not mandatory. Voluntary standards can facilitate buyer-seller transactions, spur competition[22] and innovation, increase the efficiency of production, unify markets, and promote societal goals. When used as the basis for establishing a technical requirement in a regulation, voluntary standards can help officials harness relevant technology to achieve regulatory goals in a cost effective manner. In the United States, responsibility for developing voluntary standards rests almost exclusively, and appropriately, with the private sector, as this is where the technical know-how for sophisticated products and complex processes resides.[23]

The TBT Agreement acknowledges the diversity of standardizing bodies, and seeks to minimize unnecessary obstacles to trade that can arise from multiple standards for the same product, specifications that favor domestic goods over imported ones, lack of transparency, or dominance by a region or government in standards development. To promote greater harmonization of the technical requirements that WTO Members impose, the TBT Agreement promotes the use of and participation in the development of international standards.

Additionally, the TBT Agreement requires Members to base technical regulations and conformity assessment procedures on relevant international standards, guides and recommendations, except where they would be inappropriate or ineffective in meeting a legitimate objective. The TBT Agreement affords technical regulations based on relevant international standards a rebuttable presumption that they are not unnecessary obstacles to trade under the TBT Agreement. The TBT Agreement also strongly discourages standardizing bodies from developing standards where international standards already exist.

The TBT Agreement does not, however, designate specific standardizing bodies as "international." Instead, in its *2000 Decision on the Principles for the Development of International Standards, Guides and Recommendations (2000 Committee Decision)*, the TBT Committee adopted a set of six principles for developing international standards.[24] The *2000 Committee Decision* is designed to clarify the concept of "international standard" and to advance objectives such as greater harmonization of technical requirements across markets. The six

[22] See *Standards & Competitiveness: Coordinating for Results: Removing Standards-Related Trade Barriers Through Effective Collaboration*, International Trade Administration, 2005.

[23] Agriculture is a notable exception. USDA maintains several programs, such as the Agricultural Marketing Service, for the development of voluntary standards on the quality and identity of agricultural products sold in the U.S. market.

[24] Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement are contained in document G/TBT/1/Rev.10.

principles are: (1) openness; (2) transparency; (3) impartiality and consensus; (4) relevance and effectiveness; (5) coherence; and (6) the development dimension.

It is the policy of the U.S. government to use the term "international standard" to refer to those standards developed in conformity with the *2000 Committee Decision* principles.[25] For example, U.S. FTAs require trading partners to apply the *2000 Committee Decision* principles when determining whether a relevant international standard exists. When WTO Members use international standards developed in conformity with the *2000 Committee Decision* in their technical regulations, it can promote greater global regulatory alignment and reduce the adverse trade effects that regulatory divergences can create. Application of principles such as consensus, openness, and transparency when developing standards helps ensure standards are globally relevant and respond to both technical and regulatory needs. The *2000 Committee Decision* also helps ensure that all interested parties, including producers and consumers that may be affected by a particular standard, can participate in developing it.

Annex 3 of the TBT Agreement contains a *Code of Good Practice* for WTO Members and non-governmental standardizing bodies to follow in preparing, adopting, and applying standards. Central government standardizing bodies must adhere to the *Code*. WTO Members are required to take reasonable measures to ensure non-governmental standardizing bodies conform to the *Code* as well. In the United States, the American National Standards Institute (ANSI) has accepted the *Code of Good Practice* on behalf of the over 200 standards developing organizations (SDOs) that ANSI has accredited. ANSI, a private sector body, is the coordinator of the U.S. voluntary standards system with a membership that consists of standards developers, certification bodies, industry, government, and other stakeholders. In coordination with its membership, ANSI developed and implements the *U.S. Standards Strategy*. For more information on the ANSI system, see *Overview of the U.S. Standardization System*.

ANSI accredits SDOs based on its *Essential Requirements*. Many elements of these requirements mirror the principles contained in the *2000 Committee Decision.* The *Essential Requirements* require each SDO to maintain procedures for developing standards that ensure openness, consensus, due process, and participation by materially affected interests. ANSI also serves as the U.S. national standards body member of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Federal agency representatives participate actively in ANSI policy forums, as well as in the technical committees of ANSI-accredited SDOs, on an equal basis as other ANSI members.

OMB Circular A-119 contains guidance for Federal agencies in participating in the development of voluntary standards. *Circular A-119* directs Federal agencies to participate in private sector standards developing organizations consistent with agency missions and priorities. The Interagency Committee for Standards Policy, which NIST chairs, coordinates implementation of this guidance. More than 4,000 federal agency officials participate in the private sector standards development activities of 497 organizations[26] to support regulatory needs, enable efficient procurement, and to help devise solutions to support emerging national priorities. It is notable, however, that the governments in some regions and countries take a non-technical and

[25] The U.S. experience with the *2000 Committee Decision* is described in G/TBT/W/305.

[26] Source: NIST, 2008.

more commanding role in standards setting than federal agencies generally do. For example, some governments direct their national standards bodies or central government bodies to develop voluntary standards to achieve specific regulatory needs.

VII. Conformity Assessment Procedures

Conformity assessment enables buyers, sellers, consumers, and regulators to have confidence that products sourced in global market meet specific requirements.[27] Governments may mandate conformity assessment procedures – such as testing, sampling, and certification requirements – to ensure that the requirements they have established in standards or regulations for a product, process, system, person, or body are fulfilled. Suppliers also use conformity assessment procedures to demonstrate to their customers that their products or related processes or systems meet particular specifications.[28]

Yet, the costs and delays attributable to unnecessary, duplicative, and unclear conformity assessment requirements are frequently cited as a key concern for U.S. exporters.[29] Indeed, many specific trade concerns raised by the United States in the TBT Committee with respect to other WTO Members' measures center on difficulties associated with the Member's conformity assessment requirements. Governments can reduce or minimize such difficulties by taking into account the risks associated with a product's failure to conform to an underlying standard or requirement when choosing the type of conformity assessment procedure to apply with respect to that standard or requirement. Governments can also reduce or minimize costs associated with conformity assessment by adopting approaches that facilitate the acceptance of the results of those procedures (*e.g.*, approaches that allow products to be tested or certified in the country of export). The TBT Committee's list of approaches that facilitate this acceptance is contained in G/TBT/1/Rev.10.

In the United States, the NTTAA directs NIST to coordinate the conformity assessment activities of Federal, state, and local entities with private sector technical standards activities and conformity assessment activities. The goal is to eliminate any unnecessary duplication of these activities. Pursuant to this statutory directive, NIST issued a *Federal Register* notice in 2000 providing guidance to Federal agencies on conformity assessment. This notice calls for Federal agencies to provide sound rationales, seek public comments, look to the results of other government and private sector organizations, and use international guides and standards when incorporating conformity assessment procedures in their regulations and procurement processes**.**

[27] Conformity assessment procedures take a variety of forms, including, for example, testing, certification, registration, inspection, accreditation, and verification. The entities that conduct these procedures are referred to as conformity assessment bodies and include such bodies as testing laboratories, certification bodies, and accreditation bodies. Testing laboratories, for example, test products to evaluate their performance or product characteristics while certification bodies certify that products conform to specific standards or requirements. Accreditation bodies, for example, evaluate the competency of testing and certification bodies and verify that they comply with specific standards or requirements.

[28] For an introduction to conformity assessment, see Breitenberg, Maureen, *The ABC's of the U.S. Conformity Assessment System*, NIST, 1997.

[29] See Johnson, Christopher, *Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures*, U.S. International Trade Commission Working Paper, 2008.

Today, the conformity assessment standards and guides published by ISO and IEC are known as the "CASCO toolbox."[30]

In addition to NIST's efforts to inform and guide Federal agencies in adopting and applying conformity assessment procedures, federal agencies and private sector organizations can look to guidance in ANSI's *National Conformity Assessment Principles for the United States*. ANSI's principles provide supplemental information designed to promote increased acceptance of U.S. products in international markets through the use of competently conducted conformity assessment procedures. The TBT Agreement, NIST's guidance, and ANSI's principles all emphasize the importance of participation and use of international systems of conformity assessment in facilitating international trade.

Participation and use of international systems of conformity assessment strengthens these international systems and produces global benefits. For example, international systems for accreditation play a vital role in allowing products to be tested and certified at sites that are convenient to production facilities and reducing duplicative testing and certification requirements. International systems for accreditation enable this by establishing procedures and criteria that accreditation bodies participating in the system agree to apply when accrediting testing, certification, or other conformity assessment bodies. Accreditations issued by such entities can, in appropriate circumstances, provide governments, as well as suppliers, assurances that a body – regardless of its location – is competent to test and certify products for relevant markets.

Examples of international accreditation systems include the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). ILAC and IAF have established voluntary mutual recognition arrangements (MRAs). Under these MRAs, accreditation bodies agree to adhere to international standards and other procedures and criteria when accrediting testing and certification bodies and subject themselves to a system of peer-to-peer review to ensure that they continue to meet MRA requirements. In the United States, accreditation bodies that participate in these mutual recognition arrangements are predominately private sector entities. Increasingly, federal agencies, such as the Consumer Product Safety Commission and the Nuclear Regulatory Commission, are using international systems such as ILAC in support of their conformity assessment requirements.

[30] ISO/CASCO is the standards development and policy committee on conformity assessment of ISO.

VIII. U.S. Processes for Identifying Standards-Related Trade Barriers and Determining How to Address Them

The United States maintains rigorous, interagency processes and mechanisms for identifying, reviewing, analyzing, and addressing foreign government standards-related measures that act, or may act, as barriers to U.S. trade. USTR coordinates these processes and mechanisms through the TPSC and, more specifically, its specialized TBT subgroup, the TPSC Subcommittee on Technical Barriers to Trade (TPSC Subcommittee).

The TPSC Subcommittee, comprising representatives from federal regulatory agencies and other agencies with an interest in foreign standards-related measures, meets formally at least three times a year, but maintains an ongoing process of informal consultation and coordination on all standards-related issues as they arise. Representatives of the Subcommittee include officials from the Departments of Agriculture, Commerce, and State – as well as officials from OMB and federal regulatory agencies, such as the Food and Drug Administration and the Environmental Protection Agency. The Departments of Commerce and Agriculture serve as the primary conduits for communicating information between U.S. industry and agriculture export interests, respectively, and the TPSC Subcommittee.

Information for the TPSC Subcommittee on foreign standards-related measures is collected and evaluated on a day to day basis through a variety of government channels including: the TBT Inquiry Point at NIST, the Trade Compliance Center (TCC), the Office of Standards Liaison, and the U.S. Commercial Service (UCS) in the Department of Commerce; the Foreign Agricultural Service (FAS) and its Office of Agreements and Scientific Affairs (OASA) in the Department of Agriculture; the State Department's economic officers in U.S embassies abroad; and USTR. U.S. government outreach and consultations with U.S. stakeholders generates much of the information supplied through these channels, which are further described below.

To disseminate information to U.S. stakeholders on proposed foreign notifications, NIST operates a web-based service, *Notify U.S.*, which automatically notifies registered stakeholders of measures proposed and adopted by other WTO Members in sectors of interest. These notifications alert U.S. firms and other interested stakeholders of their opportunity to comment on proposed foreign measures that may have an impact on their exports. U.S. stakeholders may provide their comments directly to the WTO Member concerned, if its domestic processes provide for that, or through NIST, which works with relevant Federal agencies to review, compile and submit comments to the WTO Member. By providing comments through NIST, U.S. stakeholders alert federal agencies to their concerns and can enable advocacy by Federal agencies on their behalf.

In 2011, NIST's U.S. TBT Inquiry Point and Notification Authority processed and distributed over 59,000 information requests, including over 2,500 requests for information on standards and over 57,000 requests related to technical barriers to trade. The office distributed 132 U.S. government and industry comments to other WTO Members, and circulated 13 WTO Member comments on U.S. measures, as well as 28 WTO Member replies to U.S. comments, to relevant federal agencies. U.S. stakeholders monitor notifications of new or revised measures of other WTO Members in sectors of interest through the *Notify U.S.* early alert program, and contact

U.S. officials through the government channels listed above to obtain further information, to contribute to the submission of U.S. comments, and to coordinate follow-up actions. NIST's Inquiry Point and Notification Authority hosted or participated in training for six U.S. and foreign visiting delegations interested in learning how a WTO inquiry point operates. U.S. stakeholders monitor notifications of new or revised measures of other WTO Members in sectors of interest through the *Notify U.S.* early alert program, and contact U.S. officials through the government channels listed above to obtain further information, to contribute to the submission of U.S. comments, and to coordinate follow-up actions. NIST's Inquiry Point and Notification Authority hosted or participated in training for six U.S. and foreign visiting delegations interested in learning how a WTO inquiry point operates.

Through the Trade Agreements Compliance (TAC) Program, the U.S. Department of Commerce supports the enforcement prong of the National Export Initiative (NEI) by coordinating efforts and resources within the Department to systematically monitor, investigate, and help ensure foreign governments' compliance with trade agreements to which the United States is a party. The TAC Program includes an online trade complaint hotline at www.export.gov/tcc, where exporters can report and obtain assistance in overcoming foreign trade barriers. As part of the TAC Program, the Department assembles teams of specialists to investigate market access problems, including those involving standards-related measures, as well as develop strategies to address them. Compliance teams work with affected companies or industries to establish objectives and to craft and implement compliance action plans to achieve market access.

In addition, the Department regularly provides input to the TPSC based on the information on the specific trade concerns that it collects and analyzes through the TAC Program. This informs the TPSC's development of the appropriate U.S. position in the various multilateral and bilateral forums for addressing standards-related measures. Compliance officers also provide on-the-ground assistance at U.S. embassies in China, India, El Salvador, and at the U.S. Mission to the European Union in Brussels. Free, online tools include the texts of more than 250 non-agricultural trade agreements plus a checklist of the kinds of trade barriers that the TAC Program can help exporters overcome.

The Department of Agriculture's OASA provides a conduit for queries and comments on foreign standards-related measures in the agricultural sector. OASA monitors developments in relevant export markets, provides information on foreign standards-related measures through a range of publications, disseminates TBT notifications from foreign governments to interested parties, and provides translation services on key export market requirements. OASA works cooperatively with U.S. industry, as well as with technical specialists in its overseas offices and federal regulatory agencies, to develop comments and positions on specific foreign standards-related measures. In addition, the Department of Agriculture's FAS overseas offices maintain country-specific reporting and alerts that highlight commodity-specific import requirements. These officers assist with detained shipments and help to identify innovative solutions to keep trade flowing. FAS also participates in numerous relevant international organizations, such as Codex Alimentarius to proactively prevent agriculture-related issues arising from foreign standards-related measures.

In addition to these government channels, the TPSC Subcommittee receives information from the Industry and Agriculture Trade Advisory Committees (ITACs and ATACs, respectively). The ITACs and the ATACs help identify trade barriers and provide assessments regarding the

practical realities that producers face in complying with technical regulations and conformity assessment procedures. USTR and Commerce officials meet at least quarterly with the ITAC on Standards and Technical Trade Barriers (ITAC 16), which is composed of cleared advisors from manufacturers, trade associations, standards developers, and conformity assessment bodies.[31] USTR also meets with other ITACs and advisory committees to receive advice on TBT issues affecting specific industry sectors, such as steel, chemicals, automobiles, processed foods, and textiles, or specific regulatory areas, such as labor and the environment.

In developing the U.S. position on any foreign standards-related measure, the TPSC Subcommittee takes into account how the United States regulates the same or similar products. Regulatory agency officials on the TBT TPSC Subcommittee also provide important information on the technical and scientific aspects of particular foreign standards-related measures, as well as insights on cooperative efforts through international organizations that may be relevant to the issue. The TPSC Subcommittee factors the views that regulatory agencies express into the positions that the United States takes in multilateral, regional, and bilateral trade discussions regarding standards-related measures. Particularly in the area of emerging technologies where standards-related activities are nascent, the technical, scientific, and policy advice that regulatory agencies provide is critical in formulating U.S. views.

Recent U.S. Initiatives to Prevent Unnecessary Obstacles to Trade

Emerging Technologies

Emerging technologies often have significant scientific, economic, and even societal impacts as they revolutionize fields as varied as materials science, electronics, medicine, communications, agriculture, and energy. Emerging technologies also often result in the creation of new products and processes with unique characteristics, which governments must decide how to regulate. As governments make decisions about regulating emerging technologies, it is essential that they coordinate across the different agencies that may have oversight over the new products and technology to ensure that the economic and public benefits of these emerging technologies and the new products and processes they create are fully realized.

In March 2011, the Emerging Technologies Interagency Policy Committee (ETIPC), which consists of USTR, OIRA and OSTP released a joint memorandum to U.S. federal government agencies, entitled "Principles for Oversight and Regulation of Emerging Technologies," that provides guidance to agencies to ensure that their regulatory approach to areas of emerging technologies is coordinated and avoids regulatory and oversight approaches that unjustifiably inhibit innovation, stigmatize new technologies, or create trade barriers. Additionally, the ETIPC developed a set of U.S. government principles specific to the regulating nanotechnology and nanomaterials. The trade facilitative U.S. regulatory approach demonstrated by these principles provides an important model as our trading partners seek to regulate emerging technologies.

[31] See http://www.ustr.gov/Who_We_Are/List_of_USTR_Advisory_Committees.html.

Engagement in Voluntary Standards Activities

Standards help enable technological innovation by defining and establishing common foundations upon which product differentiation, innovative technology development and other value-added services may be developed. Standards are also essential for enabling seamless interoperability between and across products and systems. In the United States, standards development is led by the private sector and highly informed by market needs. In areas relevant to their agency objectives, federal government agencies also engage in standardization in limited circumstances when necessary to encourage development. In January 2012, USTR, OIRA and OSTP released a joint memorandum to agencies entitled "Principles for Federal Engagement in Standards Activities to Address National Priorities." The memorandum emphasizes the strengths of the U.S. standards model of private sector leadership and articulates principles for federal agencies to follow when agencies are tasked with a coordination or convening role. The memorandum establishes four principles to guide agencies in their engagement in standards to meet U.S. priorities, and directs agencies to ensure certain objectives are met, including (1) achieving cost-efficient, timely, and effective solutions to legitimate regulatory, procurement, and policy objectives; (2) promoting standards and standardization systems that promote and sustain innovation and foster competition; (3) enhancing U.S. growth and competitiveness and ensure non-discrimination, consistent with international obligations; and (4) facilitating international trade and avoid the creation of unnecessary obstacles to trade. Here again, the U.S. approach to Federal engagement in standards development provides a trade facilitative model for our trading partners as they engage in standards development.

IX. U.S. Engagement on Standards-Related Measures in International, Regional, and Bilateral Fora

Overview of U.S. Engagement on Standards-Related Measures

The United States maintains a broad and active agenda of engagement with foreign governments to prevent unnecessary obstacles to trade and to resolve specific trade concerns arising from standards-related measures. As noted above, the TBT Committee is the principal multilateral forum for engagement on trade issues relating to standards-related measures. The mechanisms for cooperation on these measures in U.S. FTAs also play a vital role in facilitating U.S. efforts to prevent and resolve trade concerns. In addition, U.S. agencies seek to prevent potential technical barriers from emerging by engaging in multilateral, regional, and bilateral cooperative activities, information exchanges, technical assistance, and negotiations on specific agreements. These efforts are aimed at helping other governments design effective and well-conceived standards-related measures, with the goal of producing better regulatory outcomes and facilitating trade.

U.S. government cooperative efforts and information exchanges with developing countries can assist firms in those countries build their capacity to comply with foreign standards-related measures. As developing country producers increase their participation in global supply chains, they need a better understanding of foreign technical requirements and strategies to consistently meet those requirements. Cooperative activities can also serve to prevent localized high-profile incidents of the type that can disrupt trade across all markets and damage both producer reputations and consumer confidence. Close coordination among trade, regulatory, and standards officials with highly specialized technical expertise is required in order to carry out cooperation and information exchange initiatives that successfully meet these objectives. The United States provides bilateral technical assistance and capacity building to developing countries on standards-related activities through the U.S. Agency for International Development (USAID), the U.S. Trade and Development Agency (USTDA), and the Commerce Department's Commercial Law Development Program (CLDP), Market Development Cooperator Program (MDCP), and NIST. USDA's FAS also provides technical assistance on standards related to food trade. These agencies have broader missions and generally provide standards-related capacity building assistance as a component of a specific project or mission.

