

2010 REPORT ON TECHNICAL BARRIERS TO TRADE

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I. Executive Summary

The *2010 Report on Technical Barriers to Trade (TBT Report)* is a new, 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 (conformity assessment procedures). These standards-related trade measures, known in World Trade Organization (WTO) parlance as “technical barriers to trade,” play an increasingly 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 small and medium sized enterprises (SMEs). Standards-related measures also enable governments to pursue legitimate objectives such as protecting human health and the environment and preventing deceptive practices. However, standards-related measures that are non-transparent, discriminatory, or otherwise unwarranted can act as significant barriers to U.S. trade. This report is intended to describe and advance U.S. efforts to identify and eliminate such barriers, which can also present particular challenges for SMEs that typically lack the resources to identify and address such barriers. The United States and other governments have a right to adopt and enforce measures to pursue legitimate objectives such as protecting human health and the environment and preventing deceptive practices. At the same time, it is appropriate to question standards-related measures that appear non-transparent, discriminatory, or otherwise act as unwarranted barriers to U.S. trade. The U.S. Government’s efforts to reduce and eliminate these barriers are fully consistent with pursuing legitimate objectives through standards-related measures.

The opening sections of this report present an overview of technical barriers to trade and the U.S. and international mechanisms for addressing them.¹ Section II provides 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 provides 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 describes the U.S. legal framework for implementing its standards-related trade obligations. Section V elaborates on 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 elaborates 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 describes 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 explains how the United States engages with its trading partners to address standards-related measures

¹ 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

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), the North American Free Trade Agreement's (NAFTA) Committee on Standards-Related Measures, and cooperative activities under the Asia Pacific Economic Cooperation (APEC) Subcommittee on Standards and Conformance. Section IX summarizes current trends relating to standards-related measures.

The heart of this report is Section X, which identifies and describes 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. The report identifies TBT measures in 20 countries or groups of countries: Argentina, Brazil, Canada, China, Colombia, Ecuador, the European Union (EU) and its Member States, the Gulf Cooperation Council (GCC) and its Member States, India, Indonesia, Israel, Japan, Korea, Malaysia, Mexico, Russia, Taiwan, Thailand, Turkey, and Vietnam.

II. 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's 2009 Trade Policy Agenda vowed an aggressive and transparent program of defending U.S. rights and benefits under the rules-based trading system as a key element in his vision to restore the role of trade in leading economic growth and promoting higher living standards. The President's Agenda also recognized that "behind the border" measures and other non-tariff barriers have grown in significance for U.S. exporters seeking access to foreign markets.

In a [major policy speech](#) delivered at the Edgar Thomson Plant of the Mon Valley Works in Pittsburgh, Pennsylvania in July 2009, the U.S. Trade Representative, Ambassador Ron Kirk, pledged more aggressive action to break down barriers to U.S. exports. Ambassador Kirk highlighted two kinds of non-tariff measures that pose increasing challenges to U.S. producers and businesses seeking to export products abroad: sanitary and phytosanitary (SPS) measures; and standards-related measures. Standards-related measures include government measures such as mandatory product standards and testing requirements. In the WTO, measures of this type are referred to as "technical barriers to trade" (TBT).

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

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

The *2010 Report on Technical Barriers to Trade (TBT Report)* serves these goals for standards-related measures. The *TBT Report* is a new, specialized report dedicated to significant foreign barriers in the form of product standards, technical regulations, and conformity assessment procedures (standards-related measures). These measures previously have been addressed in the *National Trade Estimate Report on Foreign Trade Barriers (NTE Report)*.² The *TBT Report* broadens and deepens these past efforts. 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. Accordingly, the *2010 NTE* itself does not contain information on these measures. A separate report addressing significant foreign trade barriers in the form of SPS measures (*2010 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. 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 barriers to trade. This general information is provided to give the appropriate context that will enable better understanding of the trade concerns and issues described in the last two sections of the report. 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.

² 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.

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 in international trade in some products, overall 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 and procedures to ensure that products and processes meet those requirements. The rise in importance of standards-related measures in international trade stems in large part from the 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 to ensure that producers and consumers can purchase components and end products from a wide variety of suppliers. These measures also enable more widespread access among producers to technical innovations. Standards-related measures can offer particularly pronounced benefits to small- and medium-sized enterprises (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.

However, 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 both to help producers comply with those requirements and to help goods flow across borders.

The rules, procedures, and opportunities for engagement that international, regional, and bilateral trade agreements provide establish 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 standards-related measures with specific trading partners. The disciplines of the TBT Agreement 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 disciplines in important ways. These agreements are described in more detail in Section III 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 foreign standards-related 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 on standards-related issues in many venues, including those established by U.S. FTAs and through regional and multilateral organizations, such as the WTO, Asia Pacific Economic Cooperation (APEC) and the Organization for Economic Cooperation and Development (OECD). USTR also regularly 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 standards-related measures and to reduce or eliminate unnecessary standards-related measures 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.

III. 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 standards-related 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, as well as help ensure that testing and other

procedures used to determine product conformance with applicable standards and technical regulations 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 disciplines regarding the development and application of those measures. For example, the TBT Agreement requires governmental standards-related measures to be developed through transparent processes and to be based on relevant international standards (where effective and appropriate), as well as prohibits standards-related measures that discriminate against imported products or create unnecessary obstacles to trade. The TBT Agreement also 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 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. (Arts.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.

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,” and take comments it receives from other Members into account. (Arts. 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 inquiries from other Members and interested parties. (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 in particular 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. Accordingly, the TBT Agreement requires every WTO Member to establish a national Inquiry Point that is able to answer all reasonable questions from other Members as well as interested parties concerning its proposed or existing standards-related measures, and provide relevant documents related to those measures, 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.

In addition, the TBT Agreement requires Members to afford other Members the opportunity to participate in the development of proposed mandatory standards-related measures. Members and interested parties can take advantage of those opportunities to help ensure that other Members' standards-related measures do not become unnecessary obstacles to trade.³ In particular, the TBT Agreement requires each WTO Member to publish a notice in advance that it proposes to adopt a technical regulation or conformity assessment procedure.⁴ 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.⁵ In 2009 alone,

³ Depending on the WTO Member's domestic processes, interested parties in other Members may participate directly in the 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.

⁴ 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.

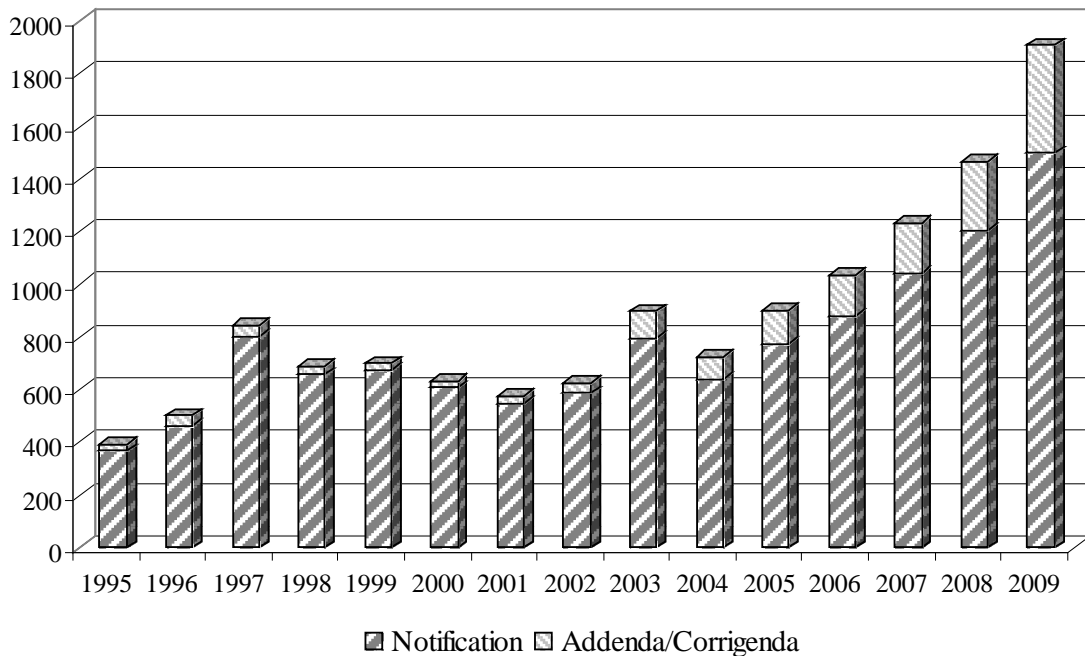
⁵ The obligations described in this paragraph apply to measures that have a significant effect on trade and are not based on relevant international standards, guides, or recommendations or in circumstances where relevant international standards, guides, or recommendations do not exist. In many instances, 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 1,490 new or amended technical regulations and conformity assessment procedures to the WTO. Box 3 shows the growth in notifications since 1995.⁶

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 and Rules of Origin, for example) that report to the WTO Council on Trade in Goods. The activities of the TBT Committee are described in detail below.

Box 3: Number of TBT Notifications to the WTO since 1995

Source: WTO,
G/TBT/28



⁶ 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).

Operation of the TBT Agreement

The TBT Agreement seeks to set out simple rules (including regarding transparency, nondiscrimination, use of international standards, and the avoidance of unnecessary trade restrictiveness) covering complex requirements (technical regulations, standards, and conformity assessment procedures) that are 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 relevant provisions of the TBT Agreement. Further, each WTO Member must inform the TBT Committee of the laws, policies, and procedures it has adopted to implement and administer the TBT Agreement.⁷

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 WTO Member's trade, regulatory, and standards officials are critical to ensuring that the WTO 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.

Further, when governments take account in developing standards-related measures how the products they propose to regulate are traded, it can make the measures they adopt more effective in fulfilling the objective of the regulation. 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 WTO 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 TBT obligations.⁸ 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. Recent Committee events have covered [Good Regulatory Practice](#), [Conformity Assessment](#), [Information Exchange](#), and the [Role of International](#)

⁷ See [G/TBT/GEN/1/Rev.8](#) for a list of Members submissions on the measures they have taken to implement and administer the TBT Agreement.

⁸ The results of the most recent triennial review are discussed in Section V.

[Standards in Economic Development](#). Planned events include the 6th Special Meeting on Information Exchange in June 2010 and a Workshop on Regulatory Cooperation in March 2011.

In addition to its triennial reviews and the special events and workshops it convenes in connection with those reviews, the TBT Committee meets three times a year. At these meetings, WTO Members may raise any specific trade concerns they have with standards-related measures that other WTO Members have proposed or adopted. The TBT Committee's discussion of specific trade concerns can serve to clarify the technical aspects of the measures concerned, promote greater understanding of how the measures might affect the trade of other WTO Members, and resolve the concerns that WTO Members have raised. In 2009, WTO Members raised 75 specific trade concerns in the TBT Committee, including, for example, concerns regarding measures relating to managing hazards arising from use of chemicals, conformity assessment systems for toys, and registration requirements for medical devices. Recently, WTO Members underscored the 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.⁹

Box 4 shows the number of specific trade concerns that WTO Members have raised in the TBT Committee since 1995. The rise in the number of concerns raised 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 standards-related 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. At recent TBT Committee meetings, roughly a third of the specific trade concerns that Members have raised related to measures of the European Union. Concerns regarding Chinese measures have been the second most frequently cited. In a few cases, concerns have remained on the TBT Committee's agenda for years, such as the European Union's regulation on the Registration, Evaluation, and Authorization of Chemicals (REACH), which was first raised in March 2003.¹⁰ Over this time, 33 Members have taken the floor at various TBT Committee meetings to voice trade concerns over REACH.¹¹ For a full accounting of the concerns raised in the Committee since 1995, see [G/TBT/28](#).

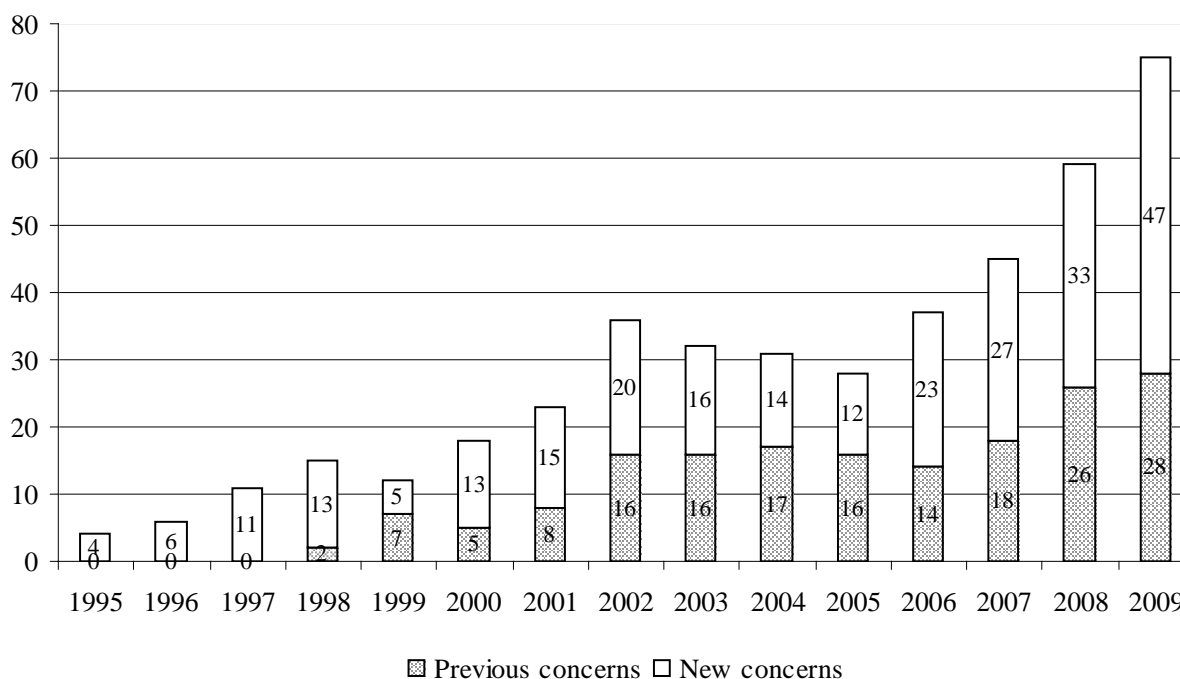
⁹ See the discussion of the Operation of the Committee in the “*Fifth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade under Article 15.4*” [G/TBT/26](#).

¹⁰ The process the United States uses to identify and raise issues in the TBT Committee is elaborated in Section VI.

¹¹ Specific trade concerns regarding REACH are addressed in Section X.

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

Source: WTO, G/TBT/28



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

In U.S. free trade agreements (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 For example, U.S. FTAs 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

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 concluded in 2003 or later. Pending FTAs with Panama, Korea, and Colombia contain similar TBT provisions. In addition to these FTAs, the North American Free Trade Agreement 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](#)).

addition, U.S. FTAs provide interested parties, as well governments, the opportunity to comment on proposed measures. This enables 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 afford their own testing and certification bodies. 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.

For example, by enhancing greater 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 alternatives before a measure is finalized. (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.) 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.

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*.¹⁴ 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 the section below on Standards.

¹⁴ 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.9](#), Part I, Section III (pp. 10-12) and Annex B (pp. 37-39).

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

The United States has negotiated free trade agreements 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, Morocco, Oman, and Peru. Pending FTAs with Panama, Korea, 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, 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>.

IV. 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 1947](#) (APA) and the [Trade Agreements Act of 1979, as amended](#) (TAA).¹⁵ 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 *Trade Agreements Act* 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 *Administrative Procedure Act* 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.¹⁶ In accordance with the APA, agencies publish proposed technical regulations and conformity assessment procedures in the *Federal Register* and solicit public comment. 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 of Management and Budget (OMB) [Circular A-4](#). E.O. 12866 lays out the philosophy, principles, and actions that

¹⁵ The standards-related provisions of the TAA are codified at [United States Code, Title 19, Chapter 13, Subchapter II, Technical Barriers to Trade \(Standards\)](#).

¹⁶The 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 of the regulatory processes and as a result help ensure that the United States fulfills key TBT Agreement and U.S. FTA obligations. GRP,¹⁷ 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, as well as the processes and procedures that give it effect, 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 by 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.

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 use¹⁸ voluntary consensus standards¹⁹ in their regulatory activities wherever possible and to avoid using "government-unique" standards.²⁰ The purpose is to discourage Federal agencies from developing their own standards where suitable voluntary consensus standards already exist and their use can effectively achieve the 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 the next section, international standards are those that recognized bodies (either

¹⁷ 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.

¹⁸ Circular A-119 defines "use" as the inclusion of a standard in whole, in part, or by reference in a regulation.

¹⁹ 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.

²⁰ Circular A-119 defines "government-unique standards" as standards developed by the government for its own uses.

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](#).

V. Standards

Voluntary standards serve a variety of functions and their use supports world trade, for example by ensuring 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 competition²¹ 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.²²

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.

To this end, 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

²¹ See [Standards & Competitiveness: Coordinating for Results: Removing Standards-Related Trade Barriers Through Effective Collaboration](#), International Trade Administration, 2005.

²² 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.

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.²³ The *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 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.²⁴ 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. Standards System](#).

ANSI accredits SDOs based on its [Essential Requirements](#). Many elements of these requirements mirror 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

²³ 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.9](#), Part I, Section III (pp. 10-12) and Annex B (on pp. 37-39).

²⁴ The U.S. experience with the *2000 Committee Decision* is described in [G/TBT/W/305](#).

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 organizations²⁵ 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 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.

VI. Conformity Assessment Procedures

Conformity assessment enables buyers, sellers, consumers, and regulators to have confidence that products sourced in global market meet specific requirements.²⁶ 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.²⁷

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.²⁸ 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 measures' conformity

²⁵ Source: NIST, 2008.

²⁶ 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.

²⁷ For an introduction to conformity assessment, see Breitenberg, Maureen, [*The ABC's of the U.S. Conformity Assessment System*](#), NIST, 1997.

²⁸ See Johnson, Christopher, [*Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures*](#), U.S. International Trade Commission Working Paper, 2008.

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.9](#).

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 conformity assessment activities. Pursuant to this statutory directive, NIST issued a *Federal Register* notice in 2000 providing [guidance to Federal agencies on conformity assessment](#). It 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. Today, the conformity assessment standards and guides published by ISO and IEC are known as the "CASCO toolbox."²⁹

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 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-

²⁹ ISO/CASCO is the standards development and policy committee on conformity assessment of ISO.

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.

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

The United States also 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 State, Agriculture and Commerce 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 Scientific and Technical Affairs (OSTA) 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, [NotifyUS](#), 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 2009, the TBT Notification Authority and Inquiry Point at NIST processed and distributed 155 U.S. government and industry comments to other WTO Members, and circulated 27 WTO Member comments on U.S. measures, as well as 67 WTO Member replies to U.S. comments, to relevant Federal agencies. NIST's service *NotifyUS* has over 5,000 registered users. U.S. stakeholders monitor notifications of new or revised measures of other WTO Members in sectors of interest through the *NotifyUS* 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.

The TCC administers the Department of Commerce's Trade Agreements Compliance Program and coordinates 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 TCC offers an online trade complaint hotline at www.trade.gov/tcc where exporters can report and obtain assistance in overcoming foreign trade barriers. The TCC helps assemble teams of specialists to investigate market access problems, including ones involving standards-related measures, and 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, TCC regularly provides input to the TPSC based on the information on the specific trade concerns that it collects and analyzes through this process. This information informs the TPSC's development of the appropriate U.S. position in the various multilateral and bilateral forums for addressing standards-related measures. On-the-ground assistance is also provided from Compliance Officers at U.S. Embassies in China, India, El Salvador, Japan, and at the U.S. Mission to the European Union in Brussels. Free, online tools include the texts of more than 270 non-agricultural trade agreements plus a checklist of the kinds of trade barriers that the Program can help exporters overcome.

OSTA provides a conduit for queries and comments on foreign standards-related measures in the agricultural sector. OSTA monitors developments in relevant export markets, provides information on foreign standards-related measures through a range of publications, disseminates WTO TBT notifications from foreign governments to interested parties, and provides translation services on key export market requirements. OSTA 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, FAS works through relevant international organizations to resolve 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 (ITAC and ATAC, respectively). The ITAC and the ATAC 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.³⁰

³⁰ See http://www.ustr.gov/Who_We_Are/List_of_USTR_Advisory_Committees.html.

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 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.

Indeed, the need for greater coordination and policy attention to emerging technologies is critical. On March 12, 2010, the Office of Science and Technology Policy and the Office of Management and Budget and USTR sent a joint memorandum to the heads of Federal departments and agencies announcing the establishment of a high level interagency group to serve as a point of coordination for identifying, and where appropriate, addressing cross-cutting issues relating to emerging technologies that affect multiple agencies. This group, the “Emerging Technologies Interagency Policy Coordination Committee” (ETIPC), will complement the work of the TPSC and the National Science and Technology Council (NSTC), by providing a forum for appropriate and timely consideration of a broad range of policy questions and to coordinate positions that Federal agencies may take when engaging on these issues internationally. The goals of the ETIPC are to ensure that U.S. policy capitalizes on the potential of emerging technologies for spurring economic growth and breaks down barriers that could stifle innovation.

VIII. 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 both 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 standards-related measures in U.S. FTAs also play a vital role in facilitating U.S. bilateral and regional efforts to prevent and resolve trade concerns. U.S. agencies also 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 (NDCP), and NIST. USDA's Foreign Agricultural Service (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 of divergences in technical requirements across markets, USTR 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 MRA to which the United States is a party 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 and examples of how they work.)

The United States also seeks to reduce foreign technical barriers by concluding "equivalency" arrangements with other governments. A recent example is the June 2009 [exchange of equivalency determinations](#) between USDA and Canada's Food Inspection Agency on organic agricultural products. As a result of that exchange, U.S. producers that a USDA-accredited agent has certified 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.

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 X.

TBT Committee

Specific Trade Concerns

The U.S. government actively seeks to prevent and eliminate technical barriers to trade through the TBT Committee, with its focused WTO Member-driven agenda. The Committee dedicates a significant portion of each of its three annual meetings to affording WTO 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 WTO 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.

In 2009, the United States raised specific trade concerns regarding 20 to 30 foreign TBT measures at each TBT Committee meeting held during the year 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, Country Specific Reports. As elaborated in the Country Specific Reports, U.S. interventions in the TBT Committee, and on its margins, have helped resolved a number of standards-related concerns affecting U.S. trade.

The Committee's annual review of its activities is contained in [G/TBT/28](#), and includes a thumbnail description of the specific trade concerns that WTO Members raised, as well as identifies the Members that raised them.

The Fifth Triennial Review of the TBT Agreement

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.9](#), which are intended to strengthen and improve the operation of the TBT Agreement. In November 2009, the TBT Committee completed its *Fifth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade Under Article 15.4*. Suggestions that the United States put forward for purposes of the review on regulatory cooperation, good regulatory practice, internal coordination, transparency, and international standards figure prominently among the Committee's recommendations in its report on the results of the review, which are set out in [G/TBT/26](#). The Committee also established an important and ambitious work program on conformity assessment in the report on the review. The report and its recommendations establish the focus of the TBT Committee's work program.

Regulatory issues featured prominently in the discussions under the review. The United States advocated for greater regulatory cooperation in a joint submission with its NAFTA partners ([G/TBT/W/317](#)). Regulatory cooperation is 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. The TBT Committee supported the proposal from the NAFTA countries, and agreed to hold a workshop to explore the variety of approaches to regulatory cooperation. The workshop is tentatively scheduled for March 2011. The Committee will be looking to use the workshop to identify whether there are avenues to promote greater regulatory alignment.

During the review, a U.S. submission on how to identify the need to regulate, [G/TBT/W/285](#), also factored into the TBT Committee’s discussions and recommendations as an important component of GRP discussions. Other Members showed significant interest in advancing work on GRP, with Brazil, Canada, China, Costa Rica, Jordan, Korea, Israel, and New Zealand submitting papers and comments relating to GRP issues. GRP carries the potential to help WTO Members: enhance their capacity for market surveillance; apply risk analysis in developing regulation; produce clarity in the definition of regulatory objectives; facilitate communication with industry and consumers; provide a basis for effective training; maximize the benefits of trade facilitation; and generally ensure policy integrity. Going forward, the TBT Committee will compile guidelines and discuss mechanisms for WTO Members to implement GRP.

In the course of the review, the United States also spearheaded in-depth discussions on the benefits and challenges of greater use of international standards. 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 March 2009, the Committee held a workshop on overcoming challenges and instituting best practices relating to the development and use of international standards to help firms in developing countries participate more fully in global markets. Experts from Peru, Pakistan, Brazil, Colombia, Chile, Egypt, and Kenya presented practical case studies illustrating how the use of international standards yielded positive economic benefits to their economies. Several developing country Members stressed 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.

Members also reaffirmed the importance during the review 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. 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. At the conclusion of the review,

the TBT Committee agreed to share experiences and examine more closely the ways in which Members implement both the *Code* and the *2000 Committee Decision*.

In previous triennial reviews, the Committee's work on conformity assessment focused on information exchange. In the course of those reviews, the Committee held several events addressing conformity assessment³¹ 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.9](#)). In the *Fifth Triennial Review*, 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.

Finally, during the *Fifth Review*, the Committee continued its focus on how Members are carrying out those provisions of the TBT Agreement that provide for Members to give notice and comment on proposed technical regulations and conformity assessment procedures. The TBT's notice and comment rules and the requirement for Members to take comments into account in finalizing the measure they notify are fundamental to preventing and minimizing unnecessary obstacle to trade. During the *Fifth Review*, Members discussed and reaffirmed the significant body of recommendations and decisions on these transparency procedures that the Committee had established in earlier reviews. In addition, reflecting the increase in standards-related regulatory activity of local governments (*e.g.*, at the state and provincial level) affecting trade, the Committee called for better coordination between central and local governments to improve Members' implementation of the TBT Agreement's transparency provisions.

APEC

In 1994, APEC³² established the Subcommittee on Standards and Conformance (SCSC) with the goal of better aligning the divergent approaches to standards and conformance issues that economies in the region have adopted. The SCSC works to reduce the negative impact of these divergences on trade and investment, as well as to facilitate increased market access through improved standards and conformance procedures. The SCSC seeks to improve these measures by promoting approaches that embody the APEC principles of market-driven interdependence

³¹ 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).

³² 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.

and open regionalism. The SCSC does not develop standards and does not support the use of regional standards. Rather, the SCSC seeks to encourage APEC economies to align their standards-related measures with international standards.

The SCSC is unique among inter-governmental forums in that it regularly brings together trade policy officials, representatives of national standards bodies, and other technical specialists³³ to advance standards-related goals through cooperation. Regulatory officials often participate in SCSC special events and initiatives. The SCSC often invites private sector representatives with specific expertise to participate in its special events. The United States has established several public-private partnerships to advance priority issues in the SCSC. These partnerships provide the SCSC with invaluable access to technical expertise and resources – and provide critical information on the practical realities that producers face in complying with technical regulations, and that governments confront in developing standards and using conformity assessment procedures.

The SCSC is a valuable forum for garnering support for policy priorities, conducting capacity building activities, and building consensus among APEC economies on standards-related measures. The Committee makes use of studies, surveys, workshops, training, and other events to achieve these objectives. The SCSC work is member-driven, with officials of different APEC countries working collaboratively to develop and implement projects and initiatives. These efforts are designed to promote greater alignment to international standards, pursue recognition arrangements for conformity assessments, encourage cooperation to develop “technical infrastructure,” and improve implementation of good regulatory practices, including through activities to promote greater understanding and cooperation on regulatory issues. The SCSC addresses both TBT and SPS issues.

Over the years, the SCSC has made important contributions to advancing progress and understanding on the trade aspects of standards-related matters, both in the region and internationally. In its work on conformity assessments, the SCSC has published reports and surveys on topics such as suppliers’ declaration of conformity, market surveillance, and the effectiveness of MRAs. The SCSC established a “Voluntary Alignment Program” that has identified priority areas for member economies to align their measures with international standards and monitored the progress of each economy has made in adopting international standards. The SCSC has also adopted a strategic plan for improving technical infrastructure that identifies capacity building priorities for each developing APEC economy in the areas of standards, accreditation, laboratory accreditation, metrology, and legal metrology.

The United States has led several important standards-related initiatives in APEC, including the APEC Toy Safety Initiative, the Partnership Training Institute Network (PTIN) of the Food Safety Cooperation Forum (FSCF), and the Strategy on Business Engagement in Standards and

³³ Representatives from the APEC “Specialized Regional Bodies” (SRBs) participate in the SCSC as technical experts. The five APEC SRBs are: the Pacific Area Standards Congress (PASC), the Asia-Pacific Metrology Program (APMP), the Pacific Accreditation Cooperation (PAC), the Asia Pacific Legal Metrology Forum (APLMF) and the Asia-Pacific Laboratory Accreditation Cooperation (APLAC). For a summary of work of the SRBs, see [“The Role of the APEC Specialist Regional Bodies: Elements of the Standards and Conformance Infrastructure”](#) March 2008.

Conformance. All three of these initiatives were developed and are being implemented as public-private partnerships. The United States also co-chairs the SCSC's Trade Facilitation Task Force (TFTF), which brings trade and technical experts together on a regular basis to share information and cooperate on product-related environmental standards-related measures. The United States recently co-sponsored a project led by Singapore on models of assistance in helping SMEs overcome technical barriers to their exports.

The APEC Toy Safety Initiative

Following high-profile incidents involving recalls of unsafe toys in 2007, APEC Leaders directed their officials to work to strengthen product safety standards and practices in the region without creating unnecessary obstacles to trade. The SCSC responded in 2008 by launching the U.S.-led APEC Toy Safety Initiative. Co-sponsored by the U.S. Toy Industry Association, the goals of the APEC Toy Safety Initiative are to strengthen toy safety, increase transparency, promote better regulatory alignment, and reduce unnecessary obstacles to trade that may arise as a result of toy safety systems. The Initiative sought to advance these goals through the “*Regulator Dialogue on Toy Safety*” held in Singapore in August 2009 and the *Survey of Toy Safety Regulators* delivered at the “*Open Dialogue on Toy Safety for All Stakeholders*” held in conjunction with the Hong Kong Toy Fair in January 2010.³⁴

The APEC Toy Safety Initiative was critical. First, of course, the safety of children is a paramount concern among APEC economies. Second, trade in toys is vital to prosperity in the region. APEC economies are home to 85 percent of the world's toy manufacturers and exporters. Further, technical requirements related to toy safety have been changing rapidly and these new requirements differ markedly across markets around the globe. In APEC alone, 11 of the 21 member economies had notified the WTO of changes to their regulatory practices regarding toys in the previous three years.³⁵ Further, over recent years WTO Members have increasingly raised trade concerns in the TBT Committee regarding new toy safety measures that other Members have proposed.

Chairman Inez Tenenbaum of the U.S. Consumer Product Safety Commission gave the keynote address to *Regulator Dialogue*, which brought together regulators from 20 APEC economies. Regulators from 10 economies provided detailed information on their regulatory schemes, and the leading technical experts from standards developing organizations discussed the similarities and divergences among three toy standards, ASTM F-963,³⁶ EN-71,³⁷ and ISO 8124. Five

³⁴ All of the agendas, presentations and reports on the APEC Toy Safety Initiative's activities are available on the website of the Toy Industry Association: <http://www.toyassociation.org>.

³⁵ WTO Members that have notified the TBT Committee of toy safety measures include Chile, China, Japan, Korea, Mexico, New Zealand, Peru, the Philippines, Taiwan, the United States, and Vietnam.

³⁶ ASTM International is non-governmental organization that develops voluntary standards for materials, products, systems, and services. ASTM-F963 is its *Standard Consumer Safety Specification for Toy Safety*.

³⁷ EN-71 is the European standard that specifies the safety requirements for all toys sold in the European market. EN-71 is developed by CEN, the European Committee for Standardization (Comité Européen de Normalisation).

economies presented information on their procedures for export inspections, compulsory certifications, pre-market inspections, and mandatory third party testing, and the role their customs authorities play in identifying unsafe toys.

A consensus emerged from the *Regulator Dialogue* that ensuring toys are safe is a responsibility that no single economy can undertake on its own, and that safety solutions must have global currency. Regulators agreed to consider ways to improve conformity assessment procedures for toys by strengthening and expanding dialogue on best practices with key stakeholders. Participants also concurred on the need to promote greater alignment of technical requirements, including by exploring ways to “expand the common set” of reference standards for toys and redoubling efforts to harmonize approaches to emerging hazards.

The *Open Dialogue on Toy Safety among All Stakeholders*, sponsored by APEC, the U.S. Toy Industry Association, and the Hong Kong Trade Development Council brought together officials from 19 economies³⁸ (11 served as speakers)³⁹ to discuss advancing trade in safe toys with representatives of consumer groups, manufacturers, retailers, standards organizations, and conformity assessment bodies. Keynote addresses affirming the commitment to seek to align toy standards were given by Chinese Vice Minister Wei of AQSIQ, CPSC Chairman Tenenbaum, and EU Consumer Commissioner Kuneva. The United States also presented the results of the *Survey of Toy Safety Regulators*, which showed the wide diversity of the regulatory regimes in the region. Eighteen of the 21 APEC economies mandate toy safety standards: 13 reference ISO 8124; 10 reference EN-71; and 7 reference ASTM F-963. (In some instances, APEC economies reference all three standards in their regulatory regimes.)

The APEC Toy Safety Initiative has advanced regulatory cooperation both within and beyond APEC, and helped to initiate relationships between regulators, standards experts, and stakeholders that will further the project’s goals. Regulators that participated in the Initiative agreed to continue this cooperation in other international organizations, and to collaborate in a project to identify successful market surveillance practices. The Initiative resulted in greater collaboration and coordination among the standards developers. ASTM and ISO pledged to support greater technical cooperation in developing toy standards and agreed to hold future joint meetings when possible.

In particular, ASTM International invited delegates to the ISO Technical Committee on Toy Safety (ISO TC/181) to attend and participate in reviewing proposed changes to ASTM F-963. Representatives from 17 countries, including some APEC economies, joined with members of the ASTM F15.22 committee on toy safety to explore enhancements to technical standards that could address potential toy hazards related to impaction, magnets, and projectiles. Further, the ISO Technical Committee on Toy Safety adopted a resolution to establish an advisory panel to determine priorities for the ISO Technical Committee that will facilitate increased cooperation

³⁸ Brunei Darussalam and Russia did not send representatives.

³⁹ Australia, Canada, China, Hong Kong, China, Indonesia, Japan, Malaysia, Mexico, New Zealand, United States, and Vietnam, plus European representatives from the European Commission, the ISO 8124 Technical Committee, Chairman of the CEN Technical Committee 52, and the World Trade Organization.

among toy standard setting bodies in the interest of promoting standards alignment and avoiding development of further divergences among major toy standards. Experts from CEN will participate in the advisory panel.

Partnership Training Institute Network of the Food Safety Cooperation Forum

Concerns about food safety in the Asia Pacific region have risen sharply in recent years and have spurred a collective mandate from APEC Leaders to improve food safety standards and practices in the region without creating unnecessary impediments 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.⁴⁰ The FSCF seeks to advance food safety and facilitate trade in safe food by addressing capacity building opportunities for APEC member economies in priority areas such as information sharing, food safety regulatory systems, and food inspection. In 2008, Leaders called for increased capacity building to improve technical competence and understanding of food safety management among stakeholders in the food supply chain, which include regulators, growers, packers, handlers, storage providers, processors, manufacturers, retailers, and food service providers.

The FSCF, co-chaired by Australia and China and composed of high-level regulatory officials responsible for food safety – including Dr. Steven Sundlof of FDA's Center for Food Safety and Nutrition and Dr. David Goldman of USDA's Food Safety and Inspection Service – set about to address this direction by identifying the capacity building priority needs in each developing APEC economy. The FSCF initiated 25 different capacity building activities, held in five cities across the region. In 2008, the United States in collaboration with the Grocery Manufacturers Association and the Joint Institute for Food Safety and Nutrition (JIFSAN) of the University of Maryland, spearheaded the establishment of the Partnership Training Institute Network under the FSCF (FSCF PTIN) to combine the expertise and resources of industry and academia to strengthen and augment the FSCF's efforts in addressing the capacity building needs in the region. The FSCF PTIN initiative was endorsed by APEC Leaders in 2008, launched in July 2009, and has now entered the implementation phase.

The goal of the FSCF PTIN is to facilitate trade and protect public health by building the capacity of stakeholders in the food supply chain to use international standards and best practices in food safety management from production to consumption. To this end, the FSCF PTIN will help APEC economies anticipate, prevent, and manage food safety incidents, and thus better assure the safety of the food supply chain in the APEC region. The FSCF PTIN will seek to fulfill this goal by creating a network of food safety institutes, trainers, and practitioners in the APEC region. This network will communicate and exchange scientific and technical information related to food safety, as well as strengthen and expand food safety management training by developing a set of curricula and training tools that support the use and understanding of international standards and best practices.

⁴⁰ The FSCF covers both SPS and TBT issues. For convenience, the activities of the FSCF are included in the *2010 TBT Report* rather than *2010 SPS Report*.

The FSCF PTIN will support training on food safety in a manner consistent with the rights and obligations of the WTO SPS and TBT Agreements. The FSCF PTIN is not intended to be an actual “bricks and mortar” facility, but instead will build on existing resources in the region to create a network of institutes with the capacity to conduct training in international best practices in food safety. FSCF PTIN training programs will draw on expert faculty and experienced practitioners from academia, industry, consulting firms, and government agencies.

Business Engagement in Standards and Conformance

The SCSC has long recognized the importance of the engagement of business and industry stakeholders from APEC economies on key topics in order to enhance cooperation on standards-related measures and facilitate trade in the region. By working together, policy makers, standards developers, and business leaders can maximize the positive contribution that standards and conformance procedures make in promoting trade and investment in the region. When APEC economies use market-relevant international standards and conformance procedures they help to expedite trade transactions, reduce costs, encourage broader product acceptance, and promote greater integration of supply networks. The SCSC seeks to promote greater participation by APEC economies in international standardization activities to ensure that the international standards adequately reflect the region’s trade interests. Moreover, when those standards take into account the market considerations in the region, APEC economies will be more likely to adopt them, and result in greater alignment of technical requirements in the APEC region.

The SCSC is seeking through this initiative, co-led by Vietnam and the United States, to develop a long term strategy to increase business involvement with the SCSC in support of these goals. In August 2009, business and industry representatives with expertise in standards and conformity assessment joined the SCSC to discuss potential areas for facilitating trade in the region through on-going cooperative activities. Participants discussed current engagement by APEC economies in developing standards for such products as smart cards, Information Technology (IT)-based vehicle control logic for intelligent transport systems, and mobile technologies for e-commerce, as well as product safety design in IT products.

Participants stressed how important it is for governments to establish market relevant conformity assessment procedures and for businesses to develop strategies to monitor and comply with emerging technical regulations. The SCSC convened a Conference on Business Engagement, co-sponsored by ANSI, the U.S. Chamber of Commerce, and the National Association of Manufacturers. Mr. Teng Theng Dar, 2009 Chair of the APEC Business Advisory Council and CEO of the Singapore Business Federation, provided the keynote address. The Conference resulted in over 50 recommendations to the SCSC for possible future collaboration with businesses in the APEC region to promote further progress on ensuring trade-facilitative approaches to standards and conformity assessment procedures in the region.