To reduce the negative impact on trade from divergences in technical requirements across markets, the United States negotiates bilateral, regional, and multilateral mutual recognition agreements (MRAs) with U.S. trading partners. These agreements establish procedures for each party to accept the results of conformity assessment procedures for specified products carried out in the other party's territory or to accept the other government's technical specifications for those products as sufficient to meet its own requirements. MRAs with trading partners that have a regulatory approach compatible with that of the United States and a similar level of technical capacity can help facilitate trade in select sectors where trade flows are significant and technical requirements can be complex, such as in the telecommunication equipment sector.

NIST maintains a complete inventory of the government-to-government MRAs to which the United States is a party. It also maintains a listing of the accreditation requirements for

conformity assessment bodies under each of these MRAs and a list of conformity assessment bodies that NIST has designated pursuant to each MRA as competent to perform tests or certify products to ensure they conform to the other MRA party's technical requirements. (The Federal Communications Commission (FCC) website provides useful background information on U.S. MRAs in the telecommunications sector and examples of how they work.)

The United States also seeks to reduce foreign technical barriers by concluding equivalency arrangements with other governments. In 2009, the United States exchanged equivalency determinations with Canada on organic agricultural products. As a result of that exchange, U.S. producers that a USDA-accredited agent certify as meeting U.S. National Organic Program standards do not need to be certified under the Canada's National Organic Standard in order to market their products in Canada as "organic." The exchange provides for Canadian producers to receive a similar accommodation for products they export to the United States. On February 15, 2012, the United States signed an organics equivalence arrangement with the European Union. The new partnership allows for organic products certified in Europe or in the United States to be sold as organic in either market, without additional certification. This arrangement between the world's two largest organic producers will establish a strong foundation from which to promote organic agriculture, benefiting the growing organic industry and supporting jobs on a global scale. The United States continues to work with Korea and Japan to open their organic markets to U.S. organics as well.

U.S. engagement on standards-related measures in various international and regional fora is detailed below. U.S. bilateral engagement with its trading partners on standards-related measures is detailed in individual Country Specific Reports in Section XI.

WTO TBT Committee

The U.S. government actively seeks to prevent and eliminate unnecessary technical barriers to trade through the focused WTO Member-driven agenda of the TBT Committee. The Committee dedicates a significant portion of each of its three annual meetings to affording Members the opportunity to raise specific trade concerns on measures that other Members have proposed or adopted. WTO Members may also use Committee sessions to share experiences, case studies, or concerns relating to cross-cutting issues regarding how Members are implementing the TBT Agreement. The TBT Committee often holds workshops or other events on special topics alongside its formal meetings. On the margins of each meeting, Members engage in informal bilateral and plurilateral meetings to clarify and resolve specific trade concerns and to discuss how to resolve other issues of mutual interest.

Specific Trade Concerns

In 2011, the United States raised specific trade concerns regarding 20 to 30 foreign TBT measures at each TBT Committee meeting and in the informal meetings it held with individual or groups of WTO Members. The details and status of many of the specific trade concerns that the United States raised in, and on the margins of, the TBT Committee sessions are described in Section X of this report. As elaborated in Section X, U.S. interventions in the TBT Committee, and on its margins, have helped resolve a number of standards-related concerns affecting U.S. trade. The Committee's annual review of its activities is contained in G/TBT/29, which

includes a thumbnail description of the specific trade concerns that WTO Members raised, as well as identifies the Members that raised them.

Systemic Issues

The TBT Agreement calls for the TBT Committee to review the implementation and operation of the Agreement every three years. These triennial reviews provide an important opportunity for WTO Members to clarify particular provisions of the Agreement. Triennial reviews have resulted in a significant body of agreed recommendations and decisions, contained in G/TBT/1/Rev.10, which are intended to strengthen and improve the operation of the TBT Agreement. Each triennial review also results in a report on the systemic issues the Committee has discussed, along with a work plan to explore ways in which WTO Members can more effectively implement their TBT obligations.

In November 2011, the TBT Committee initiated its *Sixth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade Under Article 15.4.* In the review, which will conclude in November 2012, the Committee will take stock of progress on the work called for under the fifth review, and seek to build upon and deepen engagement on that work through Member submissions and by discussing Member experiences. The key recommendations from the fifth review covered conformity assessment, good regulatory practice, internal coordination, transparency, and international standards. Those recommendations are set out in G/TBT/26, and the collected decisions of the Committee are contained in G/TBT/1/Rev.10.

Regulatory cooperation featured prominently in discussions under the *Fifth Triennial Review*. In 2011, the Committee held a workshop to advance understanding of how cooperation on regulatory issues can be used as an avenue for reducing unnecessary technical divergences as well as for achieving better regulatory outcomes – both of which can help to facilitate and expand trade. For example, regulatory efforts that effectively reduce the incidence of unsafe products benefit both the consumers who purchase those products as well as the producers that produce those products. In the *Sixth Triennial Review*, the Committee will discuss the outcomes of the workshop and seek to identify avenues to promote greater regulatory alignment.

The Committee will also seek to advance implementation of good regulatory practice (GRP) over the course of the sixth review. One result of the fifth review was the development of a reference tool for Members seeking further information on available studies, guidelines, and case studies on implementing GRP. The Committee's "Compilation of Sources on Good Regulatory Practice" (G/TBT/W/341) was published in September 2011, and is expected to be regularly updated in the future. Implementation of GRP is critically important because it carries the potential to help WTO Members in the following ways: enhance their capacity for market surveillance; apply risk analysis in developing regulation; produce clarity in the definition of regulatory objectives; facilitate communication with industry, consumers and other stakeholders; provide a basis for effective training; maximize the benefits of trade facilitation; and generally ensure policy integrity.

The benefits and challenges of greater use of international standards are also likely to feature in the Committee's discussions under the *Sixth Triennial Review*. Worldwide use of international standards facilitates trade by helping firms achieve economies of scale in production, source

low-cost global inputs, and achieve greater acceptance for their products across countries. In recent years, the Committee has discussed ways to overcome challenges and institute best practices relating to the development and use of international standards to help firms in developing countries participate more fully in global markets. Developing country Members often stress the challenges confronting their producers in complying with multiple or conflicting standards around the world. Many U.S. exporters strongly support the principle that governments should avoid mandating unnecessary local specifications for globally traded products.

In earlier triennial reviews, WTO Members have shared experiences and reaffirmed the importance of both the TBT Agreement's *Code of Good Practice* for developing, adopting, and using standards and the *2000 Committee Decision* on the development of international standards. (In fact, the *2000 Committee Decision* is an outcome of the *Second Triennial Review*.) The *Code* calls on Members to ensure that their standardizing bodies at the central level of government do not adopt standards that create unnecessary obstacles to trade, and to take reasonable measures to ensure that standardizing bodies at sub-central levels of government as well as private standardizing bodies do not produce standards that create unnecessary obstacles to trade. The *2000 Committee Decision* states that processes for developing international standards should be transparent, consensus-based, and open to all interested parties. Both the *Code* and the *2000 Committee Decision* seek to avoid duplication in standards development.

In previous triennial reviews, the Committee's work has also focused on conformity assessment. In the course of those reviews, the Committee held several events addressing conformity assessment[32] and developed an indicative list of approaches that Members can use to facilitate the acceptance of results of conformity assessment procedures performed in other countries (see G/TBT/1/Rev.10). In the *Fifth Triennial Revie*w, Members agreed to continue to exchange information on this subject, but broadened the scope of that exchange to include the criteria, methods of analysis, and concepts that Members use to inform their evaluation and choose conformity assessment procedures for specific purposes, including in the context of a risk management framework. Further, based on these exchanges, the TBT Committee agreed to initiate work on developing practical guidelines on how to choose and design efficient and effective mechanisms aimed at strengthening the implementation of the conformity assessment provisions of the TBT Agreement. The Committee will aim to advance this work in the *Sixth Triennial Review*.

Ways to improve how WTO Members implement the transparency requirements set out in the TBT Agreement always feature prominently in discussions under the triennial reviews. In particular, Members have focused on how to strengthen the manner in which Members are carrying out provisions of the TBT Agreement that require Members to give notice and comment on proposed technical regulations and conformity assessment procedures. The TBT

[32] These events were: (i) a Symposium on Conformity Assessment Procedures was held on 8-9 June 1999 (G/TBT/9, 13 November 2000, Annex 1); (ii) a Special Meeting dedicated to Conformity Assessment Procedures was held on 29 June 2004 (G/TBT/M/33/Add.1, 21 October 2004); (iii) a Workshop on Supplier's Declaration of Conformity (SDoC) was held on 21 March 2005 (Annex 1 of G/TBT/M/35, 24 May 2005); and, (iv) a Workshop on the Different Approaches to Conformity Assessment, including on the Acceptance of Conformity Assessment Results, was held on 16-17 March 2006 (G/TBT/M/38/Add.1, 6 June 2006).

Agreement's notice and comment rules, and the requirement for Members to take comments into account in finalizing the measures they notify, are fundamental to preventing and minimizing unnecessary obstacle to trade. The Committee has produced a significant body of recommendations and decisions on these transparency procedures.

Asia Pacific Economic Cooperation

2011: The U.S. APEC Year

APEC[33] is the Asia-Pacific region's premier inter-governmental economic organization. Its core mission is to strengthen regional economic integration by addressing barriers to trade and investment. APEC's 21 member economies comprise nearly half the world's population and more than half of the global economy. These member economies account for 55 percent of global GDP, purchase 58 percent of U.S. goods exports, and comprise a market of 2.7 billion customers. In fact, seven of America's top 15 trade partners are in APEC. As host of APEC in 2011, the United States used this historic opportunity to advance a trade and investment agenda to assist in sustaining economic recovery by supporting growth in trade, investment and jobs in the region. The United States chaired a series of ministerial and other meetings throughout the year, including the Trade Ministers meeting in Big Sky, Montana on May 19-20, 2011, and the APEC Leaders' Meeting hosted by President Obama in Honolulu on November 12-13, 2011.

In its role as APEC chair, the United States emphasized the importance of building towards a seamless regional economy by achieving practical, concrete, and ambitious outcomes in three priority areas:

- strengthening regional economic integration and expanding trade;
- promoting green growth; and
- expanding regulatory cooperation and advancing regulatory convergence.

Specifically, the United States achieved a series of practical, concrete, and ambitious outcomes that will advance regulatory convergence and cooperation in the region, including by improving the regulatory environment in the region. First, the United States succeeded in persuading the APEC economies to agree to take specific steps to strengthen their implementation of good regulatory practices (GRPs). This initiative complements the work that APEC has conducted since its inception in 1989 to promote those practices, encourage greater alignment of international standards, reform testing and certification programs, and advance development of a standards and conformity assessment infrastructure in the region.

[33] The APEC members are Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, the Philippines, Russia, Singapore, Taiwan, Thailand, Vietnam, and the United States.

The United States also gained agreement on specific recommendations to prevent and eliminate unnecessary technical barriers related to emerging green technologies, including commercial green buildings, solar technologies, and smart grid. Additionally, the United States worked to encourage APEC economies to adopt standards and conformity assessment procedures that promote greener growth by encouraging alignment of energy efficiency standards and conformity assessment procedures to information and communication technology (ICT) equipment and applying ISO 50001, an international energy management systems standard that will establish a framework for industrial plants, commercial facilities, or entire organizations to manage their energy use. Finally, the United States led efforts to establish a Global Food Safety Partnership Program at the World Bank, with USAID and private sector support, to strengthen food safety and facilitate trade through public - private collaboration based on the partnership training model pioneered in APEC.

These initiatives are described in more detail below. In 2012, the United States will seek to advance the work that the United States and its APEC partners initiated or strengthened during the U.S. APEC year.

Good Regulatory Practices

In close cooperation with New Zealand, Australia, and Mexico, the United States spearheaded a proposal that was adopted by all of APEC economies to take specific steps to implement GRPs by the end of 2013, including by ensuring internal coordination of rulemaking, assessing the economic impact of regulations, and conducting public consultations, in order to reduce unnecessary burdens on businesses that cost time and money. This achievement came as a result of a year-long series of activities to support implementation of GRPs,[34] beginning with the APEC's 6th Conference on Good Regulatory Practice in March 2011, which brought together experts from governments, business, and international organizations to discuss the critical regulatory issues facing the APEC community.

The initiative also resulted in the completion of two important studies: (1) a study of the ways in which GRPs support the goals and obligations of the TBT Agreement, entitled "Supporting the TBT Agreement with Good Regulatory Practices: Implementation Options for APEC Members,"[35]; and (2) a report on the specific ways in which APEC member economies have implemented GRPs to date, entitled "Good Regulatory Practices in APEC Member Economies: A Baseline Study."[36] The former study provides an in-depth examination of the relationship between implementing GRPs and the requirement under the TBT Agreement to prevent unnecessary obstacles to trade. The latter study reviews the application of selected GRPs from the APEC-OECD Integrated Checklist for Regulatory Reform[37] across the 21 APEC members,

[34] Final Report of the Subcommittee on Standards and Conformance's 6th Conference on Good Regulatory Practice can be found in the APEC Meetings Document Database, Document Number 2011/SOM1/SCSC/032rev1.

[35] "Supporting the TBT Agreement with Good Regulatory Practices: Implementation Options for APEC Members" can be found at http://publications.apec.org/publication-detail.php?pub_id=1266.

[36] "Good Regulatory Practices in APEC Member Economies: A Baseline Study" can be found in the APEC Meetings Document Database, Document Number 2011/CSOM/032.

[37] The APEC-OECD Integrated Checklist on Regulatory Reform can be found at http://www.oecd.org/dataoecd/41/9/34989455.pdf .

with a focus on several procedures that promote regulatory quality standards important to trade and investment, such as accountability, consultation, efficiency, and transparency.

Smart Grid

The APEC Committee on Trade and Investment (CTI) launched an "APEC Regulatory Cooperation Advancement Mechanism" (ARCAM) in 2011 on the topic of smart grid interoperability standards. Following an intensive dialogue on the topic, APEC economies agreed in November on a set of actions and principles designed to prevent unnecessary obstacles to trade and investment arising from smart grid interoperability standards, which can hinder the achievement of broader economic and societal benefits resulting from the deployment of smart grid technologies across the region. Among the set of actions and principles that the APEC economies agreed to include increasing collaboration on technical solutions related to smart grid interoperability standards; fostering coherence in architectural approaches to interoperability; and promoting standards and conformance solutions that facilitate trade and investment across the APEC region and globally. The APEC economies also agreed to take steps to promote transparency, collaboration, and global solutions in the development of smart grid interoperability standards; to take actions to enable competition and innovation in specific markets for smart grid technologies; and to integrate ARCAM principles into collaborative work in other international and regional fora.

The United States will seek to prompt further progress in this area by conducting a second workshop for smart grid regulators, entitled, "Regulatory Approaches to Smart Grid Investment and Deployment," on the margins of the World Forum on Energy Regulation on May 16-17, 2012, in Quebec City, Canada.

Green Buildings

For the first time, the SCSC, led by the United States, addressed trade related standards and conformity assessment measures for new commercial green buildings with an ambitious project that drew support from a broad constituency of green building stakeholders from the private sector.

Products used in green buildings offer significant export potential for U.S. manufacturers as well as energy savings for the urbanizing Asia Pacific region. Green buildings constitute an exciting new technology sector and APEC can help make APEC member green building standards consistent, transparent, and appropriate and thus avoid creating unnecessary obstacles to trade in the sector. The SCSC's work, which reflected the green growth priority that was a key element of the U.S. APEC year, included a survey of APEC members, workshops, and case studies on green building issues.

The SCSC's survey examined green building standards and codes in the region and established baseline data for the remainder of the project. The Subcommittee convened two workshops on green building standards and rating systems, which provided a forum for APEC member experts to develop goals for facilitating trade in green building products. The SCSC conducted two case studies on green building rating systems and practices related to life cycle assessment for

building products. The studies provide APEC members detailed information on the opportunities and challenges in APEC markets to obtain the necessary certifications and requirements for acceptance and access.

In November 2011 APEC Leaders noted the importance of pursuing common objectives to prevent technical barriers to trade related to emerging green technologies, including green buildings. The United States expects to advance work in APEC in 2012 to promote the free flow of trade in green building products.

Solar Technologies

The United States led a new initiative in the SCSC on Solar Technologies Standards and Conformance, along with Chinese Taipei, Japan, Indonesia, and Peru. The purpose of the initiative was to determine the state-of-play for standards and conformity assessment for solar technologies in the Asia Pacific region, to increase transparency in developing and applying those measures and to encourage APEC economies to align those measures to international standards and conformity assessment schemes for photovoltaics, solar water heating, and concentrated solar power.

As a result of the SCSC's year-long work on these solar technologies, APEC members identified concrete areas for collaboration on standards and conformity assessment that will facilitate trade and investment in solar technologies. These outcomes consisted of practical ways to reduce costs, increase safety, and improve reliability of these three major solar technologies with the goal of increasing the performance of solar technologies and speeding their adoption thereby advancing significant environmental and societal benefits in and beyond the APEC region. The November 2011 APEC Leaders Statement endorsed the importance of these outcomes, and stressed the need for further work to prevent technical barriers to trade related solar technologies. The United States expects to advance work in APEC in 2012 toward developing a multi-year project to ensure the free flow of solar technology products.

Information and Communication Technologies

In line with the 2010 APEC Leaders' statement on the importance of work on standards and conformance to reduce the impact of non-tariff barriers on free and open trade and investment, the United States led an initiative in 2011 to explore opportunities for converging energy efficiency regulations for information and communication technology (ICT) products across APEC economies. By converging energy efficiency regulations, APEC economies can was avoid adopting disparate regulatory requirements and minimize trade barriers for ICT products, thereby promoting trade in those products and reaping energy efficiency gains in other sectors that can benefit by deploying these technologies. The U.S. initiative led to a clearer understanding of new energy efficiency requirements for ICT products across the region, and examined ways in which the public and private sectors can better collaborate on energy efficiency targets in order to facilitate trade for ICT products and services.[38] The energy efficiency experts who participated in the initiative reached agreement on principles to consider

[38] Outcomes of the Conference on Aligning Energy Efficiency Regulations for ICT Products can be found in the APEC Meeting Documents Database, Document Number 2011/SOM3/SCSC/039.

when developing energy efficiency regulations, which were subsequently endorsed by the APEC economies.

To continue to make progress in 2011 on converging ICT energy efficiency regulations, the United States has proposed that APEC economies should consider ways to refine and implement the agreed principles.

Food Safety

Trade in food and agricultural products in the Asia Pacific is vital to U.S. interests, yet concerns about food safety in the region have spiked in recent years following a series of high-profile food safety incidents, prompting APEC Leaders to issue a collective mandate to improve food safety standards and practices in the region without creating unnecessary barriers to trade. In response, the SCSC established the Food Safety Cooperation Forum (FSCF) in 2007 with the goal of improving food safety regulatory systems in APEC economies, including food inspection, assurance, and certification systems that are consistent with WTO Members' rights and obligations under both the SPS and TBT Agreements.[39] Additionally, in 2008, APEC Leaders called for increased capacity building to improve technical competence and understanding of food safety management among stakeholders in the food supply chain through the U.S.-led initiative, the Partnership Training Institute Network (PTIN).

Work by the United States to build food safety capacity in the Asia Pacific region through these mechanisms led to several groundbreaking events in 2011. For example, at Big Sky, the APEC countries agreed to initiatives to reduce unnecessary requirements in official export certificates; to promote greater harmonization to international standards and to improve laboratory proficiency and competency in order to improve food safety and to facilitate trade. In addition, APEC and the World Bank signed a landmark Memorandum of Understanding (MOU) marking an ongoing commitment to boost food safety in the region. The MOU laid the groundwork for the creation of a Global Food Safety Partnership, announced in November.