Trade Facilitation Task Force (TFTF)

The proliferation and diversity of product-related environmental regulations, particularly those of the European Union, prompted the need for an APEC forum to promote information exchange

and cooperation to reduce the potential adverse trade impact on APEC economies of these emerging technical requirements. In 2006, the SCSC established the Trade Facilitation Task Force (TFTF). The TFTF, co-chaired by Korea and the United States, brings together trade and technical experts to exchange information on specific trade concerns affecting APEC economies (whether imposed by other APEC economies or countries outside the APEC region) and to promote cooperation in international standardization activities associated with product-specific environmental regulations. Experts from industry, academia, international or regional bodies, and other relevant authorities participate in TFTF activities.

In February 2009, the TFTF met in Singapore to exchange information and promote cooperation on several topics. First, the TFTF reviewed technical work on standards under way in various standardizing bodies, such as IEC and ASTM International, to help producers implement and comply with material declaration aspects of product-specific environmental regulations (such as the EU Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), the EU Directive on Energy Using Products (EuP), and EU REACH.) The TFTF also explored new areas of work including trade and technical aspects of current work related to carbon emission estimation and sustainability.

Carbon footprinting is one method that can assist governments, industry, and consumers in promoting the use and development of low carbon products. During the TFTF meeting, experts from government, academia, and standards organizations exchanged information on the methodological and conceptual challenges involved in developing estimates of a product's "carbon footprint." The TFTF also discussed the challenges associated with carbon footprint labeling programs – particularly difficulties relating to comparability of estimates across products and to the ability to communicate complex information to consumers in an understandable, reliable, and concise form.

The TFTF also reviewed the status of international standardization activities related to carbon footprinting, such as through ISO TC 207/SC7/WG2 (an ISO working group that develops standards addressing greenhouse gas management in the value or supply chain). Participants noted that few APEC economies have been involved in these activities to date, and questions were raised regarding the representation of trade perspectives in this work and the potential implications for the market relevance of the standards being developed.

The TFTF also regularly collaborates with experts from the APEC Chemical Dialogue Steering Group and the APEC Energy Working Group's Expert Group on Energy Efficiency and Conservation on work underway in those bodies related to regulatory practices and standards development.

Export Assistance Models for Small and Medium Sized Enterprises (ETAM)

Businesses, in particular SMEs, that seek to export overseas, often face difficulties in learning about and understanding foreign regulatory requirements applicable to their products. Finding effective ways to assist SMEs overcome TBTs as they seek to export is a priority for the United States. Accordingly, the U.S. Department of Commerce took on a leadership role in co-sponsoring an initiative that Singapore is leading in the SCSC to study the existing models in the

various APEC economies for providing this type of assistance, with a view to gaining insights into working models and learning best practices to inform policy makers in all APEC economies. U.S. programs to assist SMEs will be featured in the final report of this initiative. Many APEC economies have launched initiatives to help their businesses address this problem. Singapore would also like to help develop a network of APEC member agencies that provide these services to share information and work together, especially when dealing with new and existing technical regulations in major export markets around the world. The SCSC will review this study and develop recommendations in 2010.

North American Free Trade Agreement

Under NAFTA, the parties established the CSRM and related subcommittees. This forum is an important venue for discussing standards-related matters affecting North American trade. In addition, the three NAFTA governments have long acknowledged the positive effects of improved trilateral regulatory cooperation, which acts to lower costs for North American businesses, producers, governments and consumers; maximize trade in goods and services across North American borders; and protect health, safety, and the environment. In March 2005, the Leaders of Canada, Mexico and United States launched a Regulatory Cooperation Framework (RCF) in the context of the Security and Prosperity Partnership of North America, with three general goals: (1) to strengthen regulatory cooperation, including at the outset of the regulatory process; (2) to streamline regulations and regulatory processes; and (3) to encourage compatibility of regulations, promote the use or adoption of relevant international standards in regulations, and eliminate redundant testing and certification requirements, consistent with each country's WTO obligations. While the work of the RCF extends beyond standards-related measures, many key areas of the RCF's work concern or relate to standards-related measures.

Under the RCF, the United States, Canada, and Mexico agreed to a set of common regulatory principles to guide North American regulators as they develop regulations.⁴¹ These common principles are rooted in WTO rules and mirror closely OECD principles. They include minimizing the adverse impact of regulations on fair and competitive market economies; minimizing unnecessary duplicative requirements within North America; identifying alternatives to addressing public policy objectives, including non-regulatory options; and ensuring that regulations are developed and implemented in a transparent fashion. The three governments also established a list of illustrative "best practices" that provide concrete guidance, in each of the three countries, on how to achieve these common principles.⁴² These best practices encompass government efforts to streamline the regulatory process, increase the use of regulatory impact assessments, and improve transparency through effective public consultations throughout the rulemaking process.

In addition, the NAFTA governments established a trilateral forum on Regulatory Impact Analysis (RIA)⁴³ under the RCF, which brings together regulatory policy experts from the three

⁴¹ See http://www.spp.gov/docs/RCF_Common_Regulatory_Principles_Inventory_Best_Practices_FINAL.doc.

⁴² Ibid.

⁴³ For an explanation of regulatory impact analysis, see OECD. *Regulatory Impact Analyses: Best Practices in OECD Countries*. Paris: OECD, 1997.

countries to strengthen their collaboration on procedures, practices, and tools that underpin new regulatory proposals. In 2008, this forum undertook a trilateral review of an existing U.S. Department of Transportation RIA on electronic stability control for motor vehicles, allowing Canada and Mexico the opportunity to provide comments on the analysis. This joint pilot project also allowed representatives from regulatory agencies and departments, as well as representatives from federal agencies in the three governments that are responsible for regulatory policy in the three countries, to discuss the similarities and differences between the analyses and methodologies each country applies in developing regulations. The participants found the discussion to be highly instructive and the three governments intend to pursue similar reviews in the future. The United States believes that this type of analytical work and dialogue are key for developing compatible approaches to technical regulations.

In the food and agricultural sector, the United States, Canada, and Mexico have been working together for many years to improve sector-related product regulations and practices. The three governments have established NAFTA technical working groups (TWGs) to address issues such as food labeling and packaging. TWGs and forums such as the North American Biotechnology Initiative play a significant role in enhancing regulatory cooperation in this sector, in particular through collaboration on a wide range of regulatory projects. One such project, for example, sought to enhance cooperation between the three countries regarding food laboratories by: (1) establishing a procedure to share information on laboratory methods; (2) exchanging information on proficiency testing programs in each country; and (3) identifying gaps where programs are not available. In another project, the three countries have agreed on a harmonized approach to the scientific basis they use to update dietary reference values for labeling food products.

The United States, Canada, and Mexico are also undertaking several joint activities with the goal of reducing air pollution and greenhouse gas emissions from vehicles and engines and ensuring that significantly cleaner vehicles and fuels are marketed throughout North America while enhancing regulatory cooperation among the three countries. The three governments have shared information on policies and programs on standards for vehicle fuel efficiency, standby power consumption, and the potential for natural gas to support optimal energy use for the future. The three governments undertook a comprehensive analysis of various emissions inventories of the three countries to prepare a trilateral strategy to make them more compatible. Additional areas for future cooperation could include activities such as exchanging of information on vehicle and engine testing, as well as sharing information on developing and using voluntary partnerships to reduce in-use fleet emissions.

The United States, Canada, and Mexico have also collaborated to enhance auto safety, guard against vehicle theft, and promote fuel economy. The three countries are also working towards harmonizing regulations and streamlining the regulatory process for the auto sector in order to help the North American auto industry remain competitive. Specifically, the U.S. Department of Transportation (DOT) and Transport Canada (TC) signed a bilateral Memorandum of Cooperation (MOC) in the area of motor vehicle safety regulation. The Mexican Ministry of Communications and Transportation and Ministry of Economy have agreed to commence negotiations to join in this effort and conclude a trilateral North American MOC.

The United States, Canada, and Mexico have also developed a trilateral approach to apply the results of ongoing efforts to: (1) assess, prioritize, and take appropriate action on existing

chemicals in the United States; (2) update information on inventories of such chemicals in Canada's Chemicals Management Plan; and (3) assist Mexico in developing a chemical inventory. The objective of this work is to achieve the following by 2020: (1) establishing or updating inventories of chemicals in commerce in all three countries; (2) enhancing capacity in Mexico to assess and manage chemicals; and (3) achieving sound management of chemicals in North America as articulated by the World Summit on Sustainable Development Johannesburg Plan of Implementation and reinforced by the Strategic Approach to International Chemicals Management. These efforts are designed to contribute to improving regulation to protect human health and the environment, while avoiding unnecessary obstacles to trade, through a practical and focused approach to strengthen chemical management in North America over the long term.

In July 2007, the three countries also concluded an agreement on energy science and technology – a framework designed to stimulate innovation and to share and help build capacity in all three countries. Ministers emphasized that developing cleaner and more efficient ways to produce and use conventional energy and advancing knowledge of renewable energy, science, and technology were fundamental to increasing energy security, sustaining economic prosperity, and protecting the environment, and that greater regulatory cooperation increased the potential return on investment in energy science and technology.

The three NAFTA countries have also harmonized their energy efficiency performance standards for freezers and refrigerators, three-phase motors, and room air conditioners as part of a larger effort under the RCF to systematize energy efficiency harmonization among the three countries. The three governments have also held workshops on Standby Power and Transportation Efficiency. The NAFTA governments are also committed to further aligning their energy efficiency standards on key consumer products, and identifying specific ways to increase cooperation on research and development and to reduce barriers to deployment of new technologies in a wide variety of areas, including biofuels, gas hydrates, hydrogen, carbon capture and storage, clean coal, and electricity transmission.

In short, the NAFTA approach to regulatory cooperation emphasizes the importance of regulatory alignment (including reduction of regulatory inconsistencies and redundancies), administrative simplification, and the use of practical, science- and risk-based tools, to attain critical health, safety, environmental, and security goals in a way that avoids unnecessary obstacles to trade. Such an approach enables the NAFTA partners to attain their legitimate regulatory objectives while reducing rather than increasing the burden on businesses and consumers.

Doha Round Negotiations Regarding Standards-Related Measures

The United States has tabled three proposals in the WTO's Doha Round of Trade Negotiations on Non-Agricultural Market Access (NAMA) aimed at reducing standards-related non-tariff barriers (NTBs). These proposals cover: (1) textiles, apparel, footwear, and travel goods (TAFT);⁴⁴ (2) electronic goods;⁴⁵ and (3) automotive goods.⁴⁶ WTO Member "senior officials"

⁴⁴ Understanding on the Interpretation of the Agreement on Technical Barriers to Trade with respect to the Labelling of Textiles, Clothing, Footwear, and Travel Goods (TN/MA/W/93/Rev.1, 15 September 2009).

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.⁴⁷

Each of the three proposals seeks to facilitate trade in specific sectors for which U.S. industry has expressed particular concern about standards-related NTBs. For example, the TAFT proposal grew out of U.S. industry concern that the differing approaches that WTO Members take to labeling requirements and sudden changes in those requirements can impose substantial costs and burdens on producers and delay time to market for these products, which are often seasonal. In many cases, these costs are then passed on to importers and consumers. The three proposals aim to build on existing TBT Agreement disciplines to create new or enhanced disciplines for these specific sectors in areas such as transparency, good regulatory practice, international standards, and conformity assessment procedures, while at the same time ensuring that regulators retain the ability to meet legitimate policy objectives, such as protecting health, safety, and the environment, at levels they consider appropriate.

The U.S. NAMA proposals contain a number of provisions similar to the standards-related provisions of U.S. free trade agreements. In particular, the U.S. proposals seek to ensure that U.S. exporters and other relevant stakeholders have the right to participate on a non-discriminatory basis in the process by which other WTO Members develop standards-related measures. The proposals would guarantee these stakeholders a right to submit comments on proposed measures (including voluntary standards that central government bodies develop), to have other WTO Members take their comments into account, and to see a response to their comments no later than the date the WTO Member publishes the final measure.

The U.S. autos and electronics proposals also contain provisions to encourage standardizing bodies in the territories of WTO Members to develop standards in accordance with principles designed to ensure that they are globally and technically relevant and that the processes these bodies use to develop them include a meaningful opportunity for U.S. exporters and other stakeholders to participate. The proposals would do this by directing WTO Members to base their decisions on whether a standard is "international" on whether the body that developed the standard did so in accordance with the six principles of the *2000 Committee Decision* discussed in Section V of this report.

The autos and electronics proposals also seek to require WTO Members to provide national treatment with respect to the criteria and procedures they use to accredit or otherwise approve conformity assessment bodies to test and certify products for their markets and to accept test results performed by competent facilities outside a WTO Member's territory. In addition, the autos and electronics proposal would require WTO Members to review their existing technical

⁴⁵ Agreement on Non-Tariff Barriers Pertaining to the Electrical Safety and Electromagnetic Compatibility (EMC) of Electronic Goods (TN/MA/W/105/Rev.2, 15 September 2009).

⁴⁶ Agreement on Non-Tariff Barriers Pertaining to Standards, Technical Regulations, and Conformity Assessment Procedures for Automotive Products (TN/MA/W/120, 15 September 2009).

⁴⁷ 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.

regulations and conformity assessment procedures in these sectors at regularly-scheduled intervals and ensure that they have adequate domestic procedures in place to review the actions their regulators take in applying technical regulations and conformity assessment procedures in these sectors.

In addition, the U.S. autos and electronics proposals would require WTO Members that are preparing or proposing to adopt a technical regulation or conformity assessment procedure to consider the costs of complying with the proposed measure, recognizing that considering the cost of compliance can both inform Members' regulatory analyses and help them ensure that the requirements they adopt do not create unnecessary obstacles to trade. Further, the U.S. autos proposal would require Members to assess, when they prepare or propose to adopt a technical regulation or conformity assessment procedure, whether regulatory and non-regulatory alternatives are available.

The provisions in the U.S. proposals to enhance transparency, good regulatory practice, and reliance on the *2000 Committee Decision* principles seek to help U.S. stakeholders influence the development standards-related measures in WTO Member countries in ways that minimize their effect on trade. These provisions also promote greater alignment of standards-related measures across WTO Members. If adopted, these provisions will help ensure, for example, that as regulators in various WTO Members develop standards-related measures to address common problems, stakeholders have the opportunity to provide relevant information and to advocate for solutions that are consistent across jurisdictions (*e.g.*, that rely on a common standard or conformity assessment approach). These provisions also help hold regulators accountable by requiring them to take into account and respond to such comments. These provisions will increase the likelihood that regulators in different countries will reach similar conclusions, such as on the risks associated with a particular product and appropriate measures to mitigate those risks, and develop and adopt more efficient and effective measures.

In addition to these provisions, the U.S. TAFT proposal seeks to facilitate trade in textiles, apparel, footwear, and travel goods through provisions that would promote greater alignment of labeling requirements, which should, in turn, reduce costs for suppliers, exporters, and consumers. The proposal would promote greater alignment of labeling requirements by presumptively deeming that certain types of labeling requirements (such as requirements to include care instructions or fiber content on a label) comply with the TBT Agreement's rule that technical regulations should be "no more trade restrictive than necessary to meet a legitimate objective" and by prohibiting other requirements (such as requirements for labels to be certified or made of certain materials). The proposal would also encourage Members to use non-permanent labels. Under the proposal, regulators would retain their ability to require information on permanent labels needed to inform and protect consumers (*e.g.*, flammability information on labels for children's sleepwear).

The U.S. proposal on electronic goods seeks to commit WTO Members to one of two forms of conformity assessment procedures in the areas of electrical safety and electro-magnetic compatibility – third party certification or a suppliers' declaration of conformity. The proposal would establish disciplines for both types of procedures that ensure, for example, any product

testing a Member requires can be performed in the exporting country and that U.S. testing and certification bodies are treated no less favorably than equivalent bodies in other WTO Members.

Finally, the U.S. proposal on automotive products seeks to encourage Members to (a) participate in the work of international standardizing bodies as a way of harmonizing technical regulations and conformity assessment procedures for those products; (b) consider other Members' automotive technical regulations and conformity assessment procedures when they determine that there is a need to regulate and explain any proposed deviations in substance from relevant international standards; and (c) provide at least 18 months for producers to comply with a new technical regulation that would require substantial change in automobile design or technology.

Organization for Economic Cooperation and Development

The OECD is an organization comprising 30 governments that seeks to support sustainable economic growth, boost employment, raise living standards, maintain financial stability, assist other countries develop economically, and contribute to growth in world trade. As part of its [work program on non-tariff barriers to trade](#), the OECD conducts a variety of activities and studies to deepen understanding of the nature and magnitude of the trade effects that standards-related measures can produce. The United States actively supports this research by facilitating the exchange of information between U.S. and OECD experts through papers, discussions, and workshops. The OECD Secretariat has work underway or recently completed on several TBT topics.

The OECD is currently looking at the extent to which WTO Members use relevant international standards when they establish technical regulations, as the TBT Agreement generally requires. The Secretariat is also pursuing work in the area of product labeling, where government requirements have grown more complex and divergent in recent years with potentially negative implications for trade. Other recent current studies include an assessment of trade problems related to the use of conformity assessment procedures and a comparison of TBT provisions in regional trade agreements. The OECD also regularly holds workshops on the nexus of trade policy and standards-related activities.

IX. Trends

The U.S. government actively seeks to prevent and eliminate technical barriers to trade through a variety of venues and on many levels. Previous sections of this report reviewed U.S. government engagement in bilateral and multilateral venues on specific trade concerns and on systemic issues. Section X provides a summary of the specific concerns of the United States with standards-related activities in specific countries or groups of countries. This section reviews trends that appear across various U.S. trading partners' markets as well as trends, or systemic issues, observed within a single trading partners' market. These trends concern standards-related measures or policies that can significantly affect the ability of U.S. businesses and producers to access foreign markets.

European Union's Approach to Standards and Conformity Assessment

Several years after the completion of the 1992 European single market initiative, the European Commission announced its intention to encourage its trading partners to adopt standards and regulatory approaches based on, or compatible with, European practice.⁴⁸ The European Commission noted in a 2007 strategy paper submitted to the European Council and Parliament that its single market can act as a global standard setter to enhance the competitiveness of European industry. This strategy paper recommended that the EU “promote greater global regulatory convergence – including where appropriate the adoption of European standards – internationally through international organizations and bilateral agreements.”⁴⁹ This section lays out several ways in which the European Commission promotes European standards and how this provides an advantage to European industry.

One way the EU promotes use of European standards is through its New Approach Directive. Under the EU New Approach, the European Commission requests European standards bodies CEN, CENELEC and ETSI⁵⁰ to develop standards to meet “essential requirements” of various other EU directives. Non-EU persons cannot vote in the CEN and CENELEC technical committees. These EU directives then identify CEN, CENELEC or ETSI standards that, if complied with, create a “presumption of compliance” with the essential requirements of the corresponding EU directive.

While the New Approach allows other standards to be used to meet essential requirements, U.S. producers report that in practice the costs and uncertainty associated with not using a CEN or CENELEC standard⁵¹ and attempting to demonstrate that their use of alternative standards will fulfill the essential requirements can be prohibitive. As a result, U.S. producers often feel

⁴⁸ European Commission, "Community External Trade Policy in the Assessment" (COM(96)564 final, 13.11.96), Jan. 13, 1997, p. 1.

⁴⁹ Commission of the European Communities, “Communication from the Commission to the Council, The European Parliament, The European Economic and Social Committee and the Committee of the Regions: A Single Market for Citizens,” COM (2007) 60 Final, Brussels, 21.2.2007, p. 7.