The MOU and the Global Food Safety Partnership are based on the model of public-private collaboration on food safety pioneered through the PTIN. In 2011, the PTIN continued its food safety capacity building efforts by hosting workshops on food incident management and laboratory competency as well as developing a strategy for improving laboratory proficiency in the region. The PTIN also hosted a public-private sector roundtable in May 2011 that brought together more than 100 government, industry, and academic stakeholders to identify the most urgent food safety capacity building needs for 2011-2013.

The United States will continue to work to improve the capacity of APEC and other economies to regulate food safety consistent with international standards and further the adoption of science- and risk-based approaches that will improve public health while also facilitating trade in the processed food sector. In 2012, the FSCF PTIN will work with the Global Food Safety Partnership Program to begin initiating pilot programs and plan workshops on export certificates and laboratory capacity building, as well as launch the first use of reproducible training modules with a pilot trainer workshop in China focused on supply chain management.

[39] The FSCF covers both SPS and TBT issues and descriptions of the activities of the FSCF are included in both the *2012 TBT Report* and the *2012 SPS Report*.

Wine Regulatory Forum

In 2008, the SCSC created a Wine Regulatory Forum (WRF) to promote ways to regulate wine in a manner that facilitates trade. Wine exports are critically important to several APEC economies, with these economies exporting $3.6 billion in wine products in 2010. In 2011, the WRF held a workshop marking the first-ever meeting of wine regulators and industry representatives from both wine producing and consuming economies in the APEC region.[40] The goal of the workshop was to prevent unnecessary impediments to wine trade, including by streamlining wine import and export regulations. Participating regulators also shared best practices on wine certification, analysis, winemaking practices, and wine labeling.

The WRF seminar produced a "Compendium of Wine Import Certificate Requirements of APEC Economies." The compendium outlines the five types of certification requirements in use in APEC economies and illustrates how difficult it is for exporters to understand the differences between the various requirements. These diverse requirements currently impose unnecessary costs and other obstacles to intra-APEC wine trade. The seminar encouraged APEC economies to streamline documentation requirements to minimize unnecessary restrictions to trade.

Trans-Pacific Partnership

In November 2009, President Obama announced that the United States would participate in negotiations to conclude an ambitious, next-generation trade agreement in the Asia-Pacific region that reflects U.S. priorities and values. The Trans-Pacific Partnership (TPP) agreement is a key initiative through which the United States seeks to advance the multi-faceted U.S. trade and investment interests in the Asia-Pacific region by negotiating an ambitious, 21st-century regional trade agreement along with Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. The TPP has begun with this initial group of like-minded countries with the goal of creating a platform for regional integration across the region. In 2011, the TPP countries made substantial progress in negotiations on issues relating to standards-related measures.

In the TPP negotiations addressing standards-related issues, the United States is emphasizing several key themes, including regulatory transparency, encouraging the use of GRPs, and facilitating the acceptance of the results of conformity assessment procedures carried out in TPP countries. The overall U.S. objective is to establish rules and disciplines for standards-related measures that reduce the likelihood that TPP countries will create or maintain unnecessary technical barriers to trade.

In the modern global economy, open and transparent procedures for developing technical regulations, standards, and conformity assessment procedures are essential to avoiding unnecessary technical barriers to trade. In particular, where regulators provide early notice to interested parties at home and abroad that they are considering adopting new measures, the interested parties can help regulators obtain the information they need to design the measures in

[40] APEC Wine Regulatory Forum Report can be found in the APEC Meeting Documents Database, Document Number 2011/SOM3/SCSC/055.

a way that avoids placing unnecessary burdens on local and foreign producers. Moreover, when regulators use transparent procedures in developing regulations, they also help ensure that both domestic and foreign stakeholders will view the final regulations as legitimate. In addition, transparent implementation of measures and reasonable compliance periods will enhance legal certainty and predictability for suppliers and make it easier for them to comply.

Transparent procedures in developing regulations are also vital in crafting high quality, science-based regulations. In particular, these procedures help governments avoid adopting unneeded, inappropriate, or overly burdensome technical regulations, while enhancing the competitiveness. The United States is also working to reach agreement in the TPP negotiations on the principle that suppliers do not need to have their facilities inspected more than once or have their products tested more than once in order to demonstrate that they comply with technical regulations and standards in place in a particular export market. In addition, the United States is seeking commitment from each TPP government that it will permit suppliers in other TPP countries to allow testing to be carried out by a conformity assessment body of their choice, regardless of where it is located, as long as the body meets the importing country's criteria for approved assessment bodies.

CAFTA-DR

In 2010, the United States hosted the first meeting of the TBT committee, which was established in the Central America and Dominican Republic Free Trade Agreement (CAFTA-DR), originally signed by Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, the Dominican Republic, and the United States in 2005. Following the 2010 meeting, the United States launched an initiative to provide technical assistance to the CAFTA-DR countries to ensure compliance with the CAFTA-DR TBT chapter.

The 2011 TBT Committee meeting was coupled with a workshop co-hosted by the United States and Costa Rica to further these capacity building objectives. The workshop consisted of four sessions that covered the following topics: (1) best practices in the development and implementation of technical regulations, standards, and conformity assessment procedures; (2) an overview of good practices in achieving the objective of safe consumer products; (3) a discussion of building resilient and reliable telecommunications structures through regulatory approaches that enable a dynamic telecommunications market; and (4) TBT issues in food trade. The CAFTA-DR countries all reported a positive experience with the workshop and are planning to hold more workshops to continue the spread of best practices in carrying out the obligations of the CAFTA-DR TBT chapter.

Regulatory Cooperation Fora

The United States participates in three bilateral regulatory cooperation forums aimed at promoting regulatory best practices and aligning regulatory approaches in economically significant sectors. In addition, the United States attempted to advance these goals through the Doha Round negotiations at the WTO.

European Union

The EU's approach to standards related measures (as described in the 2011 TBT Report), and its efforts to encourage governments around the world to adopt its approach, presents a strategic challenge for the United States in the area of standards-related measures. In 2011, U.S. officials continued to encourage systemic changes in the EU approach in existing bilateral fora, such as the Transatlantic Economic Council (TEC) and the United States – European Union High-Level Regulatory Cooperation Forum (HLRCF). The TEC is designed to give high-level political direction to bilateral initiatives aimed at promoting increased bilateral trade, job creation, and economic growth through deeper transatlantic economic integration. The HLRCF, comprising U.S. and EU regulatory and policy officials, oversees a program of bilateral cooperation on regulatory issues. The group has convened in advance of each of the previous three TEC meetings to identify projects for the TEC to consider.

In 2011, the United States and the EU accomplished several cross-cutting TEC-directed initiatives through the HLRCF, including the development of a shared set of principles and best practices for regulation ("Common Understanding on Regulatory Principles and Best Practices"), and an agreement on "Building Bridges between the U.S. and the EU Standards Systems." During the November 2011 TEC meeting, the United States and EU agreed to implement this agreement and to engage in sustained dialogue through the HLRCF to exchange views and information on regulatory developments and to identify promising projects for regulatory and standards issues.

At the November TEC meeting, the United States and the EU also agreed to foster meaningful cross-cutting exchanges among economic policy makers, regulators, and standard-setting bodies, and to avoid creating new and unintended barriers to bilateral trade and investment, especially in key emerging technologies and innovative sectors, such as nanotechnology. The United States and the EU agreed that their relevant agencies would enter into a regular dialogue to exchange information, views on developments relevant for regulatory compliance, and to report on regulatory developments.

Mexico

In May 2010, President Obama and Mexican President Calderón committed to enhance significantly the economic competitiveness and the economic well-being of the United States and Mexico through improved regulatory cooperation. The Presidents directed the creation of a United States – Mexico High-Level Regulatory Cooperation Council (HLRCC), comprising senior-level regulatory, trade, and foreign affairs officials from each country.

In February 2012, the HLRCC released its first work plan, which outlines cooperative activities on nanotechnology, motor vehicle safety, e-health and other topics.[41]

[41] The U.S.-Mexico HLRCC work plan can be found at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/united-states-mexico-high-level-regulatory-cooperation-council-work-plan.pdf.

Canada

In February 2011, President Obama and Canadian Prime Minister Harper directed the creation of a United States – Canada Regulatory Cooperation Council (RCC), composed of senior regulatory, trade, and foreign affairs officials from each government. The RCC has a two-year mandate to promote economic growth, job creation, and benefits to U.S. and Canadian consumers and businesses by enhancing regulatory transparency and coordination, with a focus on sectors characterized by high levels of integration, significant growth potential, and rapidly evolving technologies.

On December 7, 2011, the United States and Canada released an RCC joint action plan covering initiatives pertaining to transportation, agriculture and food, personal care products, pharmaceuticals, environment, nanotechnology, and occupational safety.[42] Regulatory officials from the United States and Canada met in January 2012 to cover issues included in the joint action plan, and plan to continue working through the RCC to provide early notice of regulations with potential cross-border effects, strengthen the analytical basis of their regulations, and help make their regulations more compatible.

Doha Round Negotiations

The United States has sponsored three non-tariff barrier (NTB) proposals in the WTO's Doha Development Agenda negotiations on of the Non-Agricultural Market Access (NAMA) aimed at reducing standards-related barriers to trade. These proposals cover: (1) textiles, apparel, footwear, and travel goods (TAFT);[43] (2) electronic goods;[44] and (3) automotive goods.[45] WTO Members have set all three of these proposals for priority negotiations as part of the overall NAMA NTB negotiations and the proposals were included in the NAMA Chair's December 2008 negotiating text[46] as well as the Chair's April 2011 report on the state of play in the negotiations.[47] The 2010 and 2011 *TBT Reports* address these proposals in detail.

During 2011, the NAMA Chair led small group negotiations on the U.S. textile proposal and on a transparency proposal largely based on provisions in the U.S. electronics and automotive goods texts. These meetings generated working documents that reflect a broad consensus among small group participants and satisfy many priority U.S. NTB negotiating goals. But gaps

[42] More information on the U.S.-Canada Regulatory Cooperation Council, including the Joint Action Plan, can be found at http://www.trade.gov/rcc/.

[43] Understanding on the Interpretation of the Agreement on Technical Barriers to Trade with respect to the Labeling of Textiles, Clothing, Footwear, and Travel Goods (TN/MA/W/93/Rev.2, 8 November 2010).

[44] Understanding on Non-Tariff Barriers Pertaining to the Electrical Safety and Electromagnetic Compatibility (EMC) of Electronic Goods (TN/MA/W/105/Rev.3, 26 November 2010).

[45] Understanding on Non-Tariff Barriers Pertaining to Standards, Technical Regulations, and Conformity Assessment Procedures for Automotive Products (TN/MA/W/120, 9 July 2010).

[46] Fourth Revision of the Draft Modalities for Non-Agricultural Market Access (TN/MA/W/103/Rev.3, 6 December 2008. The list of proposals is in paragraph 24.).

[47] Textual report by the Chairman, Ambassador Luzius Wasescha, on the state of play of the NAMA negotiations (TN/MA/W/103/Rev.3/Add.1, 21 April 2011).

still remain in key areas and the wider WTO membership has not fully vetted the working documents. Thus, while the small group negotiations have been productive, further work is required to reach agreement among all WTO Members. While the outlook for the NTB negotiations in 2012 is uncertain due to the broader impasse in the Doha Development Agenda, the United States will remain attentive to possibilities in the WTO and in other negotiating forums to pursue its objectives on textiles labeling and transparency, as well as for other priority NTB areas, such as electronics and autos.

X. Trends in 2011

The U.S. government actively seeks to prevent and eliminate unnecessary technical barriers to trade by participating in a variety of forums and engaging through many different levels of the government. The preceding sections of this report reviewed U.S. government engagement in bilateral and multilateral venues on specific trade concerns and on systemic issues. Section XI provides a summary of many of the specific concerns of the United States with standards-related activities in specific countries. This section reviews trends that appear across various U.S. trading partners' markets, as well as standards-related systemic issues, that can significantly affect the ability of U.S. businesses and producers to access foreign markets.

Regulatory Measures on Goods with Cryptographic Capabilities

A number of U.S. trading partners, including China, India, and Russia, have adopted or are considering adopting measures that block or restrict U.S. exports of products with cryptographic capabilities for commercial use. As an increasing number of products for commercial use are being designed with cryptographic capabilities to protect data integrity and confidentiality, these measures have the potential to significantly impede trade in a wide range of industrial products and systems. As one example, China is considering implementing rules for its Multi-Level Protection Scheme that could limit access to China's market solely to those firms that are willing to disclose their proprietary encryption technology to the government. Likewise, China, India, and other countries require – or are considering requiring – U.S. companies to enter into joint ventures with indigenous partners, thus jeopardizing business proprietary information, or requiring U.S. companies to use a country-specific cipher or algorithm. These measures tend to favor or require the use of specific domestic technologies that might not offer the strongest protection available, and they may lead to the forced transfer of intellectual property. Consequently, these measures could stifle innovation and have a chilling effect on trade.

The United States is working with its trading partners to resolve these specific market access concerns and to ensure that other trading partners do not adopt similar troublesome practices in the future. The United States will promote non-discrimination, the use of relevant international standards as a basis for regulation, and transparency and predictability in the development and implementation of measures regarding goods with cryptographic capabilities. Further, the United States is evaluating other opportunities to collaborate with its trading partners to help prevent the spread of problematic practices in the encryption sphere, including through the TPP negotiations.

Mandatory Labeling of Genetically Engineered Foods

During 2011, the United States continued to have trade concerns regarding mandatory, process-based labeling of foods produced from genetically-engineered (GE) products, such as varieties of GE corn or GE soybeans (GE foods). The 2011 TBT Report detailed the trade concerns arising from mandatory labeling practices for GE foods. (For a full description of these concerns, and concerns raised by similar barriers, see pages 49-50 of the 2011 TBT Report.)

In May 2011, following 20 years of discussions and negotiations, the Codex adopted a "Compilation of Codex Texts Relevant to Labeling of Foods Derived from Modern Biotechnology." The compilation summarizes existing Codex texts and confirms that many

Codex labeling guidance documents developed for foods generally also apply to foods derived from modern biotechnology. Most importantly, the compilation confirms that foods derived from modern biotechnology are not necessarily different from other foods simply as a result of the way they are produced. Consistent with that view, the FDA applies a science-based approach to food safety, which requires labeling of foods derived from modern biotechnology only if such labeling is necessary to reveal any material information that differs significantly from conventionally produced food in order to avoid misbranding. Such information includes proper use of the food, nutritional properties, and allergens.

During 2011, Colombia, Peru, and Ukraine notified the WTO of proposed new labeling requirements for GE foods. These measures vary considerably in their consistency with Codex guidance. Colombia's proposal stipulates that mandatory GE labeling will not be required for prepackaged GE food if it is substantially equivalent to a non-GE counterpart that is already on the market. In line with Codex guidance, Colombia's proposal will require labeling only in limited cases, such as when: (1) nutritional components are not substantially equivalent to those in the non-GE counterpart; (2) handling requirements differ from those for the non-GE counterpart; (3) the GE-derived food contains unexpected allergens; or (4) certain other properties of the GE-food differ from those of the non-GE counterpart. By contrast, the Ukrainian and Peruvian measures raise trade concerns, as they appear to require all food products containing certain GE ingredients to be identified on the product label, with only limit exceptions.

The United States is also concerned that a recent European Court of Justice (ECJ) ruling could extend the EU's practice of mandatory labeling for GE foods to honey. The ECJ recently ruled that honey containing pollen with GE material should be considered an "ingredient" rather than a natural constituent. As a result, honey with pollen from GE plants would have to be approved under the EU's laws for "genetically modified organisms" and labeled for GE content when sold in the EU. At the November 2011 TBT Committee meeting, several WTO Members objected to the European requirements. They observed that the relevant Codex standard does not treat pollen as an ingredient and they urged the EU to withdraw its requirement for honey producers to include a reference to pollen from GE plants on their labels.

The United States will continue to raise trade-related concerns with mandatory biotechnology labeling requirements in 2012 that are based on the manner in which food is produced rather than on scientific principles.

Alcoholic Beverage Regulations

Regulations and requirements that foreign governments impose on alcoholic beverages are the subject of about one-third of all the concerns the United States has raised in multilateral and bilateral fora regarding technical barriers to trade in food and beverages. U.S. exports in the sector have increased by 32 percent over the last five years, to $2.5 billion in 2011. At the same time, governments continue to impose unnecessary barriers to U.S. exports in this sector, including by adopting labeling requirements, definitions specific to products of a specific region, and unique standards for specific spirits, and certification practices that restrain trade.

The United States supports the goal of reducing alcohol abuse, including through the use of appropriate alcoholic beverage warning labels, as well as other labeling requirements designed to communicate appropriate information to consumers. A number of governments have adopted labeling measures, however, that may impose unnecessary costs or raise other barriers to trade in these products. For example, Russia, Thailand, and Kenya promulgated measures requiring over-size warning labels for all alcoholic beverages (which in some cases may cover up to 30

percent of the bottle) that have the potential to cover trademarks and other brand information. In addition, Israel and Russia recently adopted EU region-specific definitions for distilled spirits, creating trade barriers for certain U.S. whiskeys. The adoption of country or region-specific standards for distilled spirits, as several countries, such as Brazil and Colombia are considering, may also be problematic for U.S. exporters.

The United States achieved some progress in addressing barriers to its wine exports in 2011, including with respect to efforts to reduce burdensome or unnecessary testing requirements. In APEC, for example, wine regulators met for the first time and compared certification requirements across the Asia Pacific. Understanding the complexity and diversity of these testing requirements is a necessary first step to promote greater alignment. In addition, in 2011 the United States reached agreement with Vietnam on its processing requirements for alcoholic beverages, including chemical and microbiological parameters, heavy metals, and food additive and labeling requirements. Most significantly, Vietnam acknowledged that there is no widely accepted scientific or technical basis for imposing limits on aldehyde content and repealed a law that imposed a maximum limit on this naturally occurring substance that is present in many distilled spirits.

More details on this subject can be found in the country reports on Brazil, Colombia, the EU, Kenya, Russia, Thailand, and Vietnam in Section XI.

Organic Product Standards

Divergences in regulatory approaches to organic products can make exporting U.S. organic products a costly and burdensome endeavor and, in some instances, prohibitively so. In the organics sector, the United States has negotiated three types of agreements with major trading partners in an attempt to facilitate trade in organic products:

- Under a "recognition agreement," an importing country agrees to recognize USDA's National Organic Program (NOP) to accredit agents within the United States to certify products as organic under the importing country's requirements.

- Under an "equivalency arrangement," the United States and another country agree to allow some or all products produced and certified to the exporting country's organic requirements to be sold as organic in the importing country.

- Under an "export arrangement," U.S. organics producers can sell their products as organic in another market, provided that their products meet specific requirements of the importing country.

(For some example of the agreements signed by the United States in the organics sector, see page 52 of the *2011 TBT Report*.) U.S. efforts to enter into agreements and arrangements of this nature have been highly effective in facilitating trade in organic products. For example, the United States and Canada have had an organics equivalency agreement in place since 2009. Just recently, in February 2012, the United States and the EU reached agreement on an historic organics equivalency arrangement that will allow organic products certified in Europe or in the United States may be sold as organic in either region.

The partnership between the world's two largest organics producers will establish a strong foundation from which to promote organic agriculture, benefiting the growing organic industry and supporting jobs and businesses in both the United States and Europe.

In some instances, the United States has not been able to bridge some, or all, of the differences between U.S. and foreign organics requirements using recognition agreements and equivalence arrangements, and U.S. organics exporters still face challenges. For example, Japan's restrictions on alkali extracted humic acid, a substance that USDA permits for use on U.S. organic crops, limits U.S. organics exports. Similarly, Korea's zero tolerance policy for adventitious presence of biotechnology content in organic products limits U.S. organics exports. If Korea does not adopt legislation allowing it to negotiate one or more of the equivalence arrangements outlined above, U.S. organics exports to Korea could be further restricted beginning in January 2013. Further, China currently does not allow organic products produced under foreign standards in their market. All products must be certified according to Chinese organic standards.

U.S. officials continue to engage regularly with trading partners, including Japan, Korea and China in an attempt to resolve these issues and to prevent new issues from arising.

Formula Disclosure Requirements

The *2011 TBT Report* highlighted concerns regarding a growing number of countries that require food producers to disclose proprietary product information as condition for exporting their products to those countries. These measures typically call for proprietary information to be either (1) included on a product's label; (2) disclosed at the time a product is registered for sale in the market.

Food additives may contain a single ingredient, but they may also include proprietary mixtures of multiple ingredients. Governments typically consider product ingredients, such as the flavored marinades producers inject into meat products, to be additives because they perform a technological function. If governments require producers to declare each ingredient in their marinades or other additives by weight or percentage, it would enable competitors to reproduce each other's proprietary flavors and other food additives.

As previously reported, Brazil, Indonesia, and Japan require food labels not only to list a product's ingredients but also the percentages of each ingredient. In 2011, China and Thailand considered measures that would mandate similar disclosure requirements for food additives. These requirements are inconsistent with Codex labeling standards, which recommend that all ingredients be listed in descending order of ingoing weight at the time of the manufacture of the food. Codex labeling standards also explicitly lay out separate circumstances in which percentages of ingredients must be declared, but under circumstances where a certain ingredient is emphasized on a product label or is essential to the food, to avoid misleading consumers.

Additionally, some countries, such as China, and Venezuela, have adopted measures that require companies to disclose a product's precise recipe or formula as part of their product registration process. Forcing food companies to declare proprietary recipes or formulas can damage legitimate commercial interests. While Codex guidelines allow governments to require producers to disclose essential information relating to quality and safety, there is little reason to

believe that requirements for producers to disclose the precise weight or percentage of each ingredient they use to make their products will assist governments or consumers determine whether those products are safe or meet domestic food quality standards.

During 2012 the United States will continue to work bilaterally and through international fora to eliminate unwarranted disclosure requirements of this kind.

Documentation Requirements

Across industry sectors, U.S. exporters have faced onerous documentation requirements as a condition for marketing their products abroad. These requirements may raise costs for U.S. exporters or serve as a barrier to entry when they are duplicative or simply unnecessary. For example:

- Brazil, China, Russia, and Switzerland, among other countries, require certificates of analysis from U.S. wine exporters as well as certificates verifying that their wines conform to both U.S. and the importing country's standards. Some of these countries also require these certificates to take the form of an original document issued by U.S. government officials or officially accredited organizations from the country of importation, a requirement that can impose considerable burdens and costs. For example, Russia requires U.S. wineries to pay $5,000 for the two hygiene certificates it requires and to obtain a *Gosstandart Russia* Certificate of Conformity to wine standards.

- Chile, Costa Rica, the Dominican Republic, Guatemala, Indonesia, Peru, and Vietnam, among other countries, require U.S. exporters of certain products to transmit documents to the local embassy of the country of importation for an official approval or stamp, which often requires payment of a fee, before filing applications for approval. This can result in extensive delays and add significant costs for exports without providing any clear benefit.

- China and Korea require medical device producers to submit evidence that the device offered for export has been approved in the country of manufacture or origin. Not only does this requirement add costs and delays to the approval process, it is often inapposite because the product has been designed exclusively for export.

- Similarly, a wide range U.S. food producers has repeatedly noted that unwarranted foreign government import and export certification requirements (such as "certificates of free sale") can impose substantial trade barriers. While it is difficult to estimate the costs that certification requirements impose, they include lost market share, unnecessary bureaucratic hurdles that cause lengthy delays, and costs producers incur when shipments are rejected because they do not meet certification requirements.

- Brazil requires medical device producers to submit business proprietary economic data (*e.g.*, prices in other markets, distributor mark-ups, advertising/promotion budgets) as a condition for registering or re-registering their products, even though such data may not exist or is unrelated to medical device safety or efficacy. In addition, Brazil's medical device regulator has sometimes publicized these data.

The United States works to resolve these issues as they arise in individual cases through the TBT Committee, APEC, U.S. FTAs, and bilateral engagement. The United States looks for opportunities to resolve these issues, or prevent their emergence, on a systemic basis. For example, the United States worked extensively during 2011 with its CAFTA-DR partners to address redundant and unnecessary documentation requirements that governments in the region have imposed for food products. During the CAFTA-DR TBT committee meeting in November 2011, for instance, the United States presented information on the challenges facing exporters as a result of these requirements. Following the meeting, Costa Rica took action to recognize USDA meat export certificates as equivalent to Costa Rica's import certificate requirements.

The United States is also actively working through APEC to streamline export certificate requirements for agricultural products consistent with Codex guidelines. Based on work done in 2010, the United States secured a commitment by the APEC Leaders in 2011 to reduce and streamline certification requirements where possible and to consider the use of electronic certification as a means to facilitate trade in safe food. The TPP negotiations may present another opportunity for the United States to make progress on this issue.

"Voluntary" Measures as Trade Barriers

In various product sectors, certain governments are developing and implementing so-called "voluntary" standards in a manner that effectively makes compliance mandatory. In addition, many truly voluntary standards that governments have developed (such as voluntary labeling programs related to energy efficiency or agricultural products) have created substantial trade barriers. While the TBT Agreement requires WTO Members to ensure that voluntary technical measures ("standards," in TBT parlance) do not create unnecessary obstacles to trade, they are not subject to the same rigorous transparency disciplines under the TBT Agreement as mandatory standards (which the TBT Agreement refers to as "technical regulations").

Some of the mechanisms that countries are using to turn voluntary standards into official requirements include procurement requirements (including state-owned enterprises), licensing requirements, and other government programs. Because the TBT Agreement does not require WTO Members to develop voluntary standards through procedures that include input from foreign stakeholders (although it does require Members regularly to publish the work programs of standards under development by central government bodies), voluntary standards may solely reflect domestic stakeholder interests rather than those of the larger global trading community and may not take into account the operation of global supply chains. For example:

- China is finalizing several draft "voluntary" standards related to information security that the United States is concerned China will make mandatory, either through incorporation into technical regulations, or through integration into the certification and type approval schemes of the Ministry of Industry and Information Technology (MIIT) and the Certification and Accreditation Administration (CNCA). One such standard, *Information Security Technology – Requirement for Office Devices Security*, appears to restrict the use of computer chips in ink cartridges. U.S. and other foreign companies consider that this design restriction reduces the functionality of printers and question how it relates to protecting national security. U.S. industry and the U.S. Government are concerned that China may in the future mandate the use of this standard by

incorporating it by reference into one of China's various certification regimes, for example, the CCC Mark or the MIIT telecom type approval process. U.S. industry is also concerned that various versions of the draft standard, including prohibitions of certain chips as components of printer cartridges, have diverged from the relevant international standard (IEEE 2600).

- Korea's Energy Management Corporation (KEMCO) only certifies one type of thin film solar panel – the type that Korean producers manufacture – as meeting its version of the International Electrotechnical Commission standard. While compliance with that standard is not technically required for sale of solar panels in the Korean market, a company will not be commercially viable in Korea without KEMCO certification. As a result, U.S. solar panel producers that make different kinds of thin film panels find themselves locked out of the Korean market**.**

- The organic and halal standards that several governments have adopted are technically voluntary, but they often serve to preclude U.S. products from entering the market. For example, when Malaysia put in place a voluntary standard that did not allow for halal products to be manufactured on a dedicated line within a facility that also produces non-halal products, many U.S. poultry and beef producers were effectively excluded from the Malaysian market. This is because Malaysia bans imports of non-halal poultry and beef products and it is often too costly for U.S. producers to set up separate production facilities for those products.

As with the other issues identified in this section of the report, the United States works to resolve issues concerning voluntary standards through the TBT Committee and regional and bilateral engagement as they arise in individual markets. The United States is also seeking to address these issues on a systemic basis as many of the specific trade concerns that WTO Members raise in the TBT Committee continue to be related to "standards." Currently, U.S. officials are seeking opportunities to tackle the trade issues associated with voluntary standards in the APEC Subcommittee on Standards and Conformance and the TPP negotiations. The United States will also look to discuss this issue through the TBT Committee during the *Sixth Triennial Review* of the TBT Agreement.

XI. Country Reports

Background on Specific Trade Concerns Contained in the Country Reports

This section contains individual country reports detailing TBT barriers encountered by U.S. stakeholders. The measures and practices the country reports identify raise significant trade concerns, and, in some instances, give rise to questions concerning whether a trading partner is complying with its obligations under trade agreements to which the United States is a party.[48] The decisions on which issues to include resulted from an interagency process that incorporated the expertise of a variety of government agencies.

While the tools used to address TBT barriers vary depending on the particular circumstances, in all instances, USTR's goal remains the same: to work as vigorously and expeditiously as possible to resolve the issue in question. As reflected in the country reports, in many instances USTR seeks to resolve specific concerns through dialogue with the pertinent trading partner – either bilaterally or through multilateral fora – and working collaboratively to obtain changes that result in improved market access for U.S. exporters.

The *TBT Report* provides more focused and structured reporting on country-specific standards related issues compared to what appeared in prior NTE reports. Conversely, some prior NTE reports may have included standards-related issues that USTR has not included in the *TBT Report.*

In response to USTR's outreach in compiling this report, stakeholders raised a number of new standards-related concerns. In several cases, USTR lacked sufficient information about those concerns at the time of publication to include them in this report. For purposes of this report, USTR included measures and practices about which USTR is well informed; USTR continues, however, to gather information about others. Accordingly, the omission of any issue in this report should not be taken to mean that USTR will not pursue it, as appropriate, with the trading partners concerned, in the same manner as those listed below. An analysis of the country sections of the *2012 TBT Report* demonstrates that numerous issues were recently resolved or are on a path to resolution. Despite these successes, U.S. exporters still face a variety of specific trade concerns as a result of measures adopted or proposed in 19 countries, the Central American Customs Union, and the EU, as described in the pages that follow.

Argentina

Bilateral Engagement

The United States raises TBT matters with Argentina during TBT Committee meetings.

Toys – Testing and Accreditation Requirements

In 2008, U.S. industry raised concerns regarding Ministry of Health Resolution 583/2008, which

[48] 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 TBT as opposed to the SPS Agreement).

limited the amount of phthalates in toys and other children's products. While the regulation applies to all children's products, it only called for imported children's products to be tested for compliance and accompanied by a technical report from Argentina's Center for Research and Technological Development for the Plastics Industry (INTI). U.S. industry expressed concern that there would be significant delays, costs, and burdens in exporting toys and children's products to Argentina based on INTI's limited capacity to perform testing and its inability to test these products in the country of production.

After the United States raised these concerns bilaterally and in the TBT Committee, Argentina issued a temporary measure in May 2010 to increase the efficiency of the new testing process. In February 2011, Argentina made the changes permanent, and allowed the products to be sold in Argentina if companies have submitted the products for testing to INTI. U.S. industry welcomed this improvement. The United States is continuing to monitor conformity assessment procedures in Argentina to address any unwarranted barriers to U.S. exports of children's products.

Testing of All Graphic Products for Lead

In October 2011, U.S. industry reported concerns with an Argentine regulation, Resolution 453/2010, which requires all inks, lacquers and varnishes used in producing printed materials, such as package labeling, and inserts, to undergo testing for lead content at a single laboratory in Argentina. Industry noted that that the regulation has been enforced only with respect to imported products, the designated Argentine laboratory does not have sufficient capacity to test all such materials in a timely manner, and Argentina did not notify the regulation to the TBT Committee as required. The United States raised these concerns with Argentina on the margins of the November 2011 TBT Committee and asked Argentina to notify the regulation, clarify whether the regulation will be enforced against domestic products, and allow internationally accredited laboratories outside of Argentina to certify compliance with the regulation.

The United States will continue to press Argentina on this issue in 2012.

Brazil

Bilateral Engagement

The United States and Brazil discuss TBT-related matters in various bilateral fora, including the bilateral Commercial Dialogue (led by Brazil's Ministry of Development, Industry, and Commerce and the U.S. Department of Commerce) and the Economic Partnership Dialogue (led by Brazil's Ministry of External Relations and the U.S. Department of State). The United States also discusses TBT matters with Brazil during TBT Committee meetings.

Alcoholic Beverages – Labeling and Certification Requirements

In October 2009, Brazil notified the TBT Committee of proposed revisions to its regulations governing the labeling of beverages and vinegars. During TBT Committee meetings in June and November 2010, the United States raised concerns that some of the proposed revisions could potentially prohibit imports of specific U.S.-origin spirits. Specifically, the United States

expressed concerns that the proposed revisions would:

- prohibit alcoholic beverage labels from including abbreviations for common terms;
- require product names to be printed on the product's main label in bold face and upper case letters;
- require a large decal to be placed on the label, and the decal must indicate the importer's registration number; and
- bar labels from including certain expressions (such as "home-made," "hand-crafted," "reserve," and "special reserve"), even if these expressions are associated with a company's name or trademark.

The United States also asked Brazil to clarify certain elements of its revised regulations, including:

- whether they would restrict the use of fanciful drawings and illustrations that are well-established elements of the trademark and clearly not intended to represent an ingredient of the spirit (*e.g.*, a vodka label with an illustrated "orange" to signify "orange-flavored" vodka);
- whether labels that display a drawing, figure, or illustration of any ingredient used to prepare the beverage must indicate all of the ingredients of animal or plant origin, regardless of quantity; and
- the basis for requiring beverage cans or bottles to bear the statement "*This container must be washed prior to consumption.*"

The United States continued to request clarifications and note concerns with the proposed revisions during TBT Committee meetings in 2011. In November 2011, Brazil indicated that the proposed revisions had been withdrawn and that Brazil is instead working to develop a Mercosur standard for labeling of alcoholic beverages. According to Brazil, Mercosur discussions on this subject are in the preliminary stages and Brazil has committed to notify the TBT Committee of any new labeling measure it proposes to adopt as a result of those discussions. The United States is closely monitoring progress by Mercosur countries in developing a common labeling standard.

Wine – Certification

In December 2009, Brazil instituted rules requiring certificates of origin and product analyses for imported wines, which raise costs for U.S. wine producers seeking to export to Brazil. The United States noted in bilateral meetings with Brazil in November 2010 and March 2011 that these requirements are unnecessary and duplicative because the U.S. Alcohol and Tobacco Tax and Trade Bureau issues certificates of analysis of chemical parameters and origin for U.S.

wines. The United States is continuing to work with Brazil to resolve this issue as well as to ensure that U.S. wine exports do not face any additional market access restrictions in Brazil.

Medical Devices – Inspection and Registration Requirements

The United States has raised concerns that Brazil's medical device plant inspection and product registration requirements could create market access barriers for U.S. industry.

These requirements provide that before a medical device may be marketed in Brazil, Brazilian authorities must inspect the facility that makes the device, and the manufacturer must register the product with Brazilian authorities. In particular, Resolution 25 of 2009, which Brazil notified to the WTO on May 18, 2009, required ANVISA (Brazil's medical device inspection agency) to inspect U.S. facilities that produce certain "high risk" medical devices to be sold in the Brazilian market by May 22, 2010. The United States does not contest Brazil's right to inspect U.S. facilities; in fact, the U.S. Food and Drug Administration (FDA) has equivalent authority to conduct inspections of Brazilian and other foreign facilities. The United States expressed concern, however, that ANVISA would not have sufficient resources to inspect all overseas facilities that ship these devices to the Brazilian market by the May 22, 2010, deadline, potentially disrupting hundreds of millions of dollars in U.S. exports and jeopardizing the adequate supply of essential medical devices to the Brazilian market.

In late 2009 and early 2010, U.S. Government and U.S. industry representatives engaged with ANVISA in an attempt to clarify the inspection requirements and seek assurances from Brazil that if ANVISA could not complete all of the inspections (and related registrations) in time, Brazil would not bar sales of medical devices produced in U.S. plants that had not been inspected by the deadline. In response, Brazil clarified that class I medical devices (*e.g.*, tongue depressors, bedpans) and class II devices (*e.g.*, powered wheelchairs, surgical drapes) would be exempted from the inspection requirement, and that ANVISA's inspections would apply only to the last place of manufacture (as opposed to all the supplier facilities). In addition, Brazil indicated that only plants manufacturing devices subject to re-registrations or new registrations would need to be inspected by May 22, 2010; products from other facilities could remain on the Brazilian market after the deadline pending an inspection. The United States appreciates Brazil's efforts to explain to U.S. industry how its inspection requirements operate and to help U.S. producers comply, but remains concerned that Brazil may not be able to carry out its inspection regime without impeding U.S. exports to Brazil.

In October 2010, Brazil introduced another obstacle confronting U.S. medical device producers that seek to market their products in that country. Specifically, ANVISA issued Technical Note No. 001/2010/GGTPS/*ANVISA (Requirement of Good Manufacturing Practices and Control Certificate)*, which has created a longer path to access the Brazilian market, because it prevents GMP plant inspections and product registration from being undertaken in parallel as previously was the case. U.S. industry is concerned that this two-step process is delaying the marketing of new medical devices in Brazil by over a year due to ANVISA's backlog of foreign plant inspections. The United States will continue to monitor the situation closely in 2012 to ensure that U.S. exports are not further disrupted.

Medical Devices – Data Requirements for Registration

Resolution 185 of 2001, which sets out ANVISA's registration requirements for medical devices, requires manufacturers to submit detailed economic data, including confidential and proprietary information. The data requirement does not appear to fulfill a legitimate objective related to evaluating medical device safety or efficacy. As explained in the *2011 TBT Report*, in 2009 Brazil committed to U.S. industry that it would not publish any confidential or proprietary information.

On September 14, 2010, however, ANVISA unexpectedly published company-specific pricing data that individual U.S. producers had supplied. The United States raised concerns regarding ANVISA's action with Brazilian officials on the margins of the TBT Committee meeting in November 2010. Despite the fact that the United States alerted Brazil to its concerns, ANVISA published additional U.S. company-specific pricing data on its website in 2011.

In response, the United States again voiced concerns with Brazil regarding its persistent disclosure of proprietary U.S. producer data. The United States noted that Brazil's disclosures fail to protect legitimate commercial interests and conflict with Brazil's previous assurances that it would protect confidential business information. The United States continues to urge ANVISA to remove the proprietary data from its website and will continue to monitor the situation closely in 2012 to ensure that U.S. exports are not disadvantaged.

Telecommunications – Acceptance of Test Results

Brazil's National Telecommunications Regulatory Agency (ANATEL) does not accept test data generated outside Brazil, except in cases where the equipment is too large or too costly to transport. Accordingly, U.S. suppliers must submit virtually all of their information technology and telecommunications equipment for testing to laboratories located in Brazil before that equipment can be placed on the Brazilian market. This requirement results in redundant testing to be conducted, and consequently, both higher costs and delayed time to market in Brazil.

In response, the United States has urged Brazil to implement the CITEL (Inter-American Telecommunication Commission) MRA, which provides for the mutual recognition of conformity assessment bodies, and mutual acceptance of the results of testing and equipment certification procedures undertaken by those bodies in assessing the conformity of equipment to the importing country's technical regulations. The United States and Canada are participants within the CITEL MRA. If Brazil implemented the CITEL MRA, it would benefit Brazilian suppliers seeking to sell telecommunications equipment into the U.S. market by enabling them to use test results from laboratories located in Brazil to certify that their products meet FCC requirements. The United States will continue in 2012 to encourage Brazil to implement the CITEL MRA.

Products of Animal Origin – Labeling Registration Form

As explained in the *2011 TBT Report*, in 2010 Brazil notified the TBT Committee of changes to its labeling registration form for food products of animal origin. The new registration form required the health or veterinary authority of the exporting country to certify that an exporter's establishment is "in compliance" with Brazilian market standards and legislation. When

governments condition access to their markets for animal products on certifications of this nature it can raise barriers to U.S. exports as U.S. law does not authorize U.S health and veterinary authorities to attest that a U.S. production facility complies with a foreign country's market standards or legislation.

In response to U.S concerns, Brazil revised its registration form in December 2010 so that it no longer explicitly requires an exporting country's health or veterinary authority to certify that exported food products conform to Brazilian legislation and standards. The United States remains concerned, however, that the revised registration form could still be read to imply that the health or veterinary authority is certifying the information provided by the producer. The revised registration form is also problematic because it requires producers to provide detailed, product-specific information in the form, such as ingredients, additives, and the processing aids they use, which could allow competitors to replicate their proprietary formulas.

In 2012, the United States has engaged in technical exchanges with Brazil with respect to the registration form. The United States will continue to work with Brazilian authorities to resolve the issue.