⁵⁰ CEN – the European Committee for Standardization – and CENELEC– the European Committee for Electrotechnical Standardization – are the two primary European standardizing bodies. ETSI, the European Telecommunications Standards Institute, a recognized body, operates differently than CEN and CENELEC.

⁵¹ An example of the costs and uncertainties with using non-European standards is U.S. stakeholders’ experience with the EU [Pressure Equipment Directive \(97/23/EC\)](#). The PED provides a presumption of compliance with the PED’s essential requirements for products that conform to certain CEN standards; products that conform to other standards do not enjoy that presumption. Under the PED, a producer seeking to use other standards has two options: (1) obtain a “particular material appraisal” (PMA) from the Commission indicating that when a particular manufacturer uses a particular material in a particular product it meets the relevant PED essential requirement; or obtain a European Approval of Materials (EAM) indicating that when any pressure equipment is made of a particular material by any manufacturer it meets the relevant PED essential requirements. However, industry reports that both options demand significant time and resources. Moreover, PMAs are limited to a particular manufacturer’s use of a particular material in a particular product and, while EAMs apply more broadly, they are difficult to obtain in practice *inter alia* because they include review by the Member States. In the case of the PED, industry estimates that only about a third of industry EAM applications have been approved through 2008.

compelled to use the relevant CEN or CENELEC standard for products they seek to sell on the EU market.

However, because non-EU persons cannot vote in the CEN or CENELEC technical committee, when a U.S. producer uses a CEN or CENELEC standard it may be using a standard that has been developed through a process in which it had no meaningful opportunity to participate. This is particularly the case for SMEs and other companies that do not have a European presence. The opportunity for U.S. stakeholders to influence the technical content of EU directives setting out essential requirements (*i.e.*, technical regulations) is also limited. This is because when the EU notifies proposed directives containing essential requirements to the WTO, the EU does not identify the specific CEN or CENELEC standards for which the presumption of compliance will be given. As a consequence, U.S. stakeholders often do not have the opportunity to comment on critical technical elements of proposed technical regulations and conformity assessment procedures contained in EU directives.

The EU also promotes adoption of European standards in other markets – and often requires the subrogation of non-EU standards to EU standards as a condition of providing assistance to, or affiliation with, other countries – which can give EU companies commercial advantages in those markets. The EU and some Member States have established standards initiatives as part of foreign-aid programs. European entities promote the use of EU directives and European standards to developing countries through technical training. European entities are known to link provision of technical assistance to the adoption of European standards and legislation. At a recent TBT Committee workshop on standards, one developing country stated that the EU had conditioned roughly 2 million Euros in technical assistance on the country's adoption of 10,000 European standards.

The EU promotes European standards through its use of Partnership Standardization Body (PSB) agreements with national standards bodies. Negotiated by CEN and CENELEC with their counterpart organizations in developing countries that have an FTA or other links with the EU, such agreements provide developing country standards authorities with free access to European standards but oblige them to use those standards and delete any standards that conflict with such standards from their national codes. The deleted standards can be standards that U.S. producers use and that may be of equal or superior quality to the CEN or CENELEC standards that replaced them. U.S. producers would then need to choose between the cost of redesigning or reconfiguring the product or exiting the market. CEN has 20 affiliate members, while CENELEC has eleven, including the national standards bodies Israel, Turkey, and the Ukraine. U.S. companies report that European standards are incorporated into other countries' legal codes, affecting U.S. exports to those markets as well.

The EU strategy is evident in its influence on the development of international standards and guides as well. Through the Vienna Agreement between CEN and ISO and the Dresden Agreement between CENELEC and IEC, the EU is able to bypass a portion of the deliberative and consensus building processes that generally characterize translation of new standards proposals into international standards through ISO and IEC. For example, when standards are developed through those agreements with a CEN or CENELEC lead, the CEN and CENELEC technical committees do not need to submit their standards to ISO and IEC for a vote until the

standards reach the “draft International Standard” stage – at which point it is often difficult to make substantive changes to the standard. If the parallel ISO or IEC committee disagrees with the technical content of a draft standard, the CEN or CENELEC technical committee may choose to develop a regional standard rather than participate in technical work of ISO or IEC.

In some instances, this choice may influence ISO and IEC technical committees to agree to develop standards under the Vienna and Dresden Agreements. It can also dampen opposition to provisions of CEN or CENELEC-drafted standards by non-EU members of the ISO and IEC technical committees when those provisions eventually come before those committees for review and voting. For example, after a French ride-on lawnmower standard failed to gain support in ISO, France sought to have the standard developed in CEN. The United States has expressed concerns with this standard, including its deviation from standards used in the United States and other EU Member States. (See the European Union Country Report in Section X for further details on concerns the United States has raised with respect to the French lawnmower requirement.) Similarly, the ISO technical committee on nanotechnologies, TC229, agreed to develop jointly a nanotechnology labeling standard that some committee members believed was unnecessary because the alternative was that CEN would develop the standard on its own.

Even where a standard is not developed through the Vienna or Dresden Agreements, the participation of 27 EU Member States can result in the EU having greater influence in ISO and IEC technical committees than other countries. This influence can facilitate the incorporation of EU standards and technical requirements into ISO and IEC standards. To counter this regional influence, ISO and IEC have in recent years adopted policies to promote the “global relevance” of their standards. Under this policy, the technical content of ISO and IEC standards should be able to be implemented anywhere in the world, and not give preference to the characteristics of a particular country or region. The adoption of these global relevance policies should help ensure that ISO and IEC standards support global trade and do not create trade barriers. In some instances, however, implementation of global relevance policies at the technical level, particularly with respect to the incorporation of “essential differences,” has been inadequate.

For example, several IEC standards for wireless devices contain provisions accounting for differences in the electrical infrastructures of several EU Member States. However, U.S. producers report that their proposals to modify these standards to take into account the electrical infrastructures of countries outside the EU were not supported by European members of the relevant technical committees. As a result, U.S. and other non-EU competitors in the electrical equipment business cannot claim that their products comply with the IEC standards or utilize the IEC CB scheme.⁵² Compliance with IEC standards can give companies a competitive advantage in emerging markets that are developing electrical infrastructure and regulations to support that infrastructure. In a few cases, U.S. producers report that EU companies have urged other countries to adopt these IEC standards and to delete the standards used by U.S. companies from their national codes, which could push U.S. products out of those markets.

⁵² The [IECEE CB Scheme](#) is international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products.

With respect to the Codex Alimentarius Commission,⁵³ the participation of 27 EU Member States and the EU's special status as a Regional Economic Integration Organization has in some cases enabled European standards and regulatory approaches at odds with those of other countries to influence Codex work. For instance, the EU maintains a mandatory biotechnology labeling regime and has been pressing for over a decade to have Codex develop a biotechnology labeling standard that reflects the EU approach. The United States and other trading partners have consistently voiced concerns about the EU's mandatory biotechnology labeling requirement and its negative impact on U.S. and other foreign producers' ability to export safe biotechnology products to the EU.

There are other examples as well. Some EU Member States are attempting to obtain a modification to one of the parameters for extra virgin olive oil, linolenic acid, in the Codex standard for extra virgin olive oil. If they are successful, olives grown in Europe could be used to produce olive oil to be labeled "extra virgin." However, due to differences in climatic and geographic conditions, the levels of linolenic acid in authentic extra virgin olive oils produced in other countries – *e.g.*, Argentina, Australia, Chile, Mexico, New Zealand, South Africa, and the United States – may not meet the levels set out in the modification proposed by the EU. EU Members States have also previously successfully advocated for the inclusion of annexes setting out European cheese-making standards and practices in 16⁵⁴ separate Codex cheese standards and, most recently, successfully lobbied to maintain these annexes within these standards.

The EU also seeks to promote its approach to the accreditation of testing and certification bodies. The EU has explained for example that it seeks to "promote, in its international relations, the European model of accreditation."⁵⁵ Under the EU approach, each Member State must designate a single, not-for-profit entity that may accredit conformity assessment bodies in Europe. The EU approach provides for recognition of accreditation bodies in other countries, provided they have been designated by their governments as the country's single, not-for-profit accreditation body. In the United States alone there are over 200 accreditation bodies; choosing a single body to accredit all conformity assessment bodies in the United States would be impracticable and inappropriate.

As a result, the United States is concerned that U.S. accreditation bodies may no longer be recognized in the European Union, irrespective of their competence and status under ILAC or

⁵³ The Codex Alimentarius Commission is an intergovernmental body established in 1963 by the [Food and Agriculture Organization](#) of the [United Nations](#) (FAO) and the [World Health Organization](#) (WHO). The Commission's main aims are to [protect the health of consumers](#) and ensure fair practices in the international food trade. The SPS Agreement recognizes the Codex Alimentarius Commission as a source of international standards for the purposes of the SPS Agreement.

⁵⁴ Codex standards for Cheddar (C-1), Danbo (C-3), Edam (C-4), Gouda (C-5), Havarti C-6, Samsø (C-7), Emmental (C-9), Tilsiter (C-11), Saint-Paulin (C-13), Provolone (C-15), cottage cheese (C-16), Coulommiers (C-18), cream cheese (C-31), Camembert (C-33), Brie (C-34), and mozzarella (c-46).

⁵⁵ See "General Guidelines for Cooperation between the European co-operation for Accreditation and the European Commission, the European Free Trade Area and the competent national authorities," European Commission Enterprise and Industry Directorate-General, Certif doc 2009-01, pages 4, 7-8.

IAF. There is also significant concern in the United States and elsewhere that the EU approach may undermine the ILAC and IAF international accreditation systems. In particular, by leaving to Members States' discretion whether to recognize these systems, conformity assessment bodies in other countries accredited by ILAC and IAF signatories may no longer be recognized in Europe. Other countries, particularly developing countries, may find that the only way to have their accreditation bodies recognized in Europe is to adopt the EU approach. (See the EU Country Report in Section X for further details on this issue.)

The EU approach to promoting its standards and conformance system also includes efforts to establish ISO, IEC and other bodies in which Europe is represented by its 27 member states as the exclusive developers of "international standards" and to require its trading partners to use these particular standards as the basis for their technical regulations. For example, in several venues the EU has sought to establish that the relevant international standards for a particular sector or sectors are developed exclusively by these bodies. Thus, for example, the EU-Korea FTA and the EU's electronics proposal in the WTO NAMA NTB negotiations identify ISO, IEC, and the International Telecommunications Union (ITU) as the exclusive international standardizing bodies for the electronics sector and seek to commit trading partners to base their technical requirements for electronics on standards developed by these bodies.

The EU's autos proposal in the WTO NAMA NTB negotiations is another example. That proposal identifies the World Forum for the Harmonization of Vehicle Regulations, within the framework of the United Nations Economic Commission for Europe (UNECE), as the "main international standardizing body" for automotive products and would require that WTO Members adopt all standards developed by this body within ten years. The vast majority of autos standards developed under the UNECE framework have been developed pursuant to procedures established in an agreement known as the "1958 Agreement." Under the 1958 Agreement procedures, a standard can be adopted by a two-thirds vote and each of the 27 EU Member States votes individually. As a result, the majority of 1958 Agreement standards were developed through a process dominated by EU Member States. Thus, the standards resulting from the 1958 Agreement process arguably resemble EU regional standards rather than "international standards."

Although the United States was the only non-European founder of the UNECE and its subsidiary body WP-29, it is not a signatory to the 1958 Agreement due to the "closed door" practice of developing standards and regulations under that Agreement. In 1995, the United States spearheaded the development of a new agreement and pushed for its conclusion in 1998. The 1998 Agreement – which entered into force in 2002 – established a more open, transparent, and consensus-based process for the development of "global technical regulations" (GTRs) under the UNECE. The 1998 Agreement established the protocols and standards development mechanisms that have led to the development of several GTRs.

The United States raises concerns with the EU's standards-related activities as they arise in the context of particular market access issues, including as they affect SMEs which, because of their more limited resources may be less able to manage the problems presented by the EU's approach. In 2010, U.S. officials intend to work to develop a more comprehensive strategy for

addressing the negative impact of the EU's approach on standards and conformance on U.S. exports to the EU as well as third countries.

China's Development and Use of Standards and Technical Regulations in the Information Technology Sector

Since its accession, China has devoted significant energy to reforming its standards, testing, and certification regimes following its WTO accession. In general, China has worked towards aligning its standards system with international practices and developing procedures for notifying its proposed technical regulations and conformity assessment procedures to the WTO. The United States remains concerned, however, about China's current approach to developing and using standards and technical regulations in the information technology sector, which in too many instances appears designed to favor China-specific approaches. Many of the standards are developed absent meaningful (if any) foreign input and tend to favor domestic producers.

First, China still does not notify some proposed technical regulations and conformity assessment procedures to the WTO, provide WTO Members an opportunity to comment, take those comments into account, or provide a reasonable time period for compliance. For instance, during bilateral talks in September 2009, the United States learned from officials from China's Ministry of Industry and Information Technology (MIIT) that China would approve hand held devices that employ the widely-used WiFi standard, but only if those devices are also enabled with the Chinese standard – the WAPI (WLAN authentication and privacy infrastructure) encryption algorithm for secure communications. MIIT officials acknowledged that there is no published or written measure setting out this requirement, and that China had not notified this requirement to the WTO. Thus, WTO Members and private sector stakeholders were unable to comment on the technical merits of the measure.

Similarly, in May 2009, China's MIIT issued a proposed measure mandating that all computers sold in China be pre-installed or packaged with the Chinese-produced "Green Dam – Escort of the Youth Flowers" Internet filtering software by July 2009. China never notified the measure to the WTO and provided a very short (*i.e.*, less than two months) implementation period. When global technology companies, worldwide media, and Chinese citizens learned of the measure, they expressed serious concerns about the stability of the Chinese software, the scope and extent of the filtering activities, and its security weaknesses. In June 2009, China announced that it was suspending the measure indefinitely.

Second, China's standards-setting process lacks openness and transparency. The vast majority of Chinese technical committees have not been fully open to foreign participation. In some cases, Chinese technical committees refuse membership to foreign firms. In other cases, the committees may permit companies with majority foreign ownership to attend but deny them the right to vote. In instances where the committees allow foreign firms to have non-voting observer status, these firms reportedly may be required to pay membership fees far in excess of those the domestic voting members pay.

The lack of openness and transparency in Chinese standards-setting processes appears to be part of China's broader strategy, outlined in the Standards Administration of China's September 2004

strategy report, to promote China's development of standards and technical regulations as a means of protecting its domestic industry as its tariff rates fall. Chinese regulators often favor the use of Chinese-developed standards despite the existence of relevant international standards, and these policies may serve to protect domestic companies from competing foreign standards and technologies.

The following examples highlight how the lack of transparency and openness in China's processes for developing technical regulations and standards have promoted China-specific approaches that may adversely impact access to the Chinese market for U.S. companies.

With respect to the WAPI standard mentioned above, China has made several attempts over the years to require incorporation of this standard in information technology products used in China, even though there is a relevant international standard – WiFi. China first sought to enforce the use of WAPI in China by mandating its use and providing a necessary algorithm only to a limited number of Chinese companies. Later, China began requiring all government agencies, quasi-government bodies, and government-affiliated organizations to give priority to WAPI-compliant products when procuring WLAN and related products using government funds. Most recently (as discussed above), China indicated that it will only approve mobile handsets sold in China incorporating the WiFi standard for WLAN technology if they are also enabled with WAPI.

China also attempted to develop a standard for mobile phone batteries that would have specified requirements for size, electrical performance, safety performance, and labeling. The proposed battery sizes were too large for many phones, especially newer, smaller phones, would have raised questions about the ability of suppliers to sell mobile phones with a built-in battery in China, and would have limited innovation in battery design, performance, and safety. China suspended development of the standard after domestic and international stakeholders, including the United States, the European Union, and Japan, raised concerns.

In addition, in 2007 China proposed to require that thirteen categories of commercially available information technology products to be tested and certified to Chinese standards for information security functions. No other country had imposed such requirements in the commercial sphere or for non-sensitive government functions. China eventually rolled back the proposal, but the compulsory certification requirement in the final measure still applies when suppliers sell certain specified information technology products to Chinese government agencies. Thus, U.S. high-tech companies are being forced to decide whether to develop one set of products for the Chinese public sector and another for the rest of the world or entirely forego the Chinese government market. The United States remains concerned about this measure and will continue to engage with China on this issue.

See Section X below for further information on U.S. efforts to address these issues.

Mandatory Biotech Labeling

A growing number of markets around the world either require or have proposed mandatory retail labeling for food products that contain or are derived from biotechnology. Details, as well as implementation, of the regimes vary from market to market. However, the mandatory nature of these regimes has impeded or, in some cases, completely blocked U.S. exports of such food products to several countries. These countries include Australia, Brazil, China, EU Member States, Indonesia, Japan, Korea, Malaysia, New Zealand, Russia, Saudi Arabia, Thailand, and Taiwan. U.S. biotechnology crops are ubiquitous and include corn, cotton, and soybeans, as well as food produced or processed from these crops. Biotechnology crops are the core of U.S. agricultural exports, which totaled \$98.6 billion in 2009. Proposed mandatory biotechnology labeling measures in Korea, Turkey, and Vietnam are discussed in Section X.

For three reasons, the mandatory labeling of food products containing or derived from biotechnology negatively affects trade. First, mandatory labeling affects the consumer's impression of a product subject to the labeling requirement. As a general matter, no requirements exist that all food be labeled to indicate the breeding technique used to produce it. A mandatory method-of-production regime that applies only to products containing or derived from biotechnology creates the impression that the labeled food is in some way different from, or less safe, than a comparable, unlabeled food not containing or derived from biotechnology. Second, mandatory biotechnology labeling for such food products has unnecessarily increased costs for consumers and industry stakeholders. It has also raised costs and presented other challenges for government officials who implement and enforce mandatory biotechnology labeling regimes. Third, the negative impact on trade of mandatory biotechnology labeling is compounded where countries lack adequate infrastructure or mechanisms to implement and enforce these regimes in a consistent and transparent manner.

In many markets, the combined effect of these three problems has caused companies to reformulate their products to eliminate the use of ingredients containing or derived from biotechnology. These companies bear additional costs of searching for alternative ingredients, some of which may be expensive or in limited supply. Many of these costs are ultimately passed on to the consumer.

Recognition of Conformity Assessment Bodies

Some governments do not permit U.S. suppliers to use competent conformity assessment bodies (*e.g.*, testing laboratories or product certifiers) located in the United States to demonstrate that their products comply with their technical regulations. Rather, U.S. exporters are required to use conformity assessment services provided by bodies in the destination market. Requiring conformity assessment procedures to be performed by conformity assessment bodies in the destination market can impose additional costs and burdens on U.S. exporters, particularly SMEs. These costs and burdens can be compounded by significant delays when the foreign market lacks sufficient domestic testing, inspection, or certification capacity.

The TBT Agreement includes several provisions relevant to this issue. First, it encourages WTO Members to permit foreign conformity assessment bodies to participate in their conformity assessment procedures on terms no less favorable than those accorded to domestic or other foreign conformity assessment bodies. The Agreement also requires Members to accept, whenever possible, test results, certifications and other forms of assurance performed in other Members' territories provided they are satisfied that they offer an assurance of conformity equivalent to their own. To advance that possibility, the Agreement encourages Member to negotiate agreements with other WTO Members to mutually recognize the results of each other's conformity assessment procedures (MRA).⁵⁶

Further, the TBT Agreement calls on Members to use, wherever practicable, international systems of conformity assessment. As discussed in Section VI, two such systems are the ILAC and the IAF⁵⁷ international accreditation systems. These systems enable WTO Members to rely on them as a basis for recognizing conformity assessment bodies, including bodies located outside their territories, to test, certify, and perform other forms of conformity assessment on products destined for their markets.

In 2009, the United States raised concerns in bilateral, regional and multilateral venues regarding the testing, certification, or accreditation procedures of several trading partners in cases where the trading partner's system does not provide for recognition of foreign conformity assessment bodies including bodies that have been accredited under the ILAC or IAF systems. As a result to sell their products in those markets, U.S. exporters must have their products tested or certified there and U.S. conformity assessment bodies have lost opportunities to provide conformity assessment services for those markets:

Argentina and Brazil: In September 2009, Brazil's toy regulator (INMETRO) announced that it would allow laboratories that have been accredited by an ILAC MRA signatory to conduct required testing of toys and other children's article in certain instances. Its previous position was that all testing would have to be conducted in Brazil, which industry feared would lead to delays to the Brazilian market. In response to similar industry concerns, Argentina is working to identify additional testing capacity, which U.S. officials hope will include recognizing laboratories outside Argentina that have been accredited by an ILAC MRA signatory to perform phthalates testing for toys to be sold on the Argentine market. In Argentina's case, suppliers are concerned that if Argentina does not identify such additional capacity and requires imported toys to be tested by a single designated Argentine laboratory, exports of toys to Argentina would face significant delays due to that laboratory's insufficient capacity.

China: One U.S.-based conformity assessment body has entered into a memorandum of understanding (MOU) with China allowing it to conduct follow-up factory inspections (but not primary inspections) of manufacturing facilities that make products for export to China that

⁵⁶ In addition, U.S. FTAs require each party to afford conformity assessment bodies of the other party treatment no less favorable than it affords its own conformity assessment bodies with respect to criteria and procedures to accredit, recognize or otherwise approve conformity assessment bodies to test, certify or perform other conformity assessment procedures.

⁵⁷ See Section VI for a discussion of the ILAC and IAF MRAs.

require the China Compulsory Certification mark (CCC mark). However, China allows only one MOU per country, so other U.S.-based conformity assessment bodies have not been granted similar rights. China has rejected suggestions that it recognize laboratories that have been accredited by ILAC MRA signatories or develop other procedures to recognize foreign conformity assessment bodies, insisting that it will accept conformity assessment bodies domiciled abroad only if their governments negotiate MRAs with China, a condition that in this instance is both unnecessary and impracticable.

European Union: The EU’s system for conformity assessment is set out in its “Global Approach to Certification and Testing.” The EU Member States have the authority to designate conformity assessment bodies – known as Notified Bodies – as competent to test, inspect, and certify products for conformance with EU mandatory requirements. Products meeting EU requirements must bear the European mark (CE mark); the EU requires the CE mark for a wide range of products sold in the EU. EU Member States, however, are not permitted to designate conformity assessment bodies outside their territories as Notified Bodies. As a result, U.S. conformity assessment bodies cannot provide conformity assessment services for the EU market unless there is a government-to-government MRA or U.S. conformity assessment bodies act as subcontractors to Notified Bodies.

The United States is also concerned that the new EU accreditation regime could disrupt the ability of U.S. accreditation bodies to accredit conformity assessment bodies to test, inspect, and certify products for compliance with EU requirements, as is now being done under the ILAC and IAF arrangements. Regulation (EC) No 765/2008, which became effective on January 1, 2010 and applies to all sectors, 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-recognized entity in each Member State will be permitted to accredit conformity assessment bodies in the EU.

In addition, the regulation appears to give discretion to Member States regarding whether to recognize non-European accreditation bodies, as well as the discretion concerning whether to accept conformity assessments issued by ILAC MRA and IAF MLA accredited bodies.⁵⁸ The European Commission, however, has not issued guidance to the EU Member States on this issue. There is significant concern that absent clear guidance from the Commission, EU Member States will refuse to recognize non-European accreditation bodies and conformity assessments issued by non-European testing and certification bodies.

While the EU advocates that authorities in key emerging markets liberalize their approaches to conformity assessment, including acceptance of ILAC and IAF accreditations, the EU continues to maintain a non-reciprocal approach to conformity assessment that other countries, such as China, have adopted.

India: Since 2007, the United States has raised concerns, both directly with India and in the TBT Committee, about a proposed Bureau of Indian Standards (BIS) conformity assessment procedure for tires. The BIS conformity assessment system for tires is a “type approval” system.

⁵⁸ See Section VI which describes the ILAC MRA and IAF MLA.

India published the final version of this measure in November 2009, with an effective date of 180 days from date of publication. The measure requires suppliers seeking to export tires to India to apply for approval for each tire family from each tire plant and send sample tires for each family to India for compliance testing at the Central Institute for Road Transport (CIRT). CIRT is currently the only laboratory BIS has authorized to conduct the testing. Given CIRT's limited capacity, industry believes that this could lead to testing backlogs and disrupt U.S. exports of tires to India. The United States continues to urge India to recognize additional test laboratories, such as foreign test laboratories that have been accredited by ILAC MRA signatories, wherever they may be located, to avoid backlogs.

Korea: In Korea, electrical safety testing and certification for the Korean market must be conducted by designated certification bodies, which must be “domestic nonprofit organizations equipped with suitable testing equipment and qualified testing personnel...” This requirement means that conformity assessment bodies located outside Korea cannot provide certification for the Korean market. In addition, Korea has not allowed foreign conformity assessment bodies with a presence in Korea to be designated as nonprofits, even those that are registered as nonprofits in the United States. Therefore, even U.S. conformity assessment bodies with a presence in Korea are denied the opportunity to test and certify products for the Korean market. While there were positive developments in Korea in 2009 in the areas of lithium ion batteries and energy efficiency testing, U.S. conformity assessment bodies are still precluded from testing and certifying products for electrical safety for the Korean market, and U.S. suppliers continue to incur additional burdens and expense caused by the requirement to have their products tested and certified in Korea.

Mexico: Under Article 908.2 of the NAFTA, Mexico is required to accredit, approve, license, or otherwise recognize U.S. conformity assessment bodies on terms no less favorable than those applied to conformity assessment bodies in Mexico. Yet action on applications that two U.S. conformity assessment bodies submitted for accreditation by the *Entidad Mexicana de Acreditación* (EMA), the body responsible for accrediting conformity assessment bodies to Mexican official standards, was delayed for years until the end of 2007/early 2008 when the two U.S. conformity assessment bodies were finally accredited to offer conformity assessment services for a limited range of products for the Mexican market. Because these and other conformity assessment bodies may want to apply for additional accreditations in the future, however, the United States has urged Mexico to: clarify whether a conformity assessment body can apply for accreditations at any time or if it must wait (as happened in the case mentioned above) until Mexican government officials request applications for specific accreditations before applying; set out a reasonable timeline for the accreditation process; and modify its accreditation rules to ensure that the application fees charged by Mexican authorities to accredit conformity assessment bodies are set in a fair and transparent manner.

Under NAFTA Article 1304.6 of the NAFTA, Mexico committed to adopt, as part of its conformity assessment procedures for telecommunications equipment, provisions necessary to accept test results from test laboratories in the United States. Mexico could meet this commitment by implementing the Inter-American Telecommunications Commission's Mutual Recognition Agreement for Conformity Assessment of Telecommunications Equipment (CITEL Telecom MRA) or the APEC Mutual Recognition Arrangement for Conformity Assessment of

Telecommunications Equipment (APEC Telecom MRA) with respect to the United States. These MRAs contain procedures for each party to recognize laboratories located in the other party's territory as competent to test or certify equipment for compliance with the party's technical requirements. If Mexico implemented the CITES or APEC Telecom MRA with the United States with respect to testing of telecommunications equipment, U.S. laboratories could test telecommunications equipment for the Mexican market, saving them the expense and burden of having to send their products to Mexico for testing. The United States has continued to press Mexico to implement the APEC or CITES Telecom MRAs with the United States and recently progress was made in this regard, as explained in the Mexico country report in Section X.

In all of these cases, recognition of additional conformity assessment bodies could provide adequate assurances of conformity that would facilitate trade while ensuring that WTO Members can still achieve their legitimate objectives. In 2010, the United States will continue to pursue bilateral engagement as well as support ongoing multilateral efforts to urge its trading partners to recognize U.S. conformity assessment bodies under their conformity assessment regimes and enhance the prospect that U.S. manufacturers are able to have their products tested and certified by competent bodies wherever they are located.

Distilled Spirits

Divergences in how governments in different regions regulate distilled spirits have also created trade problems for U.S. exporters. For instance, the EU maintains a three-year minimum aging requirement for whiskey. The EU's age threshold is based on the climatic conditions in Scotland and Ireland, where three years of aging may be necessary to produce Scotch Whiskey and Irish Whiskey. By contrast, the climatic conditions in Kentucky, Tennessee, Indiana, and other U.S. states are different, so U.S.-produced whiskey need not be aged three years to achieve the same result. The EU requirement acts to restrict U.S. exports to the EU of whiskeys that are aged less than three years or are blended with neutral spirits.

The ramifications of the U.S.-EU divergence on whiskey aging adversely affect U.S. whiskey producers when they export to other markets as well. Israel has recently adopted the same minimum aging requirement as the EU – even though Israel does not produce whiskey – and Colombia is considering doing the same. Further, Colombia is proposing that brandy be aged solely through the solera method, a system of aging that was developed in Europe. This would restrict exports to Colombia of U.S. brandy, most of which is aged using the barrel aging method.

In addition, Brazil and Colombia have proposed quality and identity requirements for vodka, gin, rum, and whiskey that differ in important respects from how North American and European regulators have traditionally regulated these beverages. North American and European regulations are based primarily on differences in the raw materials used and the process that producers use to make them. The Brazilian and Colombian proposals would define these products based primarily on whether they meet certain analytical parameters for alcohol content, congener levels, and other factors.

Whereas Brazil has clarified that its proposal would only apply to domestically-produced spirits, Colombia's proposal would apply to both domestic and imported products. As a result, if finalized in its present form, Colombia's proposal could effectively bar some U.S. spirits from the Colombian market, such as those with alcohol content levels that fall above or below the ranges specified in the proposed Colombian requirements. U.S. and Colombian regulators and trade officials continue to discuss these issues bilaterally. Recently, U.S. producers have also raised concerns about labeling requirements adopted by Brazil that could potentially prohibit U.S. exports of distilled spirits to Brazil. See the country reports on Brazil and Colombia in Section X for more details.

Organic Products

Divergences in how countries regulate organic products can make exporting U.S. organic products a more costly and burdensome endeavor – in some instances, prohibitively so. In the organics sector, the United States has negotiated three types of agreements, alone or in combination, with major trading partners in an attempt to facilitate trade in organic products and overcome such divergences.

Under a “recognition agreement,” an importing country agrees to recognize USDA's National Organic Program (NOP) to accredit certifying agents within the United States to certify products as organic under the importing country's requirements. (The United States has negotiated such an agreement with the European Union.) Similarly, USDA has accredited certifying agents in other countries to certify products as organic under the NOP.

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. The United States concluded its first equivalency arrangement with Canada, the largest U.S. organics trading partner, in 2009. In addition, the United States and the EU have begun discussions for possible equivalence negotiations to begin in 2010.

Under an “export arrangement,” U.S. organics producers can sell their products as organic in another market (*e.g.*, Japan, Taiwan), provided that their products meet specific requirements of the importing country.

These efforts have been highly effective in facilitating trade in organic products. However, in some instances it has not been possible to bridge some, or all, of the differences between U.S. and foreign organics requirements using these tools.

U.S. organics exports to Japan are limited by Japan's zero tolerance policy for pesticide and herbicide residues on organic products. U.S. organics exports to Japan are also limited by Japan's ban on alkali extracted humic acid, a substance that USDA permits for use on U.S. organic crops.

In addition, U.S. organics exports to Korea can potentially be limited by Korea's zero tolerance policy for adventitious presence of biotechnology content in organic products. U.S. organics

exports to Korea could be further restricted beginning in January 2011 if Korea does not quickly adopt regulations allowing it to negotiate one or more of the arrangements outlined above.

U.S. officials continue to engage with trading partners in an attempt to resolve these issues.

Toys and Children's Products

Following high-profile recalls of unsafe toys in 2007, many WTO Members – including the United States and ten other APEC member economies – adopted new or improved toy safety measures to protect their children from potential hazards posed by certain toys and children's articles. This is a critical policy goal and demonstrates the ability of individual countries to respond swiftly to address emerging safety hazards. While fully supporting the objective of protecting children from exposure to potentially dangerous substances in toys and other children's articles, the United States and other WTO Members have raised trade concerns in the TBT Committee with new testing requirements for toys and children's articles that Argentina, Brazil and other countries have adopted. Discussion of these new measures in the TBT Committee has sought to ensure that they do not provide less favorable treatment for imported products than for domestically-produced products and provide sufficient availability of testing facilities to ensure timely market access for toys and children's articles that fulfill such requirements.

Argentina's measure initially required that imports of toy and children's articles be accompanied upon entry by a test report issued by a single government Argentine laboratory; the measure does not require that domestic manufacturers provide such a report. In response to concerns expressed by the United States and other trading partners, Argentina suspended the requirement that imported toys be accompanied at the time of import by a test report while it develops additional testing options. In addition, at the November 2009 TBT Committee meeting, Argentina indicated that it does recognize test results in certain circumstances from conformity assessment bodies that had been accredited by an ILAC MRA signatory.

Brazil's measure initially gave domestic producers two options for demonstrating that their products conform with Brazilian requirements, while it gave foreign producers only one option. In addition, Brazil's measure subjected imported toys and children's articles to two sets of testing – the second of which had to be performed in Brazil – while domestic products were only subject to one set of testing. In response to concerns expressed by the United States and other trading partners, Brazil eventually allowed importers to choose from both conformance options and eliminated the second testing requirement for imports. Brazil also indicated that it would recognize test results in certain circumstances from conformity assessment bodies that had been accredited by an ILAC MRA signatory.

The United States held bilateral discussions with Malaysia in 2009 on its proposed conformity assessment procedures for toys and children's articles, seeking to clarify how several aspects of the procedures would operate. In early 2010, Malaysia announced a new conformity assessment system that resolved these concerns. Among other things, the new system does not require that suppliers obtain test results solely from Malaysian laboratories.

Some elements of these countries' revised regulatory approaches appear similar to elements of the conformity assessment system that the U.S. Consumer Product Safety Commission is implementing pursuant to the Consumer Product Safety Improvement Act enacted in 2008. This illustrates the propensity of U.S. trading partners to look to the United States and the measures the United States has in place when adopting their own standards-related measures. When the United States adopts measures that facilitate trade, while ensuring that legitimate health, safety, and other objectives are met and similar approaches are adopted by U.S. trading partners, the ability of U.S. exporters to sell their products abroad is enhanced.

In 2008 at the initiative of the United States, APEC economies launched the *Toy Safety Initiative*. The United States led this project, which was co-sponsored by the U.S. Toy Industry Association. The goals of the *APEC Toy Safety Initiative* are to strengthen toy safety, increase transparency, promote better regulatory alignment and reduce unnecessary obstacles to trade that can arise from toy and children's article safety systems. The initiative has advanced regulatory cooperation both within and beyond APEC, and helped to establish relationships between regulators, standards experts, and industry stakeholders that will further the project's goals in other international fora. Regulators agreed to continue this cooperation in other international organizations and collaborate on a project to identify successful market surveillance practices. The *APEC Toy Safety Initiative* also resulted in greater collaboration and coordination among the standards developers. Section XIII contains additional information on the *APEC Toy Safety Initiative*.

Developments in the toys and children's products sector demonstrate the importance to the global trading system of U.S. leadership in (1) developing regulatory approaches that facilitate trade in safe, high-quality products while also ensuring that legitimate public policy objectives are achieved, and (2) encouraging other governments to adopt those approaches.

X. Country Reports

Background on Trade Concerns Contained in the Country Reports

This section sets out specific TBT concerns in individual country reports. The issues included in these reports are a product of U.S. government engagement at home and abroad with U.S. stakeholders concerning specific standards-related barriers that U.S. stakeholders have encountered. The selection of issues for inclusion in the *TBT Report* reflects a considered process that is based on the USTR's along with other Federal agencies' understanding and analysis of the measures and practices that give rise to those issues. The measures and practices that 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.⁵⁹

In each instance, USTR's goal is to work as vigorously and expeditiously as possible to resolve the concern. The tools the U.S. government uses vary depending on the particular issue and

⁵⁹ 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).

circumstances. 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. In appropriate instances, dispute settlement under the WTO or in another relevant forum can be a tool to address specific concerns.

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

The *TBT Report* provides more focused and structured reporting on country-specific standards-related issues than appeared in past years’ NTE reports, and past years’ NTE reports may have included standards-related issues that USTR has not included in the *TBT Report*. The *TBT Report* describes USTR’s and other Federal agencies’ current understanding of a measure or practice, why it is a concern, and how the United States is seeking to address that concern. The report is not simply a recounting of all outstanding issues that stakeholders have brought to USTR’s attention this year or in the past. For purposes of the *TBT Report*, USTR determined that the report would include measures and practices that USTR knows more about, while continuing to gather information about others. Regardless, USTR will continue to follow those concerns and pursue them, as appropriate, with the trading partners concerned, in the same manner as those listed below.

Argentina

Bilateral engagement

The United States discusses TBT matters with Argentina both bilaterally and during meetings of the TBT Committee. The next bilateral meeting between Argentina and the United States is tentatively scheduled for April 2010.

Toys – testing and accreditation requirements

On June 4, 2008, Argentina’s Ministry of Health (MoH) issued Resolution 583/2008 limiting the amount of phthalates that toys and other children’s articles may contain. While this is in itself not problematic, the resolution’s requirement that products be tested for compliance with the phthalate limit is limited to imported products. In addition, the resolution initially required that imported toys and children’s articles be accompanied at the time of import by a technical report by a single designated Argentine government laboratory, the Center of Investigation and Technological Development for the Plastics Industry (INTI). INTI is a part of the Argentine National Institute of Industrial Technology.

At the time, MoH indicated that it would not accept technical reports from other laboratories, including accredited laboratories in the country of production. U.S. industry expressed concern that Argentina lacked sufficient testing capacity to perform the required testing and that this coupled with the inability to test these products in the country of production gave rise to a high probability of significant delays, costs, and burdens for exports of toys and children's articles to Argentina. Some U.S. stakeholders exporting toys to Argentina did, in fact, experience delays, with one reporting that complying with the in-country test requirement added more than 90 days to the process of placing its products on the market in Argentina.

The United States raised this issue with Argentina in the TBT Committee in June and November 2009. The United States noted its strong support for Argentina's objective to protect children from exposure to potentially dangerous substances in toys and other children's articles, and posed several questions to Argentina, including the rationale for requiring test reports for imported, but not domestic, products. The United States noted that the resolution applies the testing requirement only to imports and asked Argentina whether any testing requirements apply to domestic toys and children's products. Argentina stated that testing requirements apply to both domestic and imported products; however, it has not provided a copy of any Argentine measure that requires domestic products to be tested. The United States also noted concerns about the requirement to perform the testing in Argentina and the overall lack of testing capacity there, which could increase costs and create substantial delays to market for exports to Argentina.

U.S. officials explained that the U.S. system for testing toys and children's articles, established pursuant to the Consumer Product Safety Improvement Act and related implementing regulations, requires mandatory third party testing of toys and children's articles, but permits such testing to be performed by any private laboratory – including one in the country of production – that has been accredited by an ILAC MRA signatory. While still fulfilling Argentina's objective to ensure that toys and children's articles are safe, U.S. officials urged Argentina to consider something similar as one potential option for its phthalates testing regime as this could be less burdensome and costly for U.S. exporters. The United States also asked Argentina to clarify in writing that domestic producers will be required to supply testing results as well.

Lastly, U.S. officials offered to facilitate discussions on this matter between Argentine regulators and officials of the U.S. Consumer Product Safety Commission which has recently implemented an ILAC-based testing regime for many toys and children's articles, including, among other things, with respect to chemical content testing. U.S. officials also noted new opportunities for Argentina to participate in APEC toy safety activities, which would enable Argentine regulators to learn how other regulators around the world are addressing these safety issues and share best practices.