Beverage Laboratory Registration

The United States has continued to work with Brazil to resolve outstanding concerns over a measure that Brazil notified to the WTO in December 2009. The measure requires the government of each exporting country to provide a list of approved production facilities for non-alcoholic beverages, distilled spirits, and malt beverages as well as a list of laboratories that will test these products to ensure they meet Brazil's import requirements. The United States is concerned that these listing requirements, in addition to impeding trade, are duplicative because Brazil already receives certificates of analysis from U.S. exporters as part of normal shipping documentation, and these certificates of analysis indicate the laboratory in which the products in the shipment have been tested.

These listing requirements, which took effect September 28, 2010, have adversely affected U.S. exports; to date Brazilian customs officials have detained at least four shipments of U.S. produced vegetable juices and sauces. While officials at the U.S. Agricultural Trade Office in Brasilia were able to secure the release of these products, these actions do not provide a basis for a viable long-term solution to the problem.

The United States continues to work with Brazil and U.S. industry to identify a solution to concerns with respect to these listing requirements.

Chile

Bilateral Engagement

The United States and Chile discuss TBT-related matters in the context of the United States – Chile Free Trade Agreement, at annual Free Trade Commission meetings, and in the TBT Committee.

Emissions Standards

In 2011, the United States worked successfully with Chile to make trade-enhancing changes to a Chilean regulation (DS No. 95/2005), which took effect in 2005, but included a clause that would have imposed emissions limits for new commercial diesel trucks in Chile beginning on January 1, 2012. The clause would have required all commercial diesel trucks sold in Chile to meet U.S. Environmental Protection Agency (EPA) 2007 emissions limits for particulate matter. Because U.S. diesel trucks engineered to the 2007 EPA standard require low sulfur fuel that is not currently available in most parts of Chile, this requirement would have effectively blocked U.S. exports of diesel trucks to Chile.

The United States provided these concerns to Chile in a meeting of the bilateral Free Trade Commission in August 2011. In response to these concerns, Chile proposed an amendment to its emissions rule to allow new commercial trucks to meet the equivalent of the 2004 EPA emissions standard until September 2014, when the appropriate low sulfur fuel is expected to be available throughout Chile. The amendment will allow U.S.-manufactured commercial diesel trucks to continue to be sold in the Chilean market.

Chile notified the amended clause to the TBT Committee in February 2012. The amendment is scheduled to take effect in April 2012. The United States will monitor developments in 2012 to ensure that Chile implements the proposed change.

China

Bilateral Engagement

The United States and China regularly engage on TBT-related issues through the U.S.-China Joint Commission on Commerce and Trade (JCCT) and bilaterally on a case-by-case basis as specific market access issues arise. The JCCT, which was established in 1983, is the main forum for addressing bilateral trade matters and promoting commercial opportunities between the United States and China. The JCCT has played a key role in helping to resolve bilateral TBT issues, including those related to medical device recalls and registration, certification of information technology products, and cotton registration requirements.

Food Additives – Formula Disclosure Requirements

In April, 2011, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released a "Specification for Import and Export of Food Additives Inspection, Quarantine and Supervision (2011 No. 52))". The Specification, which took effect on July 1, 2011, effectively requires U.S. and other foreign food producers to disclose their proprietary food additive formulas. In particular, the Specification requires food product labels to list the precise percentage of each food additive. This requirement effectively compels producers to divulge their proprietary additive formulas, thus allowing competitors to replicate those formulas, and compromise the producers' legitimate commercial interests. The requirement to disclose product formulas appears to apply only to imported food additives.

Not only does the Specification raise serious commercial concerns, China developed and implemented it in a non-transparent manner. Specifically, China did not publish the measure in

draft form and solicit comments from interested stakeholders. Nor did China notify the measure to either the TBT Committee or the SPS Committee in advance of promulgating it, as required, despite the fact that the measure lists both food quality and food safety as objectives. As a result, neither the United States nor U.S. industry stakeholders were aware of the proposed Specification, much less able to provide comments on it, before AQSIQ issued it. Finally, the measure appears to have taken effect less than six weeks after AQSIQ announced it, which did not provide suppliers with adequate time to take the steps necessary to comply before it took effect.

The United States submitted comments to China in July 2011 regarding the Specification. In its October 2011 reply, China claimed that the Specification simply implemented rules set out in its existing Food Safety Law, which took effect on June 1, 2009. In September 2009, the United States delivered comments on the Food Safety Law to China's regulators. The United States also provided these comments on its Food Safety Law to China's delegate at the November 2011 TBT Committee meeting. China also stated in its reply that the measure applied equally to domestic products; however, China did not make any revisions to the Specification to address concerns over quantitative listing of food additives.

Finally, the disclosure requirements set out in the Specification and China's Food Safety Law appear to conflict with those in China's National Food Safety Standard for the Labeling of Prepackaged Foods, which China notified to the WTO in April 2010. China's labeling measure requires only the listing of all ingredients in descending order of in-going weight, and provides that ingredients used in small amounts for the purpose of flavoring need not be declared on the label. This regulatory incoherence has created uncertainty in the trading community.

The United States urges China to revise its rules governing food additive disclosures to better comply with international standards and to harmonize its food labeling requirements.

China Compulsory Certification (CCC) Requirements – Conformity Assessment Procedures

As previously reported, since August 2003 China's Certification and Accreditation Administration (CNCA) has required a single safety mark – the CCC mark – to be used for both Chinese and foreign products. As in prior years, U.S. companies continued to express concerns in 2011 that the regulations on this subject do not make clear which products require a CCC mark. They have also reported that China is applying the CCC mark requirements inconsistently and that many Chinese-produced goods that CNCA's regulations require to bear the CCC mark continue to be sold without the mark. In addition, U.S. companies in some sectors continued to express concerns in 2011 about duplication of safety certification requirements, particularly for radio and telecommunications equipment, medical equipment and automobiles.

To date, China has authorized 153 Chinese facilities to perform safety tests and accredited 14 Chinese firms to certify products as qualifying for the CCC mark. When it joined the WTO, China committed to provide non-discriminatory treatment to majority foreign-owned conformity assessment bodies seeking to operate in China. Despite this commitment, China so far has accredited only six foreign-invested conformity assessment bodies. It is not clear whether these six bodies play any appreciable role in accrediting products sold in China. Moreover, China has not developed any alternative, less trade-restrictive approaches to third-party certification, such as recognition of a supplier's self-certification.

Because China requires testing for a wide range of products, and all such testing must be conducted in China, U.S. exporters are often required to submit their products to Chinese laboratories for tests that may be unwarranted or have already been performed abroad, resulting in greater expense and a longer time to market. One U.S.-based conformity assessment body has entered into a Memorandum of Understanding (MOU) with China allowing it to conduct follow-up inspections (but not primary inspections) of U.S. manufacturing facilities that make products for export to China requiring the CCC mark. However, China has refused to grant similar rights to other U.S.-based conformity assessment bodies, on grounds that it is prepared to conclude only one MOU per country. Reportedly, both Japan and Germany have concluded MOUs with China that allow two conformity assessment bodies in each country to conduct follow-up inspections.

In 2011, as in prior years, the United States raised its concerns about the CCC mark system and China's limitations on foreign-invested conformity assessment bodies with China both bilaterally and during TBT Committee meetings. During the November 2011 JCCT meeting, China indicated that it was actively seeking to improve its testing and certification process and that it would hold technical exchanges with the United States about streamlining its system.

WAPI Encryption Standards

The United States has serious concerns regarding China's requirement that its WAPI wireless local area networks (WLAN) standard be used in mobile handsets, despite the growing commercial success of computer products in China that comply with the internationally recognized WiFi standard developed by the Institute of Electrical and Electronics Engineers (IEEE).

In 2009, as part of its plan for encouraging an aggressive roll-out of third generation (3G) mobile handsets by Chinese telecommunications operators, many of which employ Internet-enabled via WLAN networks, China established a process for approving hand-held wireless devices such as Internet-enabled cell phones and smart phones. During bilateral talks in 2009, China indicated to the United States that it would approve devices that use the WiFi standard, but only if those devices are also enabled with the WAPI standard. China acknowledged that it had not published or made available any written measure setting out this requirement and that China had not notified the standard to the WTO as required. In 2010, the United States continued to urge China to publish the requirement in draft form, notify it to the WTO, allow a meaningful time for comments, and take the comments into account in developing any final measure.

In 2011, China's Ministry of Industry and Information Technology (MIIT) remained unwilling to approve any Internet-enabled mobile handsets or similar hand-held wireless devices unless the devices were WAPI-enabled, thus indicating that China's unpublished requirement continues to be in force. The United States continued to raise concerns with this requirement, both bilaterally and in TBT Committee meetings.

A new trade concern related to WiFi standards arose in 2011 after China published a proposed voluntary wireless LAN industry standard known as the "UHT/EUHT standard" to be used in wireless networks. China's UHT/EUHT standard appears to be an alternative to the IEEE

802.11n standard, which is the wireless LAN industry standard currently used throughout the world in Wi-Fi networks. The Chinese UHT/EUHT standard was released for a 15-day public comment period on September 20, 2011. MIIT approved the voluntary standard in February 2012. U.S. industry groups submitted comments, arguing, among other things, that the UHT/EUHT standard may not be compatible with either the existing Chinese national standard (WAPI) or the widely used IEEE 802.11 standard. Separately, the United States expressed concerns to China that, if China integrates the UHT/EUHT standard into its certification or accreditation schemes, that standard would become effectively become mandatory and therefore could restrict market access for U.S. producers. The United States will vigorously pursue a resolution of this issue in 2012.

IT Products – Mandatory Information Security Testing and Certification

The United States has raised serious concerns regarding China's proposed mandatory information security testing and certification requirements for information technology products, which were originally planned to take effect in May 2009. In particular, the proposed regulations went substantially beyond global norms by mandating testing and certification of information security in commercial IT products. In other countries, mandatory testing and certification for information security is only required for products used in sensitive government and national security applications.

The United States and other WTO Members expressed serious concerns to China about these proposed regulations in numerous bilateral meetings, including during the run-up to the September 2008 JCCT meeting, as well as in the 2008 TBT Committee meetings and during China's second WTO Trade Policy Review, held in May 2008. At the September 2008 JCCT meeting, China announced that it would delay publishing final regulations while Chinese and foreign experts continued to discuss the best ways to ensure information security in China.

In April 2009, CNCA, AQSIQ, and China's Ministry of Finance announced that they would delay implementing compulsory certification requirements for certain information security products until May 2010, and certification would only be required when products are sold to the government This step represented a significant reduction in the scope of the requirements from China's original plan. In the run-up to the October 2009 JCCT meeting, China confirmed that the compulsory certification requirement would only apply when products are sold to government agencies, and would not apply sales to state-owned enterprises or other sectors of China's economy.

In 2010, the United States continued to meet with Chinese authorities to discuss their regulation of information security products. Representatives of China's State Encryption Management Commission (SEMC) confirmed that China was considering revisions to its 1999 encryption regulations. The United States noted the earlier widespread concerns about these regulations and asked China to ensure that any revisions to these regulations would be published in draft form with opportunity for comment by interested parties. In 2011, industry reported that SEMC continues to pursue plans to revise the 1999 regulations. During 2012, the United States will continue to urge China to use transparent procedures in developing any revisions and to ensure that they will not unnecessarily restrict trade in widely-used commercial IT products.

IT Products – Multi-Level Protection Scheme

In 2010 and 2011, both bilaterally and during TBT Committee meetings, the United States raised concerns with China about its framework regulations for information security in critical infrastructure known as the Multi-Level Protection Scheme (MLPS), first issued in June 2007 by the Ministry of Public Security (MPS) and the Ministry of Industry and Information Technology (MIIT). The MLPS regulations put in place guidelines to categorize information systems according to the extent of damage a breach in the system could pose to social order, the public interest, and national security. The MLPS regulations also appear to require buyers to comply with certain information security and encryption requirements that are referenced in the MLPS regulations.

A problematic aspect of the MLPS regulations is that they bar foreign products from being incorporated into Chinese information systems graded level 3 and above (a grading system designed to classify the importance of information handled on an IT system in relation to national security, with the most sensitive systems designated as level 5). Systems labeled as grade level 3 and above, for instance, must solely contain products developed by Chinese information security companies and their key components must bear Chinese intellectual property. Moreover, companies making systems labeled as grade level 3 and above must disclose product source codes, encryption keys, and other confidential business information. To date, government agencies, firms in China's financial sector, Chinese telecommunications companies, Chinese companies operating its power grid, educational institutions, and hospitals in China have issued hundreds of request for proposals (RFPs) incorporating MLPS requirements. These RFPs cover a wide range of information security software and hardware, and by incorporating level-3 requirements, many RFPs rule out the purchase of foreign products.

Currently, China is applying the MLPS regulations only in the context of these RFPs. If China issues implementing rules for the MLPS regulations to apply the rules broadly to commercial sector networks and IT infrastructure, they could adversely affect sales by U.S. information security technology providers in China. The United States has therefore urged China to notify the WTO of any MLPS implementing rules laying down equipment-related requirements. In addition, the United States will continue to urge China to refrain from adopting any measures that mandate information security testing and certification for commercial products or that condition the receipt of government preferences on where intellectual property is owned or developed.

IT Products – Voluntary Standards

The United States has grown increasingly concerned that China may finalize several proposed voluntary standards related to information security and integrate them into certification or accreditation schemes, thus effectively making the voluntary standards mandatory.

The proposed standards include the UHT/EUHT standard discussed above in connection with China's WAPI encryption standards, as well as a series of six voluntary information security standards released for public comment in July 2011 by the China National Information Security Technical Standards Committee. Another voluntary standard, relating to information security requirements for office equipment, was released in September 2011, with a 30-day public comment period, by the China Electronics Standardization Institute, which operates under MIIT's jurisdiction, in conjunction with the China National Information Security Technical

Standards Committee. This voluntary standard appeared to be an office equipment information security standard designed to be an alternative to IEEE 2600, an international information security standard.

As in the case of the UHT/EUHT standard, the United States has made clear to China that, if voluntary standards such as its proposed office equipment standard are integrated into its certification or accreditation schemes, these standards would effectively become mandatory and U.S. information and technology products could be barred for China's market. In the November 2011 TBT Committee meeting, the United States noted its concern that China may adopt voluntary standards in the information and communication technology sector and integrate them into certification schemes, without first notifying them to the WTO. China responded by noting that both the UHT/EUHT standard and the office equipment standard are voluntary, and are still in draft. Further, China indicated that it had taken existing international standards into account in formulating its standards (although UHT/EUHT appears to be different from the existing 802.11n international standard for WiFi computing, and the office equipment standard appears to be different from IEEE 2600, an international information security standard for office equipment). China also stated that the draft standards are being considered for comment under the MIIT process, and that it will take comments into account.

In 2012, the United States will continue to monitor developments related to China's draft voluntary standards.

Medical Devices – Conformity Assessment Procedures

The United States has expressed concerns over the past few years regarding Chinese proposals governing the registration of medical devices. A draft measure circulated in 2009 would have required all medical devices to be registered in the country of export or the manufacturer's legal residence before they could be accepted for registration in China. This requirement had the potential to block, or inordinately delay, sales of safe, high-quality medical devices to the Chinese market. That is because in some instances manufacturers may decide not to seek to have their devices approved in the countries in which they are produced or in the producers' home countries for reasons unconnected with the quality or safety of their products. For example, producers may design particular medical devices specifically for patients in a third country, such as China, or may choose to produce them in a third country for export only. In these situations, a manufacturer would have no business reason to seek to have a particular device approved in its home country or the country of export and would likely forego that process in order to avoid the associated burdens of time and money.

During the October 2009 JCCT meeting, China indicated that it would not require a medical device to be registered in the country of export or in the country of legal residence of the manufacturer as part of its approval process for medical devices. However, draft measures of the State Council on Supervision and Administration of Medical Devices issued in 2010 maintained the proposed country of export registration requirement. In bilateral discussions with China in 2011, including during the 2011 JCCT meeting, the United States continued to urge China to meet with stakeholders to discuss their concerns and exclude the registration requirement from its final measure. The United States will continue to press this issue during 2012.

In addition, China's continued failure to permit U.S. suppliers to use competent conformity assessment bodies (*e.g.*, testing laboratories, inspection bodies, or product certifiers) located outside China to demonstrate that their products comply with Chinese requirements negatively affects U.S. exports of medical devices to China. Because China will not accept testing and certification results from the United States. U.S. medical device exporters must submit their products to Chinese laboratories for tests that have already been performed in the United States, resulting in greater expense and a longer time to market.

Classification of Imaging and Diagnostic Medical Equipment

Another source of concern relates to China's classification of imaging and diagnostic medical equipment. China classifies most imaging and diagnostic medical equipment as class III. This classification represents the highest risk and therefore it is the most stringent classification for medical devices. This classification is also problematic because it deviates from international practices and burdens manufacturers with additional requirements, such as conducting expensive and potentially unnecessary domestic clinical trials.

During the 2011 JCCT meeting, the United States urged China to place certain imaging and diagnostic medical equipment into a lower risk category. China's State Food and Drug Administration committed to issue, by June 2012, a complete list of x-ray equipment to be placed in a lower risk category and agreed to endeavor to release a draft *in vitro* (*e.g.*, test tube) diagnostic equipment catalog for public comment by June 2012. The United States will work to ensure that China implements this commitment in 2012.

Patents Used in Chinese National Standards

China has prioritized the development of Chinese national standards, as evidenced by its Outline for the National Medium to Long-Term Science and Technology Development Plan (2006-2020), issued by the State Council in February 2006, and amplified shortly thereafter in the 11th Five Year Plan (2006-2010) for Standardization Development, issued by the Standardization Administration of China (SAC). More recently, China has also said that when it develops standards it will rely on either non-patented technology or patented technology with prices lower than those that patent owners would otherwise seek to charge. As a result, China's treatment of patents in the standard setting process has garnered increasing attention and concern around the world, including in the United States.

In November 2009, the SAC circulated for public comment proposed Provisional Rules regarding Administration of the Establishment and Revision of National Standards Involving Patents. The rules would implement China's vision for a standards development process that uses government power to deny or lower royalty payments for patents that are incorporated into Chinese national standards. The rules would establish the general principle that mandatory national standards should not incorporate patented technologies. However, when those standards do incorporate patented technologies, the rules would provide for the possibility of a compulsory license if patent holders do not grant royalty-free licenses. Under this approach, patent owners may not be able to set reasonable limits on the use of their technology or receive reasonable compensation for their inventions.

The United States provided comments to SAC on the proposed rules in December 2009, asking

SAC to refrain from adopting the rules and consult with stakeholders. SAC reportedly received comments from 300 other interested parties as well. The China National Institute for Standards (CNIS) published a draft measure containing similar provisions in February 2010. The United States provided comments to CNIS on their draft in March 2010. As of March 2012, neither SAC nor CNIS had moved to finalize their proposed measures.

Certification of Pollution Control for Electronic Information Products

In May 2010, CNCA and MIIT jointly issued a notice proposing to adopt a "National Voluntary Certification Program for Electronic Information Products Subject to Pollution Control" ("Voluntary Certification Program"). In May 2011, the United States asked China through its TBT Inquiry Point to notify the proposed Voluntary Certification Program to the WTO. To date, China has failed to do so.

Information reported in February 2011 indicates that China may incorporate the certification procedures set out in the proposed Voluntary Certification Program into mandatory certification schemes for products listed in China's "Standards Compliance Management Catalogue for Pollution Control of Electronic and Electrical Products." More recently, MIIT and CNCA indicated that they intend to encourage electronic information product manufacturers, sellers, and importers to take advantage of the program's financial and tax incentives, and its priority standing in government procurement. According to U.S. industry, MIIT and CNCA intend to implement the Voluntary Certification Program in the near future. However, to date China does not appear to have published or otherwise described these incentives. U.S. industry is concerned that China is encouraging producers to implement potentially costly and burdensome voluntary certification procedures, which may not protect their proprietary information, without any publicly stated description of the incentives or benefits. U.S. industry is also concerned that if China notifies its Voluntary Certification Program to the WTO after the voluntary certification procedures in the Program become mandatory, it will be too late for China to introduce amendments and take industry comments into account.