Following these discussions, Argentina has indicated its willingness to work to develop technical solutions to the issues the United States has raised, including by taking steps to identify additional laboratories to perform phthalates testing, such as the possibility of recognizing laboratories accredited by ILAC MRA signatories.

Following U.S. engagement, Argentina revised Resolution 583 in October 2009 to allow producers to market toys and children's articles in Argentina if the supplier: (1) certified that the products meet Argentine product safety requirements; and (2) indicated that the producer had requested a test report from INTI prior to September 23, 2009. This revision was issued several weeks after September 23, 2009. Because Argentina issued the revision several weeks after that date, the United States raised concerns during the November 2009 TBT Committee meeting that many suppliers were likely unaware of Argentina's new flexibility and suggested that Argentina consider adopting a cut-off date that is later than September 23, 2009. The United States suggested that this could act as a short-term measure to address the current marketing delays while Argentina considered whether to modify Resolution 583 further to allow for recognition of additional test laboratories, including ones located outside Argentina, and ways to expand its domestic testing capacity.

Following this U.S. intervention, Argentina noted that it recognizes test results from laboratories that have been accredited by an ILAC MRA signatory, but that it also requires such laboratories to comply with other requirements. The United States has requested a copy of these other requirements and will engage further with Argentine officials to understand the extent to which Argentina recognizes test results from laboratories that an ILAC MRA signatory has accredited (*i.e.*, to understand whether Argentina accepts such test results in lieu of INTI test results).

In December 2009, Argentina issued Resolution 1078/2009. This resolution allows suppliers of toys and children's products to export their products to Argentina without a test report from INTI if the products are accompanied by written proof that samples of the products have been presented to, and are being analyzed by, INTI. This is a positive development that should help reduce delays while Argentina considers further revisions to its testing requirement for toys and children's products (*e.g.*, by recognizing laboratories outside of Argentina) and determines how best to expand laboratory capacity to ensure that producers can obtain test results before their products are imported into Argentina. The United States will continue to raise this issue with Argentina.

Brazil

Bilateral engagement

The United States and Brazil discuss TBT-related matters at various bilateral fora, including the Bilateral Consultative Mechanism (led by Brazil's Ministry of External Relations and USTR), the 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). At the most recent meeting of the Economic Partnership Dialogue in December 2009, the U.S. and Brazilian governments welcomed further cooperation on regulatory issues, noting the importance of working together to share information. They also agreed to continue discussing memoranda of understanding (MOUs) outlining a framework for cooperation, including a proposed MOU between the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) and Brazil's Ministry of Agriculture (MAPA). The United States also discusses TBT matters with Brazil during, and on the margins of, TBT Committee meetings.

Distilled spirits – quality and identity requirements

In spring 2008, Brazil notified the WTO of numerous proposed changes to its technical requirements for distilled spirits. U.S. industry raised concerns that the requirements differed from international practices, were not justified by health and safety considerations, and could bar exports of a number of U.S. spirits to Brazil.

In particular, the proposed Brazilian requirements make use of analytical parameters or chemical composition limits to define products that can be marketed as distilled spirits, liqueurs, or cordials in Brazil. In the United States, by contrast, rules of identity for spirits are based solely on the raw materials and production processes that producers use to make these products, not their chemical composition. The minimum and maximum alcohol content requirements set out in Brazil's proposal also do not conform to global practices for most spirit categories. For example, the proposal would establish a maximum alcohol content level of 54 percent alcohol by volume for distilled spirits. Yet none of the major spirits trading countries (*e.g.*, the United States, Canada, or EU Member States) establishes maximum limits for alcohol content. As certain U.S. spirits are bottled at significantly higher strengths than the proposed 54 percent limit, the proposal could bar many U.S. spirits from the Brazilian market. Lastly, Brazil's proposal would not recognize Bourbon and Tennessee Whiskey as distinctive products of the United States that can only be produced in the United States in conformity with U.S. requirements.

In 2009, the United States, joined by Mexico and the EU, expressed concerns in the TBT Committee that differences between the proposed Brazilian identity and quality requirements and requirements in other major markets could restrict trade in wine and spirits. In response, Brazil clarified that Article 34 of Brazil's Decree 2314 provides that beverages that are produced abroad and do not comply with Brazilian requirements can continue to be imported, provided that a certificate is presented attesting that: (1) the beverage is a typical product from its country of origin; (2) the beverage was produced in accordance with that country's laws and regulations; and (3) the beverage is regularly consumed in that country. Thus far, U.S. industry has not reported any disruption of shipments of distilled spirits to Brazil.

In October of 2009, Brazil notified additional amendments to its technical regulations establishing criteria for the labeling of beverages and products of acetic fermentations. U.S. industry raised concerns that some of the requirements could potentially prohibit imports of specific U.S. –origin, internationally-traded spirits. Specifically, their concerns include a prohibition on using abbreviations for common terms on labels, an explicit requirement for product names to be printed on the main label in bold face and upper case letters, a requirement for a large decal to be placed on the label including the importer's registration number, as well as a prohibition of the use of certain expressions on labels (such as "home-made", "hand-crafted", "reserve" and "special reserve"), even if these are associated with the company's name or trademark, among others.

Thus far, U.S. industry has not reported any disruption of shipments of distilled spirits to Brazil.

Medical devices – inspection requirements

Resolution 25, which Brazil notified to the WTO on May 18, 2009, requires ANVISA (Brazil's medical device inspection agency) to inspect 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, as the U.S. Food and Drug Administration (FDA) has analogous authority to conduct inspections of Brazilian facilities. However, the United States is concerned that ANVISA may not have sufficient resources to inspect all overseas facilities that ship these devices to the Brazilian market by the May 22, 2010 deadline that the Resolution sets, which could disrupt hundreds of millions of dollars in U.S. exports of medical devices to Brazil and jeopardize the adequate supply of essential medical devices to the Brazilian market.

In September 2009, ANVISA and the U.S. Department of Commerce co-sponsored an event on medical device regulation – the Medical Device Information Exchange Forum – in Brasilia that U.S. industry and FDA's regional representative attended, where the two sides discussed the inspection issue. In addition, on November 4, 2009, ANVISA representatives participated in a seminar that the American Chamber of Commerce hosted in São Paulo to explain Brazil's new inspection requirement to local representatives of foreign manufacturers, including how companies can apply for an inspection and what the inspections will entail. At the November 2009 TBT Committee meeting, the United States, the EU, Mexico, Canada, and Switzerland raised concerns about the inspection requirement, requesting assurances from Brazil that trade in medical devices will not be disrupted after May 2010 if ANVISA cannot complete all of the inspections (and related registrations) in time, and noting that companies still had questions about the registration and inspection processes, including how to apply for an inspection and the coverage of such inspections.

The meetings that FDA and ANVISA had during the Medical Device Information Exchange Forum were productive, and that FDA has agreed to hold follow-up technical discussions with ANVISA so that respective regulators in each country can learn more about the other's regulatory systems. This is a positive development that the United States hopes will increase the opportunities for increased dialogue on this and other issues. In addition, Brazil has now clarified that class I medical devices (*e.g.*, tongue depressors, bedpans) and class II devices (*e.g.*, powered wheelchairs, surgical drapes) are exempted from the inspection requirement, and that ANVISA's inspections will apply only to the last place of manufacture (as opposed to all the supplier facilities). In addition, only plants that manufacture devices subject to re-registrations or new registrations will need to be inspected by the May 2010 deadline. The United States understands that ANVISA has also been hiring additional inspectors and has started scheduling inspections, and will be issuing a technical note answering many of industry's questions in the coming weeks. The United States will continue to engage with Brazil on the inspection issue and work with Brazil to resolve the matter in such a way that avoids a disruption in trade in safe and effective medical devices.

Medical devices – data requirements for registration

Resolution 185 of 2001 sets out ANVISA's registration requirements for medical devices. The measure, which Brazil has not notified to the WTO, requires manufacturers to submit detailed

economic data, such as the prices they charge in other markets, advertising budgets, and distributor mark-ups, with each product registration or re-registration. The Resolution's registration requirements do not appear related to evaluating the safety or efficacy of medical devices, they lack clarity and transparency, and they seem excessively burdensome and intrusive. Moreover, they could require producers to submit information that either does not exist, could be business confidential or proprietary, or could not be obtained without giving rise to antitrust concerns since producers would have no way of obtaining the information without contacting each other.

The United States has raised these concerns with Brazil on repeated occasions, both bilaterally and in the TBT Committee. As a consequence of those discussions, ANVISA recently published a resolution that clarifies the registration requirements in Resolution 185. U.S. and industry officials have welcomed this development and are reviewing the new measure to determine whether it resolves the concerns or if additional follow-up with Brazil is necessary. Additionally, industry did not report any trade disruptions in 2009 due to the registration requirements. Brazil and the United States are currently engaged in discussions aimed at finding a long-term resolution to the issue.

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 physically large or costly to transport). Accordingly, U.S. suppliers must submit virtually all of their information technology and telecommunications equipment (*e.g.*, cell phones and optic cables) for testing to laboratories located in Brazil. This requirement results in redundant testing, higher costs for importers, and delayed time to market in Brazil.

There was some progress in 2009 in informal discussions with Brazil on this issue. However, the United States continues to urge Brazil to implement the CITES (Inter-American Telecommunication Commission) Mutual Recognition Agreement (MRA), noting that if ANATEL implements the CITES MRA, it would also benefit Brazilian suppliers who would then be free to use test results from Brazilian laboratories to certify that their telecommunications products meet U.S. FCC requirements.

Toys and children's articles – conformity assessment procedures

U.S. industry raised concerns about a proposed National Institute of Metrology, Standardization, and Industrial Quality (INMETRO) measure amending Brazil's existing conformity assessment procedures for toys and children's articles. The proposed measure would have permitted foreign manufacturers to test their toys for compliance with Brazilian toy safety requirements in the country of manufacture. At the same time, however, it would have required imported toys that had been tested abroad to undergo a second round of testing in Brazil. This measure would not have required domestically-produced toys to be tested twice. Industry also raised concerns about proposed procedures for placing INMETRO conformity assessment seals on conforming products and whether, similar to domestic producers, U.S. producers could use either the System

5 (“Compliance Imprint Certification Model”) or System 7 (“Lot Certification Model”) conformity assessment procedures for their products.

In the TBT Committee, the United States, joined by the EU, Thailand, and China, noted that it strongly shares Brazil’s objective of protecting children from exposure to potentially dangerous substances in toys and other children’s articles, but questioned the basis for Brazil’s requirement that imported toys would be subject to two sets of tests, while domestic toys would only be subject to only one.

In September 2009, INMETRO announced that it would: (1) eliminate the second test requirement on imports; (2) allow laboratories that have been accredited by an ILAC MRA signatory to conduct the testing in certain instances; (3) provide foreign producers with the option of importing under System 5 or System 7; (4) provide a transition period of a few months to one year from the date INMETRO publishes its final measure for producers to comply; (5) permit foreign producers utilizing System 5 to add the INMETRO seal at the place of manufacture; and (6) eliminate a proposed number sequencing system for the seal, which INMETRO determined would not have been efficient or practical.

In early November 2009, INMETRO published a revised measure incorporating these improvements and notified it to the WTO. The United States welcomed the new measure, which addressed most of U.S. concerns, but posed additional questions about how the new system would operate in practice, including: (1) what criteria INMETRO would use for accrediting test laboratories in cases where it found that accreditation by an ILAC MRA signatory was insufficient; (2) whether the six-month transition period for compliance that the revised measure provides is sufficient, given that INMETRO accreditation of an ISO 9001 certification body takes, on average, six months; (3) whether INMETRO would consider recognizing certification bodies that are accredited by IAF signatories; (4) whether Brazil would consider accepting toxicological evaluations by Board Certified Toxicologists instead of requiring animal testing; and (5) why Body of Product Certification (OCP) would need to select test samples rather than allowing an accredited laboratory to select its own samples. U.S. officials are following up with Brazilian authorities on these issues in 2010.

Wine – alcohol content levels and conformity assessment procedures

In mid 2008, Brazil notified proposed changes to its import procedures and other technical requirements for wine to the WTO. The U.S. government and industry raised concerns that the requirements were unjustified by health and safety considerations and could bar certain U.S. wine exports to Brazil.

For example, Brazil’s proposal, which would require foreign wineries to register with the Ministry of Agriculture, Livestock, and Food Supply (MAPA) before exporting to Brazil, appeared to be duplicative since wine importers in Brazil were already required to register. The proposal would permit MAPA to inspect foreign wineries to verify their “technological, hygienic-sanitary, and documentation conditions” – even though the TTB already thoroughly inspects U.S. wineries through its process of implementing statutory permit requirements needed prior to initiating operations, and upholds a set of comprehensive regulations regarding the safety

and security of wineries and wine products. The proposal would also require suppliers to re-register wine products each time they make even minor modifications to their wine labels, such as a change in a label's color.

Further, the proposal would limit the wine alcohol content to 14 percent by volume, unless a wine is accompanied by a statement clarifying it has "typical" or "distinctive" characteristics of a particular region (*e.g.*, wines with a geographical indication or appellation of origin). Geographic and regional factors can influence wine alcohol content, which U.S. regulations recognize by providing that wine may vary in alcohol content from 7 to 24 percent alcohol by volume. By contrast, Brazil's proposed measure does not take account of regional differences and, if applied to U.S. imports, could have blocked access to its market for many U.S. wines with an alcohol content of greater than 14 percent alcohol by volume. Thus far, Brazilian authorities have been accepting TTB-issued certificates for such wine indicating that the product is a wine, or a byproduct of grapes and wine, with typical, regional, and peculiar characteristics from the United States; or the product is a wine, or a byproduct of grapes and wine, in conformity with U.S. requirements.

In December 2009, Brazil notified a new measure that eliminated the winery registration requirement to the WTO. However, the measure also instituted a new certificate of origin and product analysis requirement for foreign wines. At present, U.S. industry is not reporting any disruption of wine shipments to Brazil.

Canada

Bilateral engagement

The United States discusses TBT matters with Canada during, and on the margins, of TBT Committee meetings, as well as bilaterally, such as in the United States-Canada Consultative Committee on Agriculture. The United States also discusses specific trade concerns and systemic issues with Canada together with Mexico in the NAFTA CSRM and subordinate Technical Working Groups (TWGs) established to address particular standards-related issues. For example, the NAFTA TWG established to address food labeling and packaging led to enhanced cooperation among the three NAFTA parties regarding food laboratories and nutritional labeling. The NAFTA parties also address standards-related measures in the context of the NAFTA RCF. For details on these fora and other trilateral cooperation regarding standards-related measures between the NAFTA parties, see Section VIII.

Cheese – compositional requirements

On June 16, 2007, Canada published proposed amendments to its Food and Drug Regulations and Dairy Products Regulations that altered the compositional requirements for cheese. The final requirements, which were published in December 2007 and entered into force in December 2008, mandate that a certain percentage of a cheese's protein content must be casein derived from raw milk rather than reintroduced whey, thereby limiting the protein content of cheese that may be derived from milk protein concentrates (MPCs). The raw milk used in Canadian cheese is primarily supplied by Canadian producers. According to U.S. industry, Canada implemented

the requirements as a means to increase demand for Canadian fluid milk and hence limit the use of MPCs, which are imported from the United States and other countries. While the regulations were under development, the United States and other trading partners raised concerns both bilaterally and in the TBT Committee that the requirements could significantly reduce access for exports of MPCs to the Canadian market.

In October 2008, several U.S. companies, in cooperation with the Canadian dairy processing industry, petitioned the Federal Court of Canada for judicial review of the cheese compositional requirements. The plaintiffs asked the Court to invalidate the regulations, contending, *inter alia*, that the regulations were promulgated for the purpose of providing an economic benefit to dairy producers at the expense of dairy processors and others. On October 7, 2009, the Court issued an opinion upholding the Canadian government's authority to issue the requirements.

In 2010, the United States will continue to monitor trade flows of dairy products between the United States and Canada as well as any additional regulatory developments in Canada.

Provincial notifications

In 2009, Canada did not notify two provincial measures to the WTO that raised potential TBT concerns for U.S. exporters: the British Columbia Recycling Regulation (B.C. Reg. 449/2004) and the Ontario Electrical Safety Authority's product safety registration process for electrical products. As a result of Canada's failure to notify these measures to the WTO in draft form, the views expressed by some U.S. stakeholders were not taken into account by Canadian provincial authorities until late in the regulatory process. The United States believes that this may be evidence of a systemic problem. In 2010, the United States hopes that Canada will take steps to improve its WTO notification practice for sub-central government technical regulations and conformity assessment procedures.

Tobacco products – restrictions on additives

In 2009, Canada enacted amendments to its Tobacco Act relating to the use of additives in cigarettes and other tobacco products. The United States strongly supports the objective of deterring youth from tobacco use. In connection with this goal, U.S. officials have sought additional information on the approach taken in Canada's measure, as well as additional information on any regulations that may be necessary to implement the amendments to Canada's Tobacco Act.

At the November 2009 TBT Committee meeting, the United States asked Canada to confirm when sections 4 and 5 of the Act relating to use of additives in the manufacture and sale of tobacco products would enter into effect, and whether the Canadian government has the authority to amend the schedule of additives that are regulated. At the meeting, U.S. officials asked whether Canada was considering any amendments to the schedule of additives. The United States also asked if Canada could provide information on the criteria used to develop the list of prohibited additives, and the specific efforts it made to identify the relationship in general between prohibited additives and products marketed to or that are innately attractive to youth.

Canada said that it would consider the comments and indicated that it would notify any implementing regulations to the WTO for comment. During the March 2010 TBT Committee meeting, Canada provided written responses to the U.S. questions. The United States stated that it would consider those responses, together with Canada's responses to questions and comments from other WTO Members, in reflecting further on the matter.

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, when specific market access issues arise. Established in 1983, the JCCT 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 IT products, and cotton registration requirements. At the October 2009 JCCT meeting, in an effort to increase collaboration on standards and conformity issues, the two sides agreed to convene a public-private meeting on standards and conformity assessment procedures in the first quarter of 2010.

Conformity assessment procedures

In August 2003, China required the China Compulsory Certification (CCC) mark to be applied to Chinese and foreign goods covering more than 159 product categories – including electrical machinery, IT equipment, household appliances, and their components. Since then, U.S. companies have continued to raise concerns that the regulations are unclear regarding which products require a CCC mark. Industry has also reported that China is applying the CCC mark regulation in an inconsistent manner. In addition, U.S. officials understand that small and medium-sized U.S. companies without a presence in China find it particularly burdensome to apply for CCC mark exemptions, such as for replacement and re-export, because China requires the applications to be submitted in China's Certification Accreditation Administration (CNCA) Beijing offices.

To date, CNCA has accredited 14 certification and 153 testing bodies to test and certify products for purposes of the CCC mark. Despite China's commitment that qualifying minority foreign-owned (upon China's accession to the WTO), and majority foreign-owned (two years later) joint venture conformity assessment bodies would be eligible for accreditation and would be accorded national treatment, China has so far accredited only six foreign-invested conformity assessment bodies. It is not clear whether these six foreign-invested conformity assessment bodies play a sizeable role in accrediting products sold in China.

As a result, exporters to China are often required to submit their products to Chinese laboratories for tests that 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 MOU with China allowing the conformity assessment body to conduct follow-up factory inspections (but not primary inspections) of manufacturing facilities that make products for export to China requiring the CCC mark. However, U.S. officials understand that China has not been willing to grant

similar rights to other U.S.-based conformity assessment bodies, claiming that it is only allowing one MOU per country, the rationale for which has not been provided.