The United States raised concerns with China during and on the margins of the June 2011 TBT Committee meeting regarding China's failure to notify its proposed Voluntary Certification Program to the WTO. The United States also urged China to postpone implementing those procedures until all interested parties have had the opportunity to submit written comments on them and to take these comments and the results of any discussions with those parties into account. The United States continues to urge China to clarify the objective and rationale of the certification procedures included in the Program and their basis in relevant international guidelines and recommendations. The United States also continues to seek clarification from China regarding the incentives or benefits that producers may receive for complying with the Program's voluntary certification procedures. The United States will carefully monitor developments on this subject in 2012.

Colombia

Bilateral Engagement

The United States discussed TBT matters with Colombia during and on the margins of TBT

Committee meetings.

Distilled Spirits – Quality, Identity and Labeling Requirements

Earlier *TBT Reports* have outlined U.S. industry concerns about quality and identity requirements that Colombia proposed in 2009 for distilled spirits, including gin, rum, vodka, and whiskey.

Colombia made positive modifications to its requirements, including by withdrawing a proposed measure that would have created standards of identity for distilled spirits based on analytical parameters, including their chemical composition. This proposal was problematic because it could have barred some U.S. spirits from the Colombian market and it was inconsistent with the standards of identity for distilled spirits sold in the United States, the European Union, Canada, and nearly every other major spirits market. Unlike Colombia's approach, these markets base their standards of identity on the raw materials and processes used to produce distilled spirits, not on their chemical composition.

Although Colombia has withdrawn its draft measure, it continues to endorse imposing analytical parameters on the chemical composition of spirits, such as a limit on congeners and other naturally occurring constituents of gin, vodka, and rum. Colombia has stated that it will develop standards for distilled spirits through other avenues, possibly through Mercosur. Colombia has also committed to notify any future proposed alcoholic beverage regulations to the WTO.

Diesel Emissions

The Colombian Government proposed to lower emissions levels from commercial diesel trucks for health and environmental reasons. While the United States supports this objective, it has raised concerns with Colombia about proposed Resolution 2604, which would specify that trucks must meet the Euro IV emissions standard. Given the design of some U.S.-manufactured diesel truck engines and the type of fuel available in Colombia, that standard would effectively exclude many U.S. heavy duty trucks from the Colombian market.

While Colombia has suggested that the Euro IV standard is more stringent than the alternative U.S. standard in controlling harmful emissions, it is not clear that the proposed standard will result in lower harmful emissions in practice. The United States raised the issue with Colombia on the margins of several TBT Committee meetings. The United States has encouraged Colombian authorities to focus efforts on removing older trucks from the road to achieve the most immediate and significant emissions reductions.

In 2012, the United States engaged in technical exchanges with Colombia on the relative merits of the U.S. and Euro IV standards in controlling harmful emissions. The United States will continue to engage Colombia on this issue.

Central American Customs Union (CACU)

Bilateral Engagement

The United States discusses TBT matters with the CACU countries (Costa Rica, El Salvador,

Guatemala, Honduras, and Nicaragua) during and on the margins of TBT Committee meetings and CAFTA-DR TBT meetings.

Processed Food – Product Registration

Costa Rica, along with the other CACU countries, requires all processed food products to be registered in the exporting country before they are eligible to be imported. A Certificate of Free Sale (CFS) is required for registration. That requirement threatened to block U.S. processed meat exports to Costa Rica and other CACU countries because the U.S. Food and Drug Administration, the agency that issues CFSs in the United States, does not have jurisdiction over most processed meat products.

The United States met with the various national CACU regulatory officials on several occasions, including in August 2010 and again in April and July 2011 to bring this issue to their attention. The United States also raised this issue in the September 2010 and December 2011 meetings of the CAFTA-DR TBT Committee. As a result of engagement by the United States, Costa Rica has formally accepted the USDA Export Certificate of Wholesomeness in lieu of a CFS and several of the CACU countries have committed to advance discussion in CACU on formal acceptance of the USDA Export Certificate of Wholesomeness in lieu of a CFS as well.

Of further concern are the frequent lengthy delays in registering processed food products with the Costa Rican Ministry of Health. Costa Rican importers indicate that the registration process ranges from three to six months. The United States has met with the Costa Rican Chamber of Food Industry and the Ministry of Health to discuss this issue.

The European Union

Bilateral Engagement

The United States has actively engaged the European Union (EU) on TBT-related matters in multilateral fora, including the TBT Committee and in this year's WTO Trade Policy Review of the EU, as well as bilaterally. The United States also uses the Transatlantic Economic Council (TEC) and the United States – European Union High-Level Regulatory Cooperation Forum (HLRCF) as forums to raise concerns and encourage systemic changes in the EU approach to key TBT issues.

In addition, the United States and the EU work together to promote the importance of maintaining open and transparent regulatory and standards development processes in emerging markets, as well as jointly advocating on specific market access issues on behalf of U.S. and EU exporters.

Accreditation Rules

As noted in previous *TBT Reports*, the United States has serious concerns regarding the EU's accreditation framework set out in Regulation (EC) No 765/2008. The regulation, which applies to all sectors, became effective on January 1, 2010. It requires each Member State to appoint a single national accreditation body and prohibits competition among Member States' national

accreditation bodies. The regulation further specifies that national accreditation bodies shall operate as public, not-for-profit entities. This means that only a single, government entity in each Member State shall be permitted to accredit conformity assessment bodies in the EU.

Because the regulation gives Member States discretion regarding whether to recognize non-European accreditation bodies and whether to accept conformity assessments issued by ILAC MRA and IAF MLA accredited bodies, it is possible that Member States may refuse to recognize non-European accreditation bodies and refuse to accept conformity assessments issued by these bodies. The regulation raises market access concerns for U.S. producers, whose products may have been tested and/or certified by conformity assessment bodies accredited by non-European accreditation bodies.

The United States raised these concerns at the June 2011 TBT Committee meeting and will continue to press the EU on these issues in 2012.

Chemicals – REACH Regulation

REACH, the EU's expansive chemical regulation, regulates chemicals as a substance, in preparations, and in products, and affects virtually every industrial sector, from automobiles to textiles. It imposes extensive registration, testing and data requirements on tens of thousands of chemicals. REACH also subjects certain chemicals to an authorization process that would prohibit them from being placed on the EU market except as authorized for specific uses by the European Commission. U.S. industry has expressed specific concerns with the fact that REACH requires polymer manufacturers and importers to register reacted monomers in many circumstances. This is problematic because reacted monomers no longer exist as individual substances in polymers and would not create exposure concerns in the EU. In addition, EU polymer manufacturers generally can rely on the registrations of their monomer suppliers and do not need to be individually registered. As a result, the reacted monomer registration requirement provides an incentive for distributors to stop importing polymers and switch to EU polymer suppliers. The United States has pressed the EU to eliminate the requirement to register reacted monomers in polymers entering the EU market.

Moreover, REACH contains notification and communication obligations with respect to substances on the Candidate List, a list of substances that may become subject to authorization. Differing interpretations between the Commission and several Member States regarding when these obligations apply has created uncertainty about how to comply with these obligations. The Commission has indicated that notification and communication obligations apply if a substance on the List is present in an article in concentrations above 0.1 percent of the article's entire weight; however, these Member States have stated that these obligations should apply when a substance on the List is present in concentrations above 0.1 percent of the weight of the article's components or homogenous parts. In 2010, these Member States pushed the Commission to reverse its position as a way of protecting the EU market from imports since a reinterpretation would impact imports. A change in interpretation would present a much more difficult compliance problem for U.S. industry since it would require companies to perform an analysis of individual component concentration levels in their products, which would be extremely time-consuming and burdensome. Given that an alteration of the EU's approach could substantially disrupt U.S. exports, the United States has asked the EU to ensure that all Member States follow the Commission's current interpretation.

Other problematic issues with the EU's REACH regime include inadequate transparency and differing registration requirements for EU and non-EU entities.

The United States has raised concerns regarding REACH at nearly every TBT Committee meeting since 2003, and has been joined by many other delegations, including Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Cuba, the Dominican Republic, Ecuador, Egypt, El Salvador,India, Israel, Japan, Korea, Malaysia, Mexico, Qatar, Russia, Singapore, Switzerland, Taiwan, and Thailand. The United States also has raised its concerns regarding REACH directly with the EU and has worked with the European Chemicals Agency on specific technical issues.

In 2011, the United States registered concerns with the EU during the TBT Committee meeting regarding a requirement under REACH rules for manufacturers outside the EU appoint "Only Representatives" (ORs). An OR is a natural or legal person established in the EU authorized to carry out the obligations that REACH imposes on importers. REACH bars U.S. producers from registering substances for use in the EU and thus must engage an OR for this purpose. The requirement for foreign producers to appoint an OR imposes substantial cost burdens on them that European manufacturers do not bear. It can be highly expensive to contract with an OR, thus placing an additional financial burden on the exportation of the chemicals to the EU.

The United States also encouraged the EU to address in its 2012 REACH review U.S. concerns regarding data compensation issues in connection with the operation of Substance Information Exchange Forums (SIEFs) that REACH creates for each registered substance. Specifically, U.S. industry has raised concerns that the "lead registrant" for each SIEF may take commercial advantage of its position in dealing with other SIEF members, particularly SMEs. Under REACH rules, other SIEF members must negotiate with the lead registrant to register their chemicals. A lead registrant could take advantage of this situation by charging those members exorbitant registration fees, thereby driving some companies (especially SMEs) out of the EU market. The United States urged the EU to consider issuing guidance for cost-sharing that would place limits on what lead registrants can charge other SIEF members, thus preventing undue financial burdens on those members, especially SMEs.

The United States will continue to monitor closely REACH implementation in 2012, and will raise trade concerns, as appropriate, in the TBT Committee and other pertinent fora.

Wine – Labeling Requirements

The EU continues to seek exclusive use of so-called "traditional terms" such as tawny, ruby, reserve, classic, and chateau on wine labels, but may allow third country producers to use such terms pursuant to an agreement with the EU or contingent on the regulation of those terms in their home market. Under the United States – EU wine agreement, the EU permitted the use of certain terms on U.S. wines sold in the EU during an initial three-year period, with the possibility of an extension for additional two-year periods. At the end of the initial three-year period, the EU declined to extend the use of those terms past March 2009. As part of its effort to redesign its Common Market Organization on wine, the EU published its new regulation (EC No 607/2009) on July 14, 2009, laying down detailed rules for implementation of EC regulation 479/2008 with regard to protected designations of origin and geographical indication, traditional

terms, labeling, and presentation of certain wine products.

The United States continues to have serious concerns regarding these measures, which severely restrict the ability of non-EU wine producers to use common or descriptive and commercially valuable terms to describe their products, on the grounds that those terms are traditionally associated with European wines. The United States is also concerned about continued EU efforts to expand the list of so-called "traditional terms" to include additional commercially valuable terms. Some of these terms do not have a common definition across all EU Member States, and the United States is not aware of any effort to monitor or limit the use of those terms within the EU. Additionally, the United States remains concerned about the EU's decision to withdraw permission to use certain "traditional terms" under the U.S. – EU wine agreement, as well as the EU's limitation on the use of traditional expressions in trademarks. While the EU attempts to justify limitations on the use of traditional terms by indicating that they could be used to mislead consumers, these terms have been used without incident on U.S. wines in the EU market for many years, which suggests that there is no such risk. In addition, the U.S. winemaking industry applied for approval of certain wine terms in June 2010, but the EU has delayed making a decision, citing objections to the proposal. During 2012, the United States will continue to coordinate with the U.S. wine exporters on how best to address and resolve concerns regarding the EU's wine policy, and will engage with EU officials at the TBT Committee and in bilateral meetings.

Distilled Spirits Regulation

The European Union requires that for a product to be labeled "whiskey" it must be aged for at least three years. This rule prohibits U.S. whiskey products that are aged for a shorter period from being marketed as "whiskey" in the EU market. Recent advances in barrel technology have enabled U.S. micro-distillers to reduce the aging time for whiskey produced in the United States. In addition, climate can affect the aging process and climate conditions in Scotland and Ireland are different from those in the United States. For these reasons, the United States views a mandatory three-year aging requirement for whiskey as constituting an unwarranted trade barrier. The EU's policy on distilled spirits also adversely affects U.S. exports to other markets that are following the EU's lead and adopting similar aging rules. Israel and Russia, for example, recently adopted the same minimum aging requirement for blended whiskeys as the EU – even though those countries do not produce whiskey. In 2012, the U.S. will continue to urge our trading partners to end whiskey aging requirements that serve as barriers to U.S. exports.

Renewable Energy Directive

The EU's renewable energy directive (RED) provides for biofuels (such as biodiesel and ethanol) and biofuel feedstocks (such those derived from soybeans or canola) to be counted toward fulfilling Member State biofuel use mandates or to benefit from RED tax incentives only if they qualify for a sustainability certificate. To qualify for this certificate, biofuels and biofuel feedstocks must meet specific sustainability criteria and conform to information tracking and auditing standards. The RED allows certificates to be issued in three ways: through private voluntary schemes authorized by the European Commission (EC), bilateral agreements with individual Member States, or bilateral agreements with the EC covering all Member States. The EU prefers the use of voluntary schemes. However, not all voluntary schemes are applicable in

all Member States and they include subjective criteria not contained in the RED. In addition, not all Member States have integrated the RED into national legislation. The use of separate approaches and sustainability criteria has created confusion in the market and has the potential to lead to significant trade disruptions.

In order to find alternative approaches to address U.S. concerns with the EU's certification scheme, the United States and the EC have begun discussions to explore a possible bilateral agreement that would recognize that longstanding U.S. conservation programs correspond to RED sustainability criteria. In July 2011, a high-level delegation from the U.S. government met with officials from the EC Directorate-Generals for Trade and Energy to address U.S. concerns. Additional discussions were held in September, November, and December 2011. In 2012, the United States will continue to push for a quick resolution of U.S. concerns and work with the EU to conclude a bilateral agreement.

India

Bilateral Engagement

The United States discusses TBT matters with India during TBT Committee meetings and on the margins of these meetings. The United States also discusses such matters through ongoing bilateral engagement, including under the U.S. – India Trade Policy Forum (TPF), the U.S. – India Commercial Dialogue, and the High-Technology Cooperation Group.

In addition, the U.S. Trade and Development Agency is funding a U.S. – India Standards and Conformance Cooperation Program with the Confederation of Indian Industry to facilitate India's development of a transparent and more streamlined system of standards, conformity assessment procedures, and technical regulations.

Cosmetics – Registration Requirements

U.S. industry continues to have serious concerns regarding India's proposed "Drugs and Cosmetics (Amendment) Rules, 2007." Specifically, industry is concerned that the rules may subject imports of U.S. drugs and cosmetics to a potentially costly and burdensome registration and licensing system. Beyond the administrative costs of conforming to the registration and licensing requirements, certain aspects of the requirements, such as in-country testing and frequent registration renewals for imported products, could result in delays in bringing U.S. cosmetic and pharmaceutical products to the Indian market.

In January 2011, U.S. industry requested additional clarification from India regarding how the rules would be implemented. Subsequently, India announced it would delay implementing the new regulations until April 1, 2012. The United States has asked India to use this time to conduct technical discussions with industry in order to ensure that the rules do not unfairly hinder imports into India.

Food and Distilled Spirits – Labeling

The United States also continued to work with India in 2011 to resolve concerns raised by the labeling requirements in India's Food Safety and Standards Regulation. Aspects of the labeling requirements, such as various formatting requirements and a requirement that flavors be listed

on the front of the product container, are inconsistent with the Codex General Standard for the Labeling of Prepackaged Foods. One way that India could ensure compliance with these types of requirements without imposing undue burdens on producers would be by allowing importers to affix supplemental labels in customs bonded warehouses after the products arrive in India rather than require that any labeling be done through pre-printing on the product container itself. That procedure would allow producers to avoid the costly practice of developing specially printed containers for the Indian market. At the June and November 2011 TBT Committee meetings, the United States supported the European Union in seeking further clarification from India regarding whether supplementary labels would comply with India's requirements. To date, India has made available only informal guidance suggesting that supplementary labels may comply with India's measure.

The United States also remains concerned about India's requirements that wine and distilled spirits labels include an ingredients list and disclose the date the product was manufactured. In addition, India has suspended – but not revoked – other potentially onerous labeling requirements for wine and spirits, such as "best before" dating requirements. The United States continues to seek a permanent exemption from this requirement for wine and spirits.

The United States has repeatedly expressed concerns about India's labeling requirements for wine and spirits through direct engagement with India and in discussions with Indian representatives on the margins of TBT Committee meetings. In addition, U.S. regulators met with their Indian counterparts in October 2011 to describe U.S. labeling requirements for alcoholic beverages, among other subjects. Despite this engagement, India has not been responsive to U.S. concerns on this subject.

The United States will continue to press India to revise its labeling requirements for food and distilled spirits in 2012.

Telecommunications Equipment – Information Security Regulations

Over the past several years, the United States and U.S. industry raised serious concerns regarding a number of telecommunications security regulations that India's Department of Telecommunications issued, including licensing amendments adopted in December 2009 and March 2010, and a "template agreement for security and business continuity" (the "template agreement") issued in July 2010. Under these measures, any vendor seeking to sell foreign manufactured telecom equipment and products to Indian telecom service providers was required to: (1) deposit its source codes with an escrow agency; (2) transfer its technology to Indian companies; and (3) meet burdensome testing and certification requirements. These requirements were mandatory for all private commercial contracts between foreign telecommunications service providers and vendors of foreign telecommunications-related equipment, products, and services in India. However, they did not apply to telecom equipment and products manufactured in India.

These regulations, which India did not notify to the WTO, generated significant uncertainty and confusion for the U.S. telecom industry. In response to U.S. concerns on the measures, India suspended the use of the "template agreement" and agreed to review its security regulations. The U.S. and global telecom equipment industries indicated that India's security regulations, if they had not been halted, would have halted billions of dollars of telecommunications

equipment sales to consumers in India. The United States continued to raise concerns regarding these measures in 2010 and 2011.

India issued revised telecom security regulations to replace the suspended regulations on May 30, 2011. India failed to notify these revised proposals to the WTO as well. During 2011TBT Committee meetings , the United States emphasized its concerns with three specific elements of India's revised telecom security regulations: (1) a requirement to have all imported information and communications technology equipment tested in Indian laboratories; (2) a requirement to allow the telecom service providers and government agencies to inspect a vendor's manufacturing facilities and supply chain, and to perform security checks of hardware and software; and (3) a provision holding vendors strictly liable and subjecting them to possible "blacklisting" for taking "inadequate" precautionary security measures. Vendors are especially concerned that they could be blacklisted because the regulations do not provide appeal and other judicial rights and procedures. The United States will continue to monitor the status of India's revised regulations and seek additional clarifications from India on how they would operate.

E-Waste Rules

In May 2010, India's Ministry of Environment and Forests (MEF) proposed new rules for managing electronic waste ("e-waste"). The rules broadly apply to producers, dealers, refurbishers, and consumers involved in the manufacture, sale, purchase, and processing of certain electrical and electronic equipment such as computers, televisions, and cell phones. The proposed rules would have:

- required producers of electrical and electronic equipment to collect and channel for recycling, refurbishing, or disposal any e-waste created during the manufacture or end-of-life cycle of an electronic product;
- permitted only those producers, collection centers, dismantlers and recyclers registered with and authorized by India's Central Pollution Control Board (CPCB) to handle e-waste;
- obligated producers to set up collection centers to oversee product recycling or disposal and inform consumers, bulk users, banks, and other businesses of the location of recycling or disposal facilities;
- required producers to ensure that the dismantlers or recyclers with which they work are registered with the CPCB;
- required producers to take responsibility for handling "historical waste" (the e-waste produced before the proposed rules took effect); and
- placed limits on the use of 20 "hazardous substances," including beryllium metal, copper beryllium alloys, liquid crystals, and mineral wools.

Following U.S. engagement with India in 2010, India notified the proposed rules to the TBT

Committee and provided stakeholders an opportunity to provide comments. The United States actively conveyed U.S. industry's concerns, including during the March 2011 TBT Meeting.
In May 2011, MEF issued a new set of e-waste rules that are scheduled to go into effect on May 1, 2012. In respect to these new rules, India's representatives have stated that MEF took into account some of the comments received from stakeholders. For example, the revised rules reduced the number of hazardous substances subject to use restrictions from 20 to six. In addition, India narrowed the rules to cover only information technology and telecommunications equipment (*e.g.*, computers, printers, and cellular phones) and certain consumer electronics (*e.g.*, television sets, refrigerators, and washing machines). Despite these improvements, U.S. industry continues to have concerns about whether India's rules will require producers to divulge proprietary information and about the apparent lack of mechanisms under the rules to assist small and medium enterprise ("SME") producers in processing their e-waste.

Toy Registration

India's Bureau of Indian Standards has proposed a "Toys and Toy Products (Compulsory Registration) Order" that would impose additional testing requirements on toys manufactured abroad. Under the proposed order, foreign manufacturers would only have 45 days to demonstrate that their toy products comply with the proposed testing requirements.

The proposed rule also appears to establish a new registration procedure that will require foreign toy producers to provide detailed and burdensome information related to toy manufacture. The information includes data on each factory's management composition, raw materials used in toy production, factory components, production machinery (including the serial numbers for all equipment on the factory floor and notification whenever particular equipment is removed from the factory, even for maintenance), factory layout, production processes, packing and storage procedures, product testing and inspection, and details concerning the producer's quality control staff.

In May 2011, the United States requested India to notify the proposed toy order to the WTO as required. The United States also asked India to postpone implementation of the order until all interested parties have had an opportunity to submit written comments and the Indian government has had an opportunity to consider those comments. As of March 2012, India had yet to notify the proposed toy order to the TBT Committee.

At the June and November 2011 TBT Committee meetings, the United States raised U.S. industry's concerns regarding the proposed order, including India's failure to explain why it is planning to require such detailed information for its proposed registration system and how India intends to keep the information confidential. The United States also noted that India's proposal, in contrast to U.S. and international best practices, would establish a *de facto* in-country testing requirement. The United States explained that India's safety objectives could be satisfied by less trade-restrictive approaches such as recognizing test results from internationally recognized laboratories, including those accredited under the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA).

Indonesia

Bilateral Engagement

The United States discusses TBT matters with Indonesia both bilaterally and during TBT Committee meetings. The United States – Indonesia TIFA Council provides a forum for bilateral discussions on a variety of trade-related issues, including standards-related issues. Indonesia also participates actively on standards and conformance issues through APEC.

Processed Foods - Bahasa Labeling Requirement

In September 2010, Indonesia's National Agency for Drug and Food Control (BPOM) announced that beginning March 1, 2011, it would require all imported processed food products to be labeled exclusively in the Bahasa language and require the labels to be affixed to product containers before they are shipped to Indonesia. The proposed policy at a minimum would have significantly raised costs for U.S. industry and at worst, could have shut U.S. exports out a market valued at $429 million on an annual basis.

In 2011, the United States raised its concerns with Indonesia both bilaterally and in TBT Committee meetings. In response to objections from the United States, Indonesia agreed to delay enforcing it labeling requirements until March 1, 2012. Also in response to U.S. concerns, Indonesia agreed to accept supplemental Bahasa language labels in lieu of original Bahasa language labeling. Indonesia has not clarified, however, whether the supplemental labeling must be completed before importation. In 2012, the United States will continue to press Indonesia to either lift its new labeling requirements, or allow the sale of processed food products with supplemental labeling that are applied in Indonesia.

Food, Supplements, Drugs, and Cosmetics – Distribution License Requirements

BPOM is considering licensing requirements for companies that distribute of food, health food supplements, drugs, and cosmetics in Indonesia, including imported products. Although the proposed licensing requirements vary by product type, they generally impose requirements that could significantly disrupt trade. For example, imported food distributors would be required to provide reference letters from the overseas production facility, certifications for health or *halal* status, and a certificate that the production process for the product was radiation free. The United States raised concerns about the proposed licensing requirements with Indonesia bilaterally and in TBT Committee meetings. BPOM issued a proposed replacement regulation in early 2011, which addresses some of the potentially burdensome requirements. For example, the revised proposal no longer requires *halal* certificates for products that do not claim to be *halal* consistent. In 2012, the United States will continue to raise its remaining concerns with the proposed licensing requirements.

Toy Certification

Indonesia's Directorate General of Manufacturing Industries is proposing to enforce in 2012 a recent toy safety standard, SNI 8124:2010. The U.S. toy industry is concerned that the safety standard will require redundant and burdensome in-country testing. The United States raised concerns regarding SNI 8124:2010 at the November 2011 TBT Committee meeting. The

United States also urged the Government of Indonesia to notify the draft measure to the WTO and to allow interested parties a reasonable period to submit comments on the standard. The United States is also encouraging Indonesia, in lieu of in-country testing, to instead allow foreign suppliers to provide laboratory test reports that are accredited by the International Laboratory Accreditation Cooperation (ILAC). The United States noted that recognition of test results from ILAC-accredited labs is common international practice in the toy safety area. Accepting ILAC reports could help prevent market-access delays without compromising regulatory effectiveness. In addition, accepting reports from ILAC accredited facilities could reduce the burden on local testing and certification facilities, which appear to lack the capacity to test imports in a timely fashion.

Indonesia is also considering another standard, SNI ISO 9001:2008, under which certain products such as toys, would be eligible for a mark that the product satisfies the safety requirements that Indonesia's National Standardization Agency has established. In 2011, the United States asked Indonesia to clarify whether it will recognize a certification that a product conforms to ISO 9001, a standard adopted by the International Organization for Standardization, as equivalent to SNI ISO 9001:2008 for purposes of receiving an SNI mark. The United States also asked Indonesia to clarify whether the SNI mark is intended to be placed on the product itself or the product packaging and whether certain reports were correct in stating that fees for obtaining the mark would be higher for imported products than for domestic products.

Indonesia has responded that its regulations on toy safety are in the preparatory stages and thus it was not in a position to address these questions. Indonesia assured the United States that it would notify any final toy safety regulatory proposals to the WTO. The United States will remain engaged on this subject as Indonesia develops its regulations.

Japan

Bilateral Engagement

The United States discusses TBT issues with Japan bilaterally, including through the U.S. – Japan Economic Harmonization Initiative (EHI) established in November 2010, as well as in multilateral fora such as the TBT Committee.

Organic Product Requirements

Japan will not certify as organic any agricultural products produced with alkali extracted humic acid or lignin sulfonate. Humic acids are used in farming to improve soil structure, increase water retention, promote seed germination, and improve yields. Lignin sulfonate is used as a flotation device for cleaning fresh fruits. U.S. organic standards permit producers to use these substances, but Japan requires producers to confirm that the neither substance has been applied before a product is exported to Japan. The United States engaged Japan on this issue in 2011, including by providing Japan in November 2011information it had requested on these substances.

In addition, Japan's national organic labeling requirements impose a zero tolerance policy for pesticide and herbicide residues on organic products. These requirements are problematic for

U.S. industry since these substances are often present in the natural environment. Japan's labeling policy also appears be inconsistent with the Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods. These guidelines apply to the process by which organic foods are produced, and do not mandate specific maximum residue levels for pesticides and contaminants.

In response to U.S. concerns, Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) is continuing its process of reviewing and revising Japan's certification requirements for organic products. During bilateral discussions in 2011 under the EHI, the United States presented alternative regulatory language on residue tolerances for MAFF to consider. MAFF is scheduled to complete its review process by the end of 2011. The United States will review the outcome of that process to ensure U.S. industry's concerns are conveyed.

The United States also continues to express concern that Japan does not allow the use of the Japan Agriculture Standard (JAS) organic logo in conjunction with U.S. logos thereby putting U.S. exporters at a disadvantage. Moreover, Japan only allows JAS accredited certifiers to issue the logo, which would require an additional accreditation for certifiers.

The United States will continue to press Japan in 2012 to modify its organics standards in a manner that will improve access to Japan's market for U.S. organic products.

Kenya

Bilateral Engagement

The United States discusses TBT matters with Kenya both bilaterally and during TBT Committee meetings. The United States – East African Community (EAC) TIFA Council also provides a forum for bilateral discussions of standards-related issues.

Alcoholic Beverage Labeling

In March 2011, Kenya notified to the WTO regulations that imposed labeling requirements for alcoholic beverages. The labeling requirements, which are presently in suspension as a result of domestic litigation, could prove onerous to U.S. exporters if they go into effect. For example, they require a warning message that comprises at least 30 percent of the package's total surface area. There is also a possibility that pictorial warnings will be incorporated as well. The United States will continue to closely monitor this issue.

Korea

Bilateral Engagement

Korea and the United States regularly discuss TBT issues through bilateral consultations. These consultations, led by USTR on the U.S. side with participation from other U.S. agencies, serve as an important forum for discussing and resolving these issues and are augmented by a broad range of senior-level policy discussions. In 2011, bilateral trade consultations were held in May and September leading to the resolution of a number of TBT issues. In addition, the United

States raises TBT issues with Korea during and on the margins of TBT Committee meetings. Opportunities for bilateral engagement on TBT issues will increase through the work of consultative mechanisms, such as a bilateral TBT Committee and an Automotive Working Group, established under the United States – Korea Free Trade Agreement, which entered into force on March 15, 2012.

Alcoholic Beverages – Radio Frequency Identification Tag

The Korean National Tax Service announced in July 2011 that it will begin requiring imported whiskey bottles to carry a radio frequency identification tag (RFID). Among the purposes for the tags is to prevent counterfeited products and tax evasion. Imported products must comply with the regulation by October 1, 2012. (Korea applied the requirement to domestic brands in 2010.) The United States submitted comments to Korea on the measure in July 2011 and February 2012. U.S. industry has expressed concerns that the requirement will impose significant costs and burdens on whiskey producers, such as the installation of RFID readers in warehouses and costs associated with the purchase and application of the RFID tags. The United States has urged Korea in bilateral meetings as well as through the TBT Committee to consider less burdensome options.

Cosmetics

In December 2010, Korea notified the WTO of a regulation it proposed to adopt on certifying cosmetic products that satisfy Korea's standard for Good Manufacturing Practices (GMPs). GMPs are a set of principles that producers should observe during the manufacturing process in order to ensure consistent product quality. A GMP certification attests that a product has been produced in a manufacturing facility that abides by certain quality control principles.

Although the proposed regulation does not appear to be mandatory, it raises national treatment concerns since it appears solely to allow domestic manufacturers to qualify for GMP certification. Companies recognized as complying with Korea's GMP standard will be granted preferential treatment, such as not being required to test every batch of cosmetics, a highly expensive process. Given the advantages of obtaining the GMP certification, the United States urged Korea to apply its GMP certification regime equally to foreign and domestic producers. Korea has indicated that it will seek to modify the regulation to allow foreign manufacturing facilities to qualify for GMP certification. The United States will monitor this process closely. Furthermore, as the GMP standard that Korea is considering is based on an international standard, ISO 22716, the United States has urged Korea to allow products to be GMP certified if independent third parties have certified that they meet the ISO standard.

In April 2011, Korea also notified the WTO of its draft "Guideline for Cosmetics Labeling and Advertising." The draft guideline lists the types of claims that producers can include on labels and in advertisements for cosmetics products. U.S. industry has raised two concerns with the guideline. First, industry is concerned that since regulations from Korea's Fair Trade Commission as well as Korea's product liability law already address personal care products, new guidelines for cosmetics labeling and advertising will be redundant and confusing. Second, U.S. industry has noted that Korea has yet to explain whether a procedure exists by which a manufacturer could assert a performance claim about a product that is not found in the proposed guidelines. The United States has raised these concerns bilaterally as well as during the

November 2011 TBT Committee meeting. Korea has indicated that it will revise the draft guideline in consultation with stakeholders, a process that the United States will follow closely.

Korea Chemicals Registration – REACH

In February 2011, Korea's Ministry of Environment (MOE) released a draft of a proposed "Act on the Registration and Evaluation of Chemicals." As announced, Korea REACH would create a complex registration system for chemical products, perhaps as early as 2014. U.S. industry has expressed concerns about the burden and lack of clarity about Korea's proposal. The United States seeks to ensure that Korea's final requirements are not unnecessarily trade-restrictive. U.S. industry submitted comments to MOE on Korea's proposal, and the United States raised this issue with Korea bilaterally and in the TBT Committee in June and November 2011. The United States will continue to monitor developments related to the proposed registration system and press Korea to take U.S. industry's comments into account.

Organic Products – Requirements and Conformity Assessment Issues

In June 2008, Korea published a proposed Processed Organic Foods Regulation, with a target implementation date of January 1, 2010. As originally drafted, the regulation would have required all products claiming to be organic to be certified as such by a body accredited by Korea's Ministry for Food, Agriculture, Forestry and Fisheries (MIFAFF). Many U.S. producers and certifiers would have been reluctant to seek certification and accreditation under the proposed regulation, due to the difficulty of finding certified ingredients that comply with the requirements, such as zero tolerance for materials prohibited by the regulation. Furthermore, because the proposed Korean regulation does not currently provide for Korea to negotiate agreements for equivalency or recognition of foreign organics programs, the proposed certification requirements could have significantly impeded, or even halted, more than $10 million worth of U.S. organics exports to Korea.

In response to concerns raised by the United States and other exporting countries, MIFAFF agreed to allow foreign organic products to be sold in Korea until December 31, 2012 without having to be certified by a MIFAFF-accredited certifier. During this interval, MIFAFF is revising and consolidating its organics regulations, including through a provision that will allow for the possibility of concluding equivalency agreements. The United States will actively pursue negotiations with Korea on an equivalency agreement 2012 with a view to concluding an arrangement that will facilitate exports of U.S. organic products.

PVC flooring

The Korean Agency for Technology and Standards has proposed to establish a content limit for certain industrial compounds known as phthalates that would effectively prohibit their use in PVC (polyvinyl chloride) flooring and wallpaper. The phthalates at issue are DBP, BBP, and DEHP, which are used as plasticizers in vinyl flooring and wallpaper in order to make them flexible, durable, and easy to maintain. Although the United States and other countries restrict the use of phthalates in children's toys and child care articles where there is concern that their use could result in potentially high exposure to children, it is not clear that such limits are necessary for flooring and wallpaper.

The United States has raised concerns with Korea over its proposed limits on the use of phthalates in PVC flooring on multiple occasions, including bilaterally and during the March, June, and November 2011 TBT Committee meetings. Korea has responded to U.S. concerns by citing a study that suggests that PVC flooring installed in Korean buildings may release phthalates because those buildings often have heated floors. Korea has not shared a copy of the report, despite requests to from the United States to do so.

Radio Waves Act

U.S. industry has been working closely with Korea's Radio Research Agency on the implementation of a 2011 amendment to Korea's Radio Waves Act. The amendment requires broadcasting and communication equipment to confirm compliance with Korean conformity assessment criteria, including safety standards, through the use of labeling. U.S. industry has expressed concerns that the amendment may require manufacturers to place labels on products in a manner that will adversely affect their performance. The United States will continue to work with Korea in 2012 to ensure that it takes U.S. industry's concerns into account.

Solar Panels – Testing Requirements

Korea requires solar panels to be certified by the Korea Management Energy Corporation (KEMCO) before they can be sold in Korea in projects receiving government support (which means in practice the vast majority of sales). KEMCO's certification standards prevent certain types of thin-film solar panels manufactured by U.S. industry from entering the Korean marketplace. For example, KEMCO has established a standard for thin film solar panels that can only be satisfied by panels manufactured from amorphous silicon. As a result, other leading types of thin film solar panels made by U.S. firms, including Cadmium Telluride (CdTe) and Copper Indium (di) Selenide (CIS), cannot be tested or certified under the Korean standard and thus remain shut out of Korea's private marketplace. The United States asked Korea bilaterally and at the March, June, and November 2011 TBT Committee meetings to adopt the relevant international standard, IEC 61646, without limiting its application solely to the type of thin-film solar panel its industry produces. That would both facilitate trade and afford Korean consumers access to the best available technologies. In response to U.S. concerns, Korea is conducting an environmental impact review on the use of cadmium in solar panels, which is expected to be completed in the first quarter of 2012. Korea has said it will consider revising its certification standard based on the results of that study. The United States will continue to press this issue with Korea in 2012.

Malaysia

Bilateral Engagement

The United States discusses TBT matters with Malaysia during TBT Committee meetings, bilaterally on the margins of those meetings, and during TPP negotiations. Malaysia also participates actively on standards and conformance issues through APEC.

Meat and Poultry Products – Halal Standards

Malaysia requires all domestic and imported meat (except pork) to be certified as *halal* (produced in accordance with Islamic practices) by Malaysian authorities. Indonesia regulations require producers' *halal* practices to be inspected and approved for compliance with Malaysian standards on a plant-by-plant basis prior to export.

In January, 2011, Malaysia implemented a food product standard, MS1500: 2009 that sets out general guidelines on *halal* food production, preparation, handling, and storage. In an effort to position Malaysian certification as the "gold standard" for *halal* products, MS1500: 2009 creates standards that go beyond the internationally recognized *halal* standards, which are contained in the Codex Alimentarius. The guidelines require slaughter plants to maintain dedicated *halal* production facilities and ensure segregated storage and transportation facilities for *halal* and non-*halal* products. These requirements appear to far exceed Codex guidelines, which allow for *halal* food to be prepared, processed, transported, or stored using facilities that have been previously used for non-*halal* foods, provided that cleaning procedures meeting Islamic religious requirements have been observed. The stringent new Malaysian guidelines could curtail or even block exports of U.S. beef and poultry products to Malaysia.

In spring 2011, Malaysia notified the WTO of a new protocol that provides additional information and guidance on complying with MS 1500: 2009. In May 2011, the United States provided comments on the protocol and subsequently raised concerns regarding the protocol during the June and November 2011 TBT Committee meetings. Malaysia has not yet addressed these concerns.

Following a request from the United States for further clarity on the new *halal* protocol, U.S. and Malaysian government representatives met in the United States in February 2012 to discuss the matter. Among other things, Malaysia's representatives noted that the while the protocol would be applied to permit mechanical slaughter, meat processing would have to take place in a dedicated *halal* facility. In addition, Malaysia's representatives said that U.S. producers could not meet Malaysia's *halal* standards by having their facilities audited on a systemic basis rather than plant-by-plant.

U.S. industry estimates that U.S. exports to Malaysia of *halal* beef and poultry could increase dramatically if Malaysia harmonizes its *halal* production standards and import licensing practices with the international norms contained in the Codex. The United States will continue to pursue this issue with Malaysia to find a mutually agreeable solution.

Mexico

Bilateral Engagement

The United States discusses TBT matters with Mexico during TBT Committee meetings and on the margins of these meetings. The United States and Mexico also engage on standards and regulatory issues as part of the U.S. – Mexico High-Level Regulatory Cooperation Council, which was established in 2010 and in the NAFTA Committee on Standards-Related Measures.

Caffeinated and Flavored Beverages

During the November 2011 TBT Committee meeting, the United States expressed concern over draft Mexican legislation that would restrict the sale of certain caffeinated energy drinks. In December 2011, Mexico published a revised legislative draft. The United States is currently reviewing this draft and will continue to engage in discussions with Mexico regarding any potential restrictions in 2012.

In January 2011, Mexico notified the WTO of a draft standard for non-alcoholic flavored beverages. The standard appears to impose design and sanitary requirements. The United States submitted comments on the draft standard to Mexico through the TBT Committee in August 2011. Specifically, the United States sought clarification on a number of issues, including the standard's documentation and recordkeeping requirements, the list of approved additives, and new mandatory advisory statements on the product containers. During the November 2011 TBT Committee meeting, Mexico stated that it was considering the comments the United States had submitted on the draft standard and that it would include responses to those comments in the final rule at the time it is published.

The United States will continue to engage with Mexico on both of these issues during 2012 to address U.S. beverage industry concerns regarding these measures.