Cotton supplier registration requirements

In August 2008, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) issued Announcement No. 87, which proposed to establish a new registration process for foreign cotton suppliers (domestic cotton suppliers were already subject to an inspection system), and notified it to the WTO. A related AQSIQ measure issued in November 2008 addressed quality assessment of cotton shipments and set out many of the details to implement Announcement No. 87. China did not notify this measure to the WTO. Under these measures, effective March 2009, consignees of foreign cotton are subject to foreign inspection at the border. Foreign suppliers that do not register under this system are automatically subject to a lower "quality credit assessment grade" and are required to include a pre-shipment inspection clause in their contracts.

At the September 2008 JCCT meeting and the March 2009 TBT Committee meeting, the United States identified these measures as a potential trade issue and began holding bilateral meetings with AQSIQ officials to discuss U.S. concerns. U.S. cotton exporters, as well as government officials and exporters from Australia, Brazil and other countries, also raised concerns. The United States noted that, by establishing a government-run regime to grade foreign exporters of cotton to China, the proposed registration and quality assessment system appeared to depart from prevailing commercial practice within the cotton trade. By contrast, in other countries, cotton quality and related issues are addressed through private contract and arbitration.

China claimed that registration was voluntary. The United States noted that exporters that did not register would be subject to pre-shipment inspection and automatically assigned the lowest rating. Because Chinese cotton mills began refusing to do business with unregistered U.S. producers, a number of exporters felt compelled to register out of economic necessity. Finally, U.S. officials expressed concern that AQSIQ was seeking confidential business information on the trading volume, value, and history of an exporter's shipments to China and requested that China explain its purpose in requiring such information. In response to these concerns, AQSIQ agreed to consider suggestions for revising particular provisions of the measure that it had received from the interested governments and foreign industry representatives.

Active dialogue continues between U.S. and Chinese experts on registration and testing requirements. In 2010, the United States will continue to monitor how AQSIQ implements these measures at issue in order to ensure that China's cotton registration requirements do not create a market access barrier for U.S. cotton exporters.

"Excessive packaging" requirements

In November 2007, China notified the WTO of proposed restrictions on "excessive packaging" for six commodities, including alcoholic beverages, cake, grains, health food, and cosmetics. The United States noted its support of China's objective of protecting the environment and conserving resources, noting that other countries, as well as some U.S. states, have chosen to

reduce the effect of waste on the environment by linking packaging cost to specific targets for recyclable content and reuse materials.

However, during TBT Committee meetings in 2008 and 2009, the United States expressed concerns about the efficacy of restricting total packaging cost in relation to product cost, as China had done, to meet its objective. U.S. officials pointed out that the cost of environmentally friendly packaging (*i.e.*, packaging with the highest recyclable content or reuse percentage) often far exceeds that of traditional packaging. Thus, if China were to limit the total cost of packaging, the result may be that industry will be forced to package more products in cheaper materials that cannot be recycled or reused. U.S. officials also noted that less expensive packaging may also contain higher levels of heavy metal contaminants and other potentially hazardous materials, and that packaging enhancements designed to protect safety, such as child safety seals, often increase packaging costs. Further, they noted that China's proposed measure may also discourage innovations in packaging, such as smart shelf life packaging, which may be more costly than cheaper packaging. The United States asked China to re-evaluate its approach to this technical issue and encouraged it to consider some of the methods that other WTO Members employ that could more effectively assist China in meeting its environmental objectives while at the same time not creating new safety and environmental issues and potentially disrupting trade.

While it did not alter its overall regulatory approach on this issue, China took steps to respond to many of the U.S. concerns with a view to enabling foreign suppliers to comply with the requirements. With respect to China's requirements regarding the "inter space ratio" of packaging, China clarified its calculation methodology in a manner that was acceptable to U.S. industry. Second, under China's original proposal, the packaging cost could not exceed 15 percent of the commodity's ex-factory price. China eventually raised the limit to 20 percent, clarified that the original package is the package in direct contact with the product and does not include the label, and indicated that the cost of the original package should not be counted in the calculation of packaging cost. Lastly, China delayed enforcement until April 1, 2010. Thus far, U.S. industry has not reported concerns with the modified requirements.

IT products – mandatory testing and certification

In August 2007, China notified to the WTO a series of thirteen proposed measures requiring certain IT products to be certified for information security functions. The proposed measures appeared to require testing and certification to certain Chinese national standards for information security which, in some areas, may differ from international standards used in the global market. In some cases, the Chinese standards require access to algorithms held by Chinese regulators, and it is unclear on what basis those algorithms will be made available. ACSIQ indicated that the thirteen proposed measures would be mandatory for all covered products as of May 1, 2009.

The United States and other WTO Members expressed serious concerns to China about these proposed measures in numerous bilateral and multilateral meetings. At the September 2008 JCCT meeting, China announced that it would delay publication of final implementing regulations while Chinese and foreign experts continued to discuss the best ways to ensure information security in China. In April 2009, CNCA, ACSIQ, and the Ministry of Finance

announced that implementation of the measures would be delayed until May 2010, and subsequently, in September 2009, China confirmed that the compulsory certification requirement will apply only when products are sold to government agencies, and not to state-owned enterprises or in other sectors of China's economy, representing a significant reduction in the scope of the requirements from China's original plan. At the October 2009 JCCT meeting, China also agreed to a dialogue with the United States regarding global best practices for trade in information security products. The United States will continue to monitor this issue in 2010.

Internet filtering software –“Green Dam”

In May 2009, China's Ministry of Industry and Information Technology (MIIT) proposed a measure that would have required imported or domestically-produced computers sold in China to be pre-installed or packaged with the Chinese-produced “Green Dam – Escort of the Youth Flowers” Internet filtering software, effective July 2009. The software regularly connects to the Internet to download a current list of content to be blocked.

U.S. government officials, as well as a broad coalition of global industry groups and officials from other countries, expressed serious concerns about this proposed measure shortly after it was made public and urged China to revoke it. Among other things, China never notified the measure to the WTO for review and comment and did not provide a reasonable period of time for manufacturers to comply. Additionally, global technology companies, Chinese citizens, and worldwide media expressed serious concerns about the stability of the software, the scope and extent of its filtering activities, and its security weaknesses.

In June 2009, China announced that it was suspending the measure indefinitely.

Medical devices – conformity assessment procedures

The United States has expressed concerns that China maintains two separate authorities — the State Food and Drug Administration (SFDA) and AQSIQ — to enforce regulations with similar, but not identical, requirements for selected medical devices. This potential overlapping and unclear delineation of responsibilities can result in additional and unnecessary regulatory procedures with no demonstrable public health benefit. For example, Decree 95, issued by AQSIQ in June 2007, would have imposed an onerous examination and supervision regime on imported medical devices, introducing additional testing and inspection redundancy to the certification schemes administered by SFDA and, in some cases, CNCA.

The United States, working closely with U.S. industry, raised these concerns as part of JCCT-related meetings with AQSIQ and China's Ministry of Commerce (MOFCOM). In November 2007, AQSIQ issued a notice suspending implementation of Decree 95. In a further step to streamline the registration process, in September 2008 SFDA and AQSIQ jointly announced that they would require only one test, one report, one fee, and one factory inspection for medical devices. Industry welcomed this commitment, projecting that by reducing redundancies this step could cut medical device approval times in half, which would provide U.S. industry with more timely access to China's medical device market.

In April 2009, SFDA circulated for public comment a draft measure intended to supersede the Administrative Measures on Medical Device Registration, originally issued in 2004, but did not notify the draft measure to the WTO. The United States subsequently expressed concerns about this draft measure in bilateral discussions with SFDA during the October 2009 JCCT meeting, and before the TBT Committee as part of China's Transitional Review Mechanism (TRM). Of particular concern was a proposal to require all medical devices to be registered in the country of export or in 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, as manufacturers may decide, for reasons unconnected with the quality or safety of their products, not to seek to have their devices approved in the countries in which they are produced or in the producers' home countries. 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.

Also in April 2009, AQSIQ circulated draft Regulations on the Recall of Defective Products, which would apply to medical devices. Given that China's Ministry of Health and SFDA had begun a process in 2008 to develop a recall system that would also cover medical devices, the United States became concerned about the possibility of redundant recall procedures. The United States raised its concerns in bilateral JCCT-related discussions, as well as during the WTO's China TRM process.

At 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 prior approval process for medical devices. China also pledged to ensure that its product recall procedures for medical devices would not be redundant, and that the Ministry of Health and SFDA would be the relevant regulatory authorities for medical device recalls. The United States will monitor developments in this area in 2010.

Mobile phones – WAPI standard

In May 2003, China issued two standards for encryption over WLANs, applicable to domestic and imported equipment containing WLAN technologies. Conformance to these standards was scheduled to become mandatory in June 2004. The standards incorporated the WAPI encryption algorithm for secure communications. China sought to enforce the use of WAPI by mandating a particular algorithm (rather than mandating the need for encryption, and leaving the choice of the algorithm to market factors) and providing the necessary algorithm only to a limited number of Chinese companies. Had the standards become mandatory, U.S. and other foreign manufacturers would have been compelled to work with and through these companies, some of which were competitors, and provide them with their proprietary technical product specifications. Following high-level bilateral engagement, China agreed in April 2004 to postpone indefinitely implementing WAPI and to work within international standards processes in developing future

wireless standards. This commitment led China to submit WAPI for consideration in ISO and IEC's Joint Technical Committee 1 (JTC1). In 2006 ballot of ISO/IEC JTC1 members, the proposed WAPI amendment did not receive enough votes to be accepted as an ISO/IEC standard.

Concerns regarding WAPI have recently re-emerged as China moved forward with plans to require the WAPI standard to be used in mobile handsets, despite the growing commercial success of computer products in China that comply with the internationally recognized standard, ISO/IEC 8802-11, otherwise known as WiFi. In this regard, over the past several years, global mobile handset makers have increasingly added WLAN/Internet capability into their mobile handsets, thus expanding the use of WLAN equipment beyond laptops and home computers to mobile handsets. The operative standard for this expansion of WLAN/Internet capability across the world has uniformly been the WiFi standard. However, until recently (as noted below) China had not issued type approvals for handsets that connect to the Internet through WLAN equipment, and instead had only issued type approvals for handsets that connect to the Internet through cellular networks, a practice that has required foreign equipment makers to disable WLAN/Internet capability before their handsets could be marketed in China.

In 2009, in concert with its plan for encouraging an aggressive roll-out of third generation (3G) mobile handsets by Chinese telecommunications operators, many of which are Internet-enabled via WLAN networks, MIIT established a process for approving hand-held wireless devices such as Internet-enabled cell phones and smart phones. During bilateral talks in September 2009, MIIT indicated to U.S. government officials that it will approve devices that use the WiFi standard, but only if those devices are also enabled with the WAPI standard. MIIT officials acknowledged that there is no published or written measure setting out this requirement and that China has not notified this requirement to the WTO.

Notification issues

China has designated MOFCOM as its authority for purposes of notifying proposed technical regulations and conformity assessment procedures to the WTO and MOFCOM has notified the WTO of a large number of these measures. This is a positive step. Almost all of the measures that MOFCOM has notified to the WTO, however, have been proposals issued by the AQSIQ, SAC, or CNCA. By contrast, MOFCOM has not notified several important trade-related measures that other agencies (*e.g.*, Green Dam, information security, WAPI) and sub-federal agencies have drafted (*e.g.*, provincial restrictions on plastic bag thickness).

Patents used in Chinese national standards

In recent years, concerns have arisen regarding China's proposed treatment of patented technology in connection with domestic standards development processes.

First, in late 2004, concerns arose after the Standardization Commission of China (SAC) issued draft *Provisional Regulations for National Standards Relating to Patents (Provisional Regulations)* and public statements by key Chinese government officials that appeared to contemplate compulsory licensing of patented technologies that are used for national standards in

China. In November 2009, SAC circulated a new draft of the *Provisional Rules Regarding Administration of the Establishment and Revision of National Standards Involving Patents* for public comment. This draft measure would implement China's vision for a standards development process. The draft measure would establish the general principle that mandatory national standards should not incorporate patented technologies. However, when they do incorporate patented technologies, the draft measure provides for the possibility of a compulsory license if a patent holder does not grant a royalty-free license. This differs from the typical practice of accredited standards developing organizations in other countries, which require disclosure of intellectual property in the standards development process and support "reasonable and nondiscriminatory" (RAND) licensing policies with respect to intellectual property that is incorporated into a standard. RAND policies require concerned patent right holders to make any intellectual property incorporated into the standards that these bodies develop available to all interested parties on RAND terms. Within the standards development process, licensing terms are typically negotiated between the right holder and parties interested in implementing the standards.

Second, in 2006, the Chinese government's Electronic Standardization Institute (CESI), a Chinese government entity, released draft intellectual property policy rules for standards-setting organizations (SSOs). These draft rules envisage Chinese government involvement in standard-setting processes, including a requirement that SSOs obtain government approval for patent claims. Such government involvement could be exercised in a way that affects private party transactions and could raise concerns under certain circumstances.

The United States will continue to monitor how China treats intellectual property through its SSOs, including the development and finalization of CESI's rules, as well as the development of SAC's revised Provisional Regulations.

Colombia

Bilateral engagement

The United States discusses TBT matters with Colombia during, and on the margins of, TBT Committee meetings. In addition, in January 2010, U.S. and Colombian regulators and trade officials held a technical discussion via digital videoconference on Colombia's proposed quality and identity, as well as labeling, requirements for distilled spirits (discussed below), and continue to work toward resolution of the remaining issues.

Distilled spirits - labeling requirements

In an effort to block sales of contraband products, Colombia has proposed two amendments to its alcohol labeling requirements over the past two years. In November 2008 and May 2009, respectively, Colombia's Ministry of Commerce and its Ministry of Social Welfare proposed amendments to Title V of Law No. 09 of 1979, which regulates alcoholic beverage production facilities, as well as alcohol production, hydration, bottling, distribution, sale, export, and import. Colombia notified both proposals to the WTO.

The United States respects Colombia's right to take measures to reduce imports of contraband products. Following discussions with U.S. officials, Colombia modified its labeling proposal so that producers will not be required to translate their brand names into Spanish or use quotation marks to indicate brand names, and to permit producers to use "ordinary course of business" lot numbers. The United States also understands that Colombia plans to consolidate related measures to reduce confusion.

The United States remains concerned about certain labeling provisions that Colombia may incorporate into the final measure. U.S. industry would appreciate flexibility to apply labels bearing the information unique to Colombia either at the place of production or by applying removable overlay "stickers" to their products after they reach Colombia but before they enter Colombia's customs territory. U.S. producers believe that, in some instances, mandating that products be labeled with Colombia-specific information at the point of production is less effective in preventing fraud than is permitting the application of overlay permanently-affixed stickers.

Colombia has indicated that producers will have eighteen months to comply with them. The United States will follow up with Colombia to confirm that producers will have 18 months to comply with these new labeling requirements.

Distilled spirits - quality and identity requirements

In November 2008, Colombia notified the WTO that it was proposing to adopt quality and identity requirements for distilled spirits. The United States and U.S. industry submitted comments to Colombia in March 2009, stating that the proposal would restrict U.S. exports of gin, rum, vodka, and whiskey.

In response to the U.S. comments, Colombia adjusted several elements of its proposed measure, including by clarifying the minimum congener requirement for vodka; indicating that age declarations for rum will be voluntary; noting that flavored spirits were included in the definition of liqueurs; and indicating that *de minimis* flavorings could be used as permitted by regulatory specifications. These changes represent important steps in addressing U.S. concerns on this issue.

The United States remains concerned, however, about Colombia's proposal to use analytical parameters to govern the sale of spirits in Colombia, particularly the prospect of imposing limits on total congeners included in gin, vodka, and rum, and the possibility of imposing minimum and maximum alcohol content limits that could bar some U.S. spirits from the Colombian market. The standards of identity for all distilled spirits sold in the United States, the European Union, Canada and nearly every other major spirits market are based solely on the raw materials and processes used to produce them, and are not defined in terms of a product's chemical composition.

Naturally occurring constituents produced in the fermentation and distillation process, including volatile acids, esters, higher alcohols, aldehydes, and furfural, are integral to the distinctive flavor characteristics of the various brands and categories of distilled spirits, and these constituents vary from product to product. These naturally occurring components are not regulated, either in minimum or maximum levels, by the TTB. Moreover, U.S. regulators are not aware of any

scientific evidence suggesting that these constituents may be harmful to consumers in the concentrations found in distilled spirits.

The United States has also asked Colombia to clarify whether it will permit brandy to be aged in a single oak barrel, in addition to using the solera aging method, and if it will permit liqueurs to contain certain synthetic colorings and *de minimis* amounts of other substances, as TTB and other regulators do.

Finally, Colombia has not implemented a ban on the sale in Colombia of spirits labeled as Kentucky Bourbon or Tennessee Whiskey but produced outside the United States. Colombia has indicated that it will implement such a ban only after the U.S. Congress approves the pending U.S.-Colombia Trade Promotion Agreement, which includes a provision recognizing Kentucky Bourbon and Tennessee Whiskey as distinctive products of the United States.

Ecuador

Bilateral Engagement

The United States discusses TBT matters with Ecuador during, and on the margins of, meetings the TBT Committee.

Various products – conformity assessment

On November 25, 2008, Ecuador's National Quality Council adopted Resolutions No. 001-2008, 002-2008 and 003-2008, which implemented various articles of the Ecuadorian Quality Control System (Law No. 2007-76). These resolutions became effective upon publication on December 1, 2008, and required importers of a number of specific products to demonstrate that they conform to new Ecuadorian product requirements by providing a certificate of conformity from an accredited certification body. Products covered by this certification requirement included apparel and footwear, rubber and tires, safety glass, transformers, ceramic and porcelain house wares and tableware, white goods and appliances, auto parts, cement, plastic, steel and aluminum products, matches, batteries, and lubricants.

Because Ecuador did not publish these resolutions and notify them to the WTO before adopting them, interested parties had no opportunity to submit comments on them, importers were unable to comply with the new requirements, and some U.S. manufactured goods subject to the new requirements were held at the border. Ecuadorian authorities blocked entry of the U.S. goods until importers either (1) demonstrated that the products met the new requirements, (2) provided a substitute certification (*e.g.*, from the American Petroleum Institute), or (3) obtained an exemption for specific shipments.

The United States conveyed the concerns of U.S. manufacturers regarding these resolutions in meetings with Ecuadorian officials on January 22, 2009, and during the TBT Committee meeting in March 2009. Several other WTO Members, including Korea, Chile, and the European Union, also raised concerns during the TBT Committee meeting about the certification requirements. U.S. officials noted that Ecuador had neither notified the WTO nor provided an opportunity for

Members to comment on the resolutions. U.S. officials asked Ecuador to explain its rationale for imposing new requirements on such a large group of products and to provide information about the evidence Ecuador considered in determining the health, safety, or other risks these products posed. The United States also outlined the difficulties the new certification requirements had caused for many U.S. exporters, in particular that they had found it difficult to identify test laboratories accredited to test many of the products subject to Ecuador's new requirements (*e.g.*, socks) because other countries do not require them to be tested.

Ecuador rescinded the new resolutions in early 2009 and notified the rescission to the WTO.

The European Union

Bilateral engagement

The United States has actively engaged the European Union on TBT-related matters in multilateral fora, including the TBT Committee, as well as bilaterally. These are the primary mechanisms through which the United States raises specific trade concerns with the EU regarding standards-related measures.