Energy Efficiency

In September 2010, Mexico's Secretariat of Energy published a catalog of electrical equipment and appliances that imposes labeling obligations for manufacturers, importers, distributors, and marketers of those products. The labels to be placed on the products must contain information regarding the product's energy efficiency and confirming that the product meets certain testing requirements. U.S. industry has raised concerns that the scope of the products subject to the catalog's labeling requirements remains unclear. Accordingly, U.S. industry has requested Mexico delay implementing the catalog until those issues are resolved. The United States raised these concerns with Mexico both bilaterally and in the June and November 2011 TBT Committee meetings. Although Mexico let the catalog take effect, it did engage with U.S industry to clarify the catalog's requirements. In 2012, a bilateral working group will be formed in order to address industry concerns.

Sanitation Pipes

Mexico's drainage and sewage pipe market includes three types of pipes: cement pipes; corrugated high-density polyethylene (HDPE) pipes (manufactured mostly by U.S.-based companies); and PVC (polyvinyl chloride) pipes (manufactured mostly by Mexican-based companies).

Mexico's National Water Commission (NWC) imposes a certification requirement that keeps U.S. HDPE pipes off the Mexican market. Specifically, Mexico requires sanitation pipes to meet a particular ISO standard. This standard addresses design and descriptive characteristics for particular pipes rather than performance abilities. Only PVC pipes meet these design and descriptive characteristics. Whether HDPE pipes would perform adequately for sanitation purposes is irrelevant under this standard. NWC will not allow U.S. HDPE pipes to be

recertified as meeting the Mexican standard.

The ISO standard is not codified in Mexican law and U.S. HDPE pipe producers learned that NWC intended to apply it when NWC denied their requests for recertification in February 2010. During the November 2011 TBT Committee meeting and in separate bilateral discussions, the United States asked Mexico to ensure that the standards NWC adopts are applied on a non-discriminatory basis, are science-based, and are developed through the transparent processes the TBT Agreement requires. The United States will continue to press Mexico regarding this issue in 2012.

Russia

Russia is a member of the Russia-Kazakhstan-Belarus Customs Union (CU) as well as the Eurasian Economic Community (EurAsEC). Technical regulations, standards and conformity assessments systems in Russia are governed at the CU or EurAsEC level as well as at the national level. The CU parties, all members of EurAsEC, have agreed to harmonize their policies and regulatory systems in the TBT arena.

Bilateral Engagement

The United States engages directly with Russia regarding its technical regulations, standards, and conformity assessment procedures on a bilateral basis. (Once Russia joins the WTO it will be required to adhere to the TBT Agreement). In addition, the Working Group on Business Development and Economic Relations established under the U.S. – Russia Bilateral Presidential Commission provides a forum for the United States and Russia to discuss, among other matters, standards-related regulatory cooperation.

Alcoholic Beverages – Tax Strip Stamp Requirement

Russia levies excise taxes on alcohol and enforces these taxes through a system that requires alcohol beverage containers to bear an excise "strip stamp" label. In February 2010, Russia amended its laws to make domestic alcohol imported alcoholic beverages subject to the same excise stamp labeling requirement. Although Russia's harmonization of its strip stamp requirements represents a significant improvement over its previous system – which accorded different treatment to imported and domestic products – U.S. industry has indicated that Russia's strip stamp requirements remain burdensome. Russia's United Federal Automated Information System (UFAIS) requires importers and domestic manufacturers to print Universal Product Code data on each strip stamp. In addition, the stamps must be sequentially-numbered, and suppliers must prepare a consolidated document at the end of the year for all the strip stamp numbers. Further, suppliers and importers must report these stamps through an automated system for purposes of taxation and a manual system for customs purposes. U.S. government reports indicate that the UFAIS requirements are expensive to fulfill, difficult to use and, thus far, have been unsuccessful in meeting the objective of tracking alcohol from manufacture or importation to the retail sales point.

Russia has recently taken steps to extend the strip stamp requirement to cover all alcohol products (except beer and beer drinks), including products below 9 percent alcohol by volume (abv). Russia has provided a grace period for domestic products that contain 9 percent abv or

less ending on January 1, 2013. Imports of those products were made subject to the strip tax requirement on January 1, 2012.

Finally, Russia is considering establishing a single point of entry for imports of alcoholic beverages in order to ensure that importers comply with Russia's excise stamp requirements. As approximately 700 million units of alcohol are imported into Russia every year, this requirement would cause significant trade delays. In 2012, the United States will continue to urge Russia to revise its strip stamp requirements in ways that will facilitate access for imported alcoholic products to Russia's market.

Alcoholic Beverages – Warehousing Requirements

In October 2010, Russia's Federal Service for Alcohol Market Regulation (FSR) adopted regulations governing the warehousing of alcoholic beverages. The United States is concerned that these regulations impose onerous and unfounded restrictions on this practice. For example, the regulations prohibit storing different types of alcohol on one pallet; require that alcohol products be stored at least 15 cm from the floor; and preclude other goods from being stored with alcohol products. It is unclear what objectives these requirements are intended to fulfill. Furthermore, the regulation unnecessarily restricts access to the Russian market for U.S. alcoholic beverage exporters. Several U.S. exporters have experienced months of delays seeking to bring their warehousing practices into conformity with the regulation after FSR inspections raised compliance issues. In 2011, U.S. and Russian [alcoholic beverage] regulators met to discuss U.S. concerns over Russia's warehousing requirements. Those discussions were productive and Russia released a new draft of the alcoholic beverage regulation was released in October 2011, which included helpful changes.

Alcoholic Beverages – Definition of Beer

In June 2011, Russia amended its alcoholic beverages law in a way that changed the scope of products that can be sold as "beer" in Russia. Among other things, the amendment allows beer to be brewed from no more than 20 percent brewing malt in grain form. It appears that products from most of the larger U.S. brewers are precluded from being marketed in Russia as beer under the new definition. Moreover, other products often marketed as beer in the United States, such as flavored malt beverages, seasonal beers, sake products, and many craft beers would not be considered beer under the new law as well. In October 2011, the Customs Union published similar draft technical regulations. In December 2011, the United States submitted comments to the Customs Union raising U.S. concerns over proposed beer definition. The United States will continue to address this issue in 2012.

Saudi Arabia

Bilateral Engagement

The United States engages with Saudi Arabia on TBT issues through the bilateral Trade and Investment Framework Agreement and during TBT Committee meetings.

Conformity Assessment Procedures – Lack of Transparency

In 2006, Saudi Arabia introduced a Certificate of Conformity (CoC) Program. With certain exceptions, this program requires every shipment of products sold in Saudi Arabia to be accompanied by a document certifying that the product conforms to the relevant Saudi technical regulation ("conformity certificate"). U.S. exporters have expressed concern about a lack of detailed public guidance in English on how to comply with this requirement. In course of discussions in bilateral discussions in 2010 and 2011, officials from the Saudi Arabia Standards Organization (SASO) clarified that this guidance is now included in the "Procedures of Issuing Certificate of Conformity for Commodities and Products to be Exported to the Kingdom of Saudi Arabia" as well as other documents available on SASO's website.

South Africa

Bilateral Engagement

The United States discusses TBT matters with South Africa during TBT Committee meetings and bilaterally on the margins of these meetings, as well as under the U.S.-South Africa trade and investment agreement. USDA and South African agriculture officials discuss TBT matters through their annual bilateral forum.

Liqueurs – Alcohol Content Restrictions

In 2009, U.S. industry expressed concerns about South Africa's classification of alcoholic beverages. Alcoholic products cannot be sold in South Africa unless they fall within a designated classification, which is determined by alcohol content. The two main classifications are liqueurs and spirit coolers. South Africa classifies "liqueurs" as beverages having a minimum alcohol content of 24 percent and classifies "spirit coolers" as beverages having 15 percent or less alcohol by volume. On the other hand, South Africa does not maintain any classification for spirit-based alcoholic beverages with an alcohol content of between 15-24 percent, with the exception of products that fall into the "Cream Liqueur" classification, namely spirit-based alcoholic beverages that contain a dairy product. As a result, any U.S. products that fall in the gap between these two classifications cannot be sold in South Africa.

Not only have these requirements kept certain U.S. products out of the market, but industry has reported that South Africa may not be applying its requirements equally to domestic and imported products. In particular, U.S. industry has reported that South Africa has granted at least one exception to its requirements for a domestic producer.

During 2012, the United States will continue to raise concerns regarding South Africa's alcoholic beverage standards and, if appropriate, will urge South Africa to eliminate or modify its "liqueur" definition, or seek another solution that facilitates trade, such as an exemption, so that U.S. alcoholic beverage producers can sell their products in South Africa.

Taiwan

Bilateral Engagement

The United States discusses TBT matters with Taiwan during TBT Committee meetings and bilaterally on the margins of these meetings as well as under the auspices of the U.S.-Taiwan TIFA.

Ceiling Panels – Requirements for Incombustibility Testing Methods

U.S. companies that manufacture finished interior building materials, such as ceiling panels and wood paneling, have raised concerns regarding the testing method that Taiwan mandates for determining whether those materials meet applicable incombustibility requirements. Industry has complained that Taiwan's current testing method for ceiling panel incombustibility, which is similar to the current ISO 5660 standard, results in inconsistent and inaccurate incombustibility measures because the ISO standard was not meant to be applied to the testing of ceiling tiles.

As a result, ceiling tiles manufactured in the United States are given a lower incombustibility rating than is otherwise warranted and, in some instances, fail the test altogether. An ISO committee has been working to develop a new version of ISO 5660 that would incorporate a testing apparatus taking into account inconsistencies in the current methodology.

The United States raised these concerns with Taiwan on the margins of the TBT Committee meeting in November 2009, as well as in subsequent bilateral meetings under the TIFA, including a meeting held in Taiwan in September 2011. In response, Taiwan's Bureau of Standards, Metrology, and Inspection has indicated it would consider adopting the new ISO standard when it is approved. In the meantime, Taiwan has indicated that it is open to accepting alternative approaches. The United States will continue to encourage Taiwan to adopt the relevant international standard when it is completed.

Commodity Goods – Labeling Requirements

U.S. industry continues to express concern that Taiwan requires all "commodity goods" (consumer goods, in U.S. parlance) to be labeled with the manufacturer's or producer's name, telephone number, and address. In addition to concerns over protecting proprietary information, industry notes that some commodity goods may be produced by several different manufacturers, and product labels may not be large enough to contain all of the required information. U.S. officials have raised these concerns with Taiwanese representatives, including on the margins of the TBT Committee meetings as well in staff-level meetings under the TIFA, including in September 2011. Taiwan is working to revise the relevant labeling requirements for textiles, garments, and 3C (computer, communication, and consumer electronics) information products. The United States will continue to monitor Taiwan's progress in addressing this issue.

Thailand

Bilateral Engagement

The United States discusses TBT matters with Thailand during, and on the margins of, TBT

Committee meetings as well as in bilateral dialogues such as the U.S. - Thailand TIFA Council and the Bilateral Consultative Mechanism. Thailand also participates actively in APEC on standards and conformity assessment issues.

Alcoholic Beverages – Labeling Requirements

In January 2010, Thailand notified the WTO of a proposed regulation that would require alcohol beverage labels to include warning statements and photo images. The images would graphically depict certain potential adverse consequences of consuming alcohol, such as road accidents and diseased organs. The draft regulation also specifies that at least 50 percent of one side of square shaped packaging, or 30 percent of round or cylindrical shaped packages, must be allocated for the warning statements and images. In addition, the draft regulation calls for the various sets of warning labels and images to be rotated every 1,000 packages.

Following engagement with Thailand on this issue in 2010, the United States raised concerns about the draft regulation during all three 2011 TBT Committee meetings. Australia, Brazil, Chile, the EU, Mexico, New Zealand, and Switzerland expressed concerns as well. In its 2011 interventions, the United States continued to express concerns that the proposed size of the warning label in proportion to the size of the container would interfere with displaying legitimate trademarks and useful consumer information on alcoholic beverage containers, such as information necessary to distinguish one product from another. The United States also indicated that the requirement to rotate warning statements every 1,000 bottles could impose an onerous and potentially trade restrictive burden on producers, and was potentially unnecessary to achieve Thailand's objective of addressing the harms associated with alcohol consumption. In light of the scale of the proposed changes, the United States asked Thailand to lengthen the implementation period for the regulation.

Thai officials have indicated that an inter-agency subcommittee is examining the proposed regulation, which will submit recommendations to the Thai committee responsible for the approval process. Thai official have indicated that the regulation will not be implemented while it is under review. The United States will continue to monitor all developments related to this issue.

Food Additives

In August 2011, Thailand notified the WTO of new rules for food additives (*i.e.*, ingredients that preserve flavor or enhance taste and appearance) that would require food product labels to list all the additives and their percentages by weight. In comments delivered in October 2011, and during bilateral discussions with Thailand on the margins of the November 2011 TBT Committee meeting, the United States expressed concern that Thailand's requirement for producers to specify the percentage of each food additive would reveal proprietary information and is unneeded to ensure food safety. In addition, the United States highlighted that Section 4.2 and 5.1 of the Codex General Standard for the Labeling of Prepackaged Foods calls for food ingredients and additives to be listed by quantity only in certain cases, such as when they are featured on the product label, , not in all cases , as Thailand's measure appears to require. The United States will continue to work with Thailand during 2012 to resolve issues concerning its additive disclosure requirement.

Turkey

Bilateral Engagement

The United States discusses standards-related issues with Turkey during TBT Committee meetings and bilaterally on the margins of those meetings. The United States also discusses these issues in consultations through the U.S.-Turkey TIFA and in the newly established bilateral ministerial level Framework for Strategic Economic and Commercial Cooperation (FSECC). The FSECC is co-chaired on the U.S. side by the U.S. Trade Representative and the U.S. Secretary of Commerce and on the Turkish side by the Turkish Deputy Prime Minister and the Minister of Economy. The FSECC is designed to reinforce the work of several bilateral sub-cabinet level dialogues on economic matters (including under the USTR-led TIFA) and to provide political-level guidance on particularly challenging commercial and economic issues.

Medical Devices – Reimbursement and Regulatory Requirements

The United States has raised concerns over Turkey's 2010 medical device reimbursement regulation, Communiqué SUT 2010/16, which appears to add a duplicative regulatory burden requiring medical device producers to supply documentation to Turkey's Social Security Institute. Turkey asserts the additional documentation is needed for quality assurance purposes. If a medical device producer fails to comply, the Turkish government can respond by canceling all payments from the public health sector reimbursement system to the device manufacturer. It is unclear how the additional documentation will help provide assurances with respect to the quality of medical devices considering that Turkey's Ministry of Health, which oversees medical device safety and efficacy, does not require such documentation. In the March, June, and November 2011 TBT Committees meetings as well as in bilateral meetings, the United States urged Turkey to notify its new requirements to the WTO, to meet with industry stakeholders, and to eliminate or modify any documentation requirements that are not required to satisfy the requirements of Turkey's Medical Device Directive. Turkey has not yet responded to these requests, and the United States will continue to engage with Turkey on this issue in 2012.

Pharmaceuticals – GMP Decree

The United States has raised several concerns about Turkey's Ministry of Health "Regulation to Amend the Regulation on the Pricing of Medicinal Products for Human Use," which took effect on March 1, 2010. The regulation requires foreign pharmaceutical producers, as a condition of exporting their products to Turkey, to secure a Good Manufacturing Practice (GMP) certificate before their products can be certified for sale in Turkey. GMP certification is contingent on a physical plant inspection by Turkish authorities.

The United States has expressed concerns that Turkey did not publish or notify the regulation to the WTO nor initially identify any health or safety issue arising from imports from the United States or other countries that prompted it to discontinue accepting GMP certificates issued by foreign regulatory authorities, such as the U.S. Food and Drug Administration. U.S. industry also raised concerns about Turkey's inspection requirement, including the fact that numerous approvals are pending and Turkey may not have sufficient capacity to inspect all foreign manufacturing plants in a timely fashion. Given the apparent lack of inspection capacity, the

United States is concerned that the process for obtaining approval could take several years, effectively shutting U.S. pharmaceutical exports out of Turkey. In the March, June, and November 2011 TBT Committee meetings as wells as in bilateral meetings, the United States raised concerns over the new inspection requirement. The United States will continue to press Turkey to address U.S. industry concerns in 2012.

Vietnam

Bilateral Engagement

The United States discusses standards-related issue with Vietnam during TBT Committee meetings and on the margins of TPP negotiations, as well as through the bilateral U.S. – Vietnam TIFA Council, which meets regularly and serves as a forum for promoting increased technical cooperation activities. The United States also works with Vietnam in advancing standards and conformity assessment issues through APEC.

Alcoholic Beverages – Food Safety Regulations for Alcohol

In March 2010, Vietnam notified to the WTO a proposed regulation aimed at ensuring that alcoholic beverages are safe to consume. The proposed regulation lays out management and technical requirements for the raw materials used in processing alcoholic beverages, including chemical and microbiological parameters, heavy metals, food additives, and labeling requirements. The proposed regulation would also require a compliance certification stamp and impose new inspection and testing requirements for products covered by the regulation.

In May 2010, the United States submitted comments to Vietnam, expressing concerns with numerous aspects of the proposal, including the proposed maximum level for aldehydes in distilled spirits of 5 mg per liter of pure alcohol. Standards of identity for spirits in most international markets are based on raw materials and production processes, not the chemical composition of the product. As such, these standards typically do not contain limits on aldehydes. In its comments, the United States also raised concerns about other aspects of Vietnam's proposal and asked Vietnam for clarification on the compliance certification stamp requirement as well as the new inspection and testing requirements.

In response to U.S. concerns, Vietnam withdrew its proposed maximum level for aldehydes in most distilled spirits in December 2010, and vodka in March 2011. Vietnam also helped to resolve U.S. concerns by providing clarifications sought by the United States, including in regard to the process for obtaining testing and inspection certifications.

Conformity Assessment Procedures – Alcohol, Cosmetics, and Mobile Phones

During 2011, Vietnam issued a series of notices that appear to require new testing requirements on a diverse group of imported products, including spirits, cosmetics, and mobile phones. In addition, the notices appear to limit entry for covered goods to three sea ports and impose a consularization requirement (*i.e.*, requiring Vietnam's consulate in the country of export to approve all exports). The United States, along with a number of other trading partners have raised concerns with these measures directly with Vietnam and in the TBT Committee.

While Vietnam provided clarifications to the United States on some aspects of the new requirements, a number of questions remain unanswered, including the extent to which the notices impose new or additional conformity assessment procedures for imported products and the extent to which domestic products are subject to similar requirements. The United States also continues to raise concerns regarding the limitation on ports of entry and the unnecessary costs and delays the consularization requirements will impose on U.S. exporters. The United States continues to urge Vietnam to notify the conformity assessment procedures associated with this measure to the TBT Committee and follow the relevant transparency procedures.

XII. Appendix A: List of Commenters

Public comments received from:

1. Herbalife International of America, Inc.
2. National Electrical Manufacturers Association
3. Royal Thai Embassy
4. Yum! Restaurants International

XIII. Appendix B: List of Frequently Used Abbreviations and Acronyms

ANSI	American National Standards Institute
APA	Administrative Procedure Act of 1946
APEC	Asia Pacific Economic Cooperation
EU	European Union
FSCF	Food Safety Cooperation Forum
FSCF PTIN	Food Safety Cooperation Forum's Partnership Training Institute Network
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
MRA	Mutual Recognition Agreement
NAFTA	North American Free Trade Agreement
NAMA	Non-Agricultural Market Access
NEI	National Export Initiative
NIST	National Institute of Standards and Technology
NTTAA	National Technology Transfer and Advancement Act
NTB	Non-Tariff Barrier
NTE	National Trade Estimate Report on Foreign Trade Barriers
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
SCSC	Subcommittee on Standards and Conformance
SDO	Standards Developing Organization
SME	Small and Medium Size Enterprise
SPS	Sanitary and Phytosanitary Measures
TAA	Trade Agreements Act of 1979
TBT	Technical Barriers to Trade
TEC	United States – European Union Transatlantic Economic Council
TFTF	Trade Facilitation Task Force
TIFA	Trade and Investment Framework Agreement
TPP	Trans-Pacific Partnership
TPSC	Trade Policy Staff Committee
USDA	U.S. Department of Agriculture

USITC ..... U.S. International Trade Commission
USTR ..... Office of the United States Trade Representative
WTO ..... World Trade Organization