In addition, cooperation between regulators has been a core element of the work of the Transatlantic Economic Council (TEC) since its inception in 2007. The Framework for Advancing Transatlantic Economic Integration between the United States of America and the European Union – the TEC founding document agreed to during the 2007 U.S.-EU Summit – established “fostering cooperation and reducing regulatory burdens” as a principal objective of the TEC. Consistent with this mandate, U.S. and EU regulators have engaged in discussions on a number of horizontal and sector-specific issues during and in periods between the four TEC meetings held since 2007. At the conclusion of its fourth meeting in October 2009, the TEC agreed to renew the mandate of U.S.-EU regulatory cooperation and identified the goal of achieving “greater compatibility of effective and economically beneficial regulation...that could promote economic integration.” TEC principals also discussed the possibility of identifying emerging sectors in which neither side had yet implemented an extensive regulatory regime so that the two sides could seek to avoid unnecessarily divergent regulatory approaches.

U.S. and EU regulators have also exchanged views and deepened cooperation in a range of areas under the U.S.-EU High-Level Regulatory Cooperation Forum (HLRCF). On the basis of recommendations contained in a joint paper prepared by OMB and the Secretariat General of the European Commission, both sides have taken steps to ensure better analysis of and greater transparency concerning the effects of proposed regulations on international trade and investment. The HLRCF presented a report on strengthening cooperation relating to the safety of imported products, which included concrete recommendations for overcoming current constraints on effective information sharing. OMB and the Commission presented papers in the HLRCF describing the U.S. and EU approaches to the use of voluntary standards in support of regulation. A “Transatlantic Risk Dialogue” will develop white papers in three focus areas: (1) development of a framework for exposure assessment; (2) uncertainty and terminology; and (3) new/rapid approaches to risk assessment.

In addition, the United States and the EU have jointly advocated to trade and regulatory officials in key emerging markets such as Brazil, China, and India the importance of maintaining open and transparent regulatory and standards development processes.

Accreditation rules

The United States continues to have serious concerns regarding the EU's new accreditation framework set out in Regulation (EC) No 765/2008. This regulation, which became effective on January 1, 2010 and applies to all sectors, 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.

The United States has raised a number of concerns about the regulation both bilaterally and in the TBT Committee. First, the regulation raises serious questions as to whether the EU or its Members States will continue to recognize non-EU accreditation bodies that have been accredited under the ILAC MRA and the IAF MLA and continue to accept conformity assessments performed by ILAC MRA and IAF MLA accredited bodies. 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 – including ILAC MRA and IAF MLA accredited ones – and refuse to accept conformity assessments issued by these bodies.

Second, the EU's basis for instituting the new framework remains unclear, including what information the EU relied on to determine that (i) its new accreditation system should limit accreditation activities to governmental bodies or bodies that act in the exercise of official authority, (ii) accreditations should be viewed with a higher degree of confidence when provided by a single national accreditation body, and (iii) competition might compromise the quality of accreditations and should therefore be limited.

Finally, the EU has offered no explanation for why the regulation imposes conditions on accreditors operating in the EU market that go beyond the relevant ISO/IEC standard used under the ILAC MRA and the IAF MLA.

The United States also expressed concern that, without clear guidance from the Commission, Member States may refuse to recognize non-European accreditation bodies and conformity assessments issued by non-European testing and certification bodies. The European co-operation for Accreditation (EA) acknowledges that attestations of conformity assessment results issued by bodies that have been accredited by non-European bodies that are ILAC MRA or IAF MLA signatories are equally reliable as those issued by European bodies complying with the new accreditation requirements set forth in Regulation 765. Yet, the Commission has indicated that the quality and validity of accreditations issued by non-European bodies that have not been accredited under Regulation 765, and attestations of conformity issued by conformity assessment bodies accredited by such bodies, could be in doubt. This raises market access concerns for

products, including many U.S. products, certified by conformity assessment bodies accredited by non-European accreditation bodies. Given the EU's stated intent to spread its accreditation approach worldwide, the United States remains concerned that the EU approach will both undermine the international accreditation system under the ILAC MRA and the IAF MLA and impede U.S. exports to the EU.

The United States continues to have a number of questions about how the new EU accreditation framework will operate in practice. For example, it is unclear under the new EU framework whether European national accreditation bodies are permitted to accredit foreign conformity assessment bodies and, if so, whether they are required to accredit such bodies on no less favorable terms than they accredit European conformity assessment bodies.

U.S. accreditation bodies and other ILAC MRA signatories continue to be concerned that the EU's response to stakeholder concerns is inadequate. The United States will continue to raise this issue with the EU bilaterally and in the TBT Committee and hopes to hold technical discussions with the EU in early 2010. In the interim, the United States urges the Commission to issue guidance to Member States indicating that accreditations by ILAC MRA and IAF MLA signatories are no less reliable than accreditations by European national bodies, and therefore that Member States are free to accept testing and certification from non-EU bodies that have been accredited by an ILAC MRA or IAF MLA signatory.

Borates and nickel compounds: classification and labeling requirements

In 2007, the EU notified an amendment (the 30th ATP) to the Dangerous Substances Directive (DSD) introducing and modifying EU harmonized classification and labeling requirements for 896 substances, including borates, nickel carbonates and other nickel compounds. The U.S. industry considers that the proposed classification of borates under Category 2 of the DSD is unnecessarily trade-restrictive, and that the scientific justification for the classification was inadequate because it was not based on "normal handling and use" of downstream products containing borates. Industry has raised further concerns that by classifying borates in Category 2 of the DSD, the amendment would lead to restrictions and bans on using borates in certain products (*e.g.*, cosmetics, detergents, and fertilizers) under related EU directives. The U.S. nickel plating industry – along with the nickel industries of Australia, Canada, Cuba, Brazil, and other Members – has raised concerns about how nickel is classified under the DSD, asserting that the EU did not properly apply the OECD's "read-across" methodology.

In December 2008, the EU promulgated the Classification, Labeling and Packaging (CLP) regulation to replace the DSD. The classifications of both borates and nickel have since been transferred – without any new analysis – to the CLP regulation, whose classification methodology and category and labeling schemes are different from those of the DSD. In September 2009, the EU published the 1st ATP (Adaptation to Technical Progress) to the CLP regulation – a combination of the 30th and 31st ATP to the DSD – which classified certain borate compounds as category 1B (that is, the equivalent of Category 2 under the DSD).

The United States has frequently raised questions regarding this issue in the TBT Committee, and has asked the EU to clarify its procedures for transferring the borates and nickel classifications from the DSD to the CLP. Industry has raised concerns that the EU has not

followed the procedures specified in the CLP regulation for harmonizing classifications. The United States has also asked the EU to clarify how the borates classification will affect cosmetics, since the EU's risk and impact assessments did not cover cosmetics. Various industrial producers have launched cases in the UK courts and in the European Court of First Instance seeking to annul the borates classification.

On a positive note, the EU recently provided additional information on its nickel classification, which U.S. officials are reviewing. The EU also recently proposed an amendment (G/TBT/N/EEC/297) of REACH Annex XVII to permit the use or placement on the market without restriction of borate compounds used in household cleaners, detergents and certain photographic mixtures. While this is a welcome development, the EU's procedures for classifying borates and certain nickel compounds continue to raise concerns, specifically regarding possible flaws in the EU's classification methodology, the procedures the EU used in transferring these classifications from the DSD to the CLP, and the effect that these classifications will have under other EU measures, such as the Cosmetics Directive and the EU's chemicals regulation REACH. The United States will continue to monitor the potential adverse trade effects of the EU's nickel and borates classifications as well as the methodological issues mentioned above.

Chemicals

While supportive of the EU's objectives of protecting human health and the environment, the United States has raised trade-related concerns with respect to the EU's chemicals regulation, REACH, which entered into force June 1, 2007. REACH impacts virtually every industrial sector, from automobiles to textiles, because it regulates chemicals as a substance, in preparations, and in products. It imposes extensive registration and testing and data requirements on tens of thousands of chemicals. The first registration deadline is November 30, 2010 with subsequent deadlines on the same day in 2013 and 2018. REACH also will subject certain chemicals to an authorization process that would prohibit chemicals from being placed on the EU market except as authorized for specific uses by the European Commission. The United States has raised a number of trade-related concerns regarding REACH.

First, unlike EU manufacturers, non-EU manufacturers lacking an EU presence cannot register substances to fulfill REACH's registration requirements. Only EU legal entities may register. To avoid having each of their importers or downstream users in the EU register their substances, non-EU manufacturers may have no alternative but to appoint "Only Representatives" (ORs) to register chemicals on their behalf. Hiring an OR is an additional cost shouldered only by non-EU manufacturers. In addition, non-EU manufacturers may be required disclose business proprietary information to an OR (or importer) in order to have their substances registered. The United States has pressed the EU to address the problems that REACH's OR provisions pose.

Further, REACH requires polymer manufacturers and importers to register reacted monomers in many circumstances. Industry has raised concerns about this requirement given that reacted monomers no longer exist as individual substances in polymers and would not create exposure concerns in the EU. By contrast, EU polymer manufacturers generally can rely on the registrations of their monomer suppliers. As a result, the reacted monomer registration

requirement provides an incentive for distributors to stop importing polymers and switch to EU polymer suppliers, since the reacted monomers in those polymers will already have been registered. The United States has pressed the EU to eliminate the requirement to register reacted monomers in polymers entering the EU market.

In addition, all pre-registrants must join a Substance Information Exchange Forum (SIEF) to facilitate data sharing between the companies and submit registration dossiers. Many SIEF members have indicated that SIEFs do not function effectively, in part because of the large number of members in some SIEFs, which may cause many companies to miss the first registration deadline. The United States has asked the EU to address these problems.

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 regarding whether these obligations apply if a substance on the Candidate List is present in an article in concentrations above 0.1 percent of the article's entire weight or above 0.1 percent of the weight of the article's components or homogenous parts have engendered uncertainty about how to comply with these obligations. The United States has asked the EU to ensure consistent interpretation of these obligations.

Under REACH, certain "phase-in substances" benefit from extended registration deadlines in 2010, 2013, and 2018. Imported substances not listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), did not qualify for pre-registration, and thus extended registration deadlines, even though they were lawfully on the EU market. Substances in the EINECS are either already considered registered or were eligible for pre-registration, with full registration required up to ten years later based on an extended "phase-in" schedule. Therefore, EU manufacturers of products containing these substances do not bear the cost and burden of registration or have an extended deadline to register. The United States has asked the EU to guarantee the same treatment it grants to "phase-in substances" to non-EU manufacturers through a transparent and legally certain solution.

Further, U.S. SMEs are concerned that REACH will put them at a disadvantage with larger companies because the registration and testing requirements that REACH imposes, as well as participation in SIEFs, will require substantial resources. The United States has asked ECHA to provide assistance to SMEs through its help desks that will aid their efforts to continue shipping to the EU market.

In addition, inadequate transparency and delays in providing legal clarification in the REACH implementation process make compliance planning difficult and limit opportunities for stakeholders to provide input. For example, the United States understands that some REACH guidance documents currently being updated will be finalized too late and will not clarify some pending issues, to help with the first registration deadline in November 30, 2010. Additionally, there has been limited opportunity for stakeholders to provide input into certain guidance documents.

Lastly, EU and U.S. stakeholders are concerned that the substantial data requirements under REACH could result in an increase the use of animal testing as implementation of REACH

proceeds. In September 2009, the European Chemicals Agency (ECHA) issued a clarification that will help prevent duplicative testing. The United States welcomes other steps to avoid unnecessary animal tests.

The United States has raised concerns regarding REACH at 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, Israel, Japan, Korea, Malaysia, Mexico, Qatar, Russia, Singapore, Switzerland, Taiwan, and Thailand. The United States also has raised its concerns regarding REACH bilaterally with the Commission. In addition, it has worked with the ECHA on specific technical issues. The United States will continue to monitor closely REACH implementation in the upcoming year, including the first registration deadline on November 30, 2010 and Member State-level implementation and enforcement regimes, as well as the REACH review process that the Commission has started this year and will be completed by June 1, 2012.

Hazardous substance restrictions

The United States has raised trade-related concerns with the RoHS directive. The RoHS directive prohibits placing certain categories of electrical and electronic equipment on the EU market that contain certain chemicals such as lead, mercury, cadmium, and hexavalent chromium. The RoHS directive includes certain application-specific exemptions from the prohibitions. Requests for additional exemptions are considered on an ongoing basis. The EU is preparing a major review of all existing exemptions.

While it supports the EU's objectives of protecting human health and the environment, the United States has raised concerns regarding the transparency and predictability of the process and timing for considering exemption requests and the absence of a common approach to enforcement in all EU Member States. With the entry into force of REACH, the United States also has pressed for clarification of the relationship between REACH and RoHS to help ensure transparency and legal certainty regarding how substances will be treated.

The EU currently is revising the RoHS directive. The legislative process is expected to be completed in late 2010 or early 2011. The United States is urging the EU to provide an adequate opportunity for U.S. stakeholders to provide input into the revision process, and to ensure that the revised RoHS directive clarifies the relationship between REACH and RoHS and includes an improved exemption process. The United States has also urged the EU to ensure that any decision to expand the RoHS directive's scope of covered products be informed by a thorough impact assessment. It also has urged the EU to ensure that any decisions regarding the scope of covered products, additional restrictions, and exemptions included in a revised RoHS directive are based on science, taking into account intended end-uses and all available scientific and technical information.

Ride-on lawnmowers – unique French requirements

The United States continues to have concerns with respect to the French Ministry of Agriculture's (MoA) "skirt" requirement for ride-on lawnmowers, a measure that France never

published as part of an official law or decree and that was not notified to the WTO. The MoA requirement for ride-on lawnmowers already has disrupted U.S. lawnmower exports to France. If other Member States were to adopt this requirement, a significant portion of the approximately \$1 billion in annual U.S. shipments of lawnmowers to Europe could be adversely affected.

The United States is not aware of any technical basis for requiring ride-on lawnmowers to be fitted with an extra piece of equipment (or “skirt”). EU and U.S. lawnmower manufacturers assert that the MoA has not presented any accident data supporting the need for the requirement, and they allege that the requirement could in fact increase the potential for safety problems by increasing the risk of fire caused by accumulating debris in the vehicle. The European Garden Machinery Industry Federation has challenged MoA’s requirement on several grounds, including France’s allegedly flawed interpretation of CEN standard, disregard of internal market norms, and alleged infringement of EU laws. U.S. officials understand that the skirt requirement represents a unique French requirement that is neither consistent with requirements in other EU Member States, nor based on internationally developed ASTM or ISO ride-on lawnmower standards used throughout the world.

The United States has urged DG Enterprise to re-evaluate its rejection of the European industry petition challenging the MoA requirement’s conformity with the Machinery Directive. The United States has reiterated a request that the Commission share accident data it believes supports the French position that installation of the lawnmower skirt would increase bystander safety, and any analysis undertaken by the MoA on the potential fire hazard that installation of the skirt could create. If this information does not exist or does not support the necessity of the skirt requirement, the United States requested that the Commission recommend that France base its ride-on lawnmower requirements on a relevant international standard, and eliminate the skirt requirement.

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, although the EU appears to be willing to “license” use of such terms to third country producers as long as those third countries regulate the terms in their home markets. Under the United States – EU wine agreement, the EU granted a three-year derogation for the use of such terms for U.S. wines sold in the EU. The derogation expired in March 2009, and the EU indicated that it would not renew the derogation. 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 regulation leaves enforcement to EU Member States. It is unclear how Member States will enforce the regulation or how the Commission plans to ensure consistency of interpretation across Member States.

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. Some of these terms do not have a common definition across

all EU Member States, and the United States is aware of no effort to monitor or limit the use of those terms within the EU. The United States remains concerned about negative trade impacts caused by the EU's March 10, 2009 termination of the three-year derogation for the use of such terms on the labels of U.S. wines sold in the EU, 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, the fact that these terms have been used without incident on U.S. wines in the EU market for many years suggest that there is no risk to consumers. Adding to the U.S. industry concern is the fact that the EU has not indicated how it intends to enforce the limitations with respect to imported wines and whether it will take action to block importation of U.S. wines bearing a traditional expression. Furthermore, the European Court of Justice has expanded the scope of the measures and, contrary to the assurances provided by EU officials, the traditional terms are now protected in languages other than the one for which protection was identified.

Each of the issues elaborated on this section of the report are ones that the United States will continue to follow closely in 2010 and to raise with the EU with a view to resolving the concerns these issues pose for U.S. exporters and producers.

Gulf Cooperation Council

Bilateral engagement

The Gulf Cooperation Council (GCC) is an economic and political policy-coordinating forum for the six Member States (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates (UAE)). The United States engages on standards-related issues with the GCC collectively and with individual Member States. The United States has concluded an FTA or Trade and Investment Framework Agreement (TIFAs) with each of the Member States. These agreements, as well as the WTO, provide context for U.S. engagement on standards-related issues arising in GCC Member States.

In October 2009, officials from the United States, the six GCC Member States and the GCC's standards body – the Gulf Standards Organization (GSO) – held a workshop in Dubai, United Arab Emirates to address a variety of standards-related matters. This workshop was co-hosted by the U.S. Department of Commerce's Commercial Law Development Program (CLDP) and the Emirati Standards and Metrology Authority (ESMA) and provided a forum for U.S., GCC Member State and GSO authorities to exchange information and hold technical discussions with a view to better understanding each other's respective regulatory and standards systems and to explore ways to further cooperation between United States and the GCC regarding their respective standards and regulatory systems. U.S. speakers included officials from USTR, the U.S. Department of Commerce, OMB's Office of Information and Regulatory Affairs, and the Consumer Product Safety Commission, and featured presentations on the TBT Agreement, the importance of transparency in facilitating trade, and comparative approaches to product safety, especially with respect to toys. The event was also attended by regional representatives of U.S.-based exporters and conformity assessment bodies, who were able to ask questions and express

their views to officials from the United States, as well as by the GSO and the GCC Member States.

In November 2009, the GSO hosted a conference on standards and conformance to continue technical discussions and exchange additional information on the U.S. and GCC standards systems. Along with representatives from GSO, representatives from NIST, ANSI, and several U.S.-domiciled standards developers participated in the conference.

After conclusion of this workshop, the Secretary General of the GSO and the Assistant USTR for Europe and the Middle East agreed to continue to increase the two sides' engagement on standards-related issues, and officials from the United States and the GSO, with input from the Member States, are currently working on an action plan to deepen bilateral engagement over the coming years.

Conformity assessment procedures – lack of transparency

In 2006, the Saudi Ministry of Commerce implemented the Certificate of Conformity (CoC) Program. 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 Arabian technical regulation ("conformity certificate"). With certain exceptions, the CoC program requires that all products sold in Saudi Arabia be tested and certified to ensure compliance with the relevant Saudi requirements.

Although at the time of its accession to the WTO Saudi Arabia committed to provide detailed public guidance in English on how to comply with the new conformity assessment program, it has not yet done so. The lack of publicly available guidance on the requirements has created confusion and uncertainty in the marketplace. The company with which Saudi authorities had contracted to provide services for the now abolished ICCP appears to be advertising (via the Internet at www.iccp.com) that its services are a requirement for access to the Saudi market. Because Saudi Arabia has not identified which companies may provide testing and certification services under the CoC system and what this company's role should be under the CoC system, use of its services appears to remain a *de facto* requirement for access to the Saudi market. As a consequence, U.S. conformity assessment bodies appear unable to provide testing and certification for the Saudi market at least without involving this company in some way.

The United States has raised this issue both bilaterally and in the TBT Committee since 2006, including its concern that Saudi Arabia has still not issued guidance in English on how to comply with its CoC requirements. The United States has urged Saudi Arabia to publish guidance on how to comply with the CoC, in particular the criteria that Saudi Arabia will use to approve bodies to test and certify products for the Saudi market, and based on such criteria, a list of conformity assessment bodies that are approved to provide testing and certification for the Saudi market.

To this end, the United States has requested that Saudi Arabia dissolve the iccp.com website and establish a new central website to provide information on CoC requirements. A central website could: (a) list entities that the Ministry of Commerce has approved to test and certify products for

the Saudi market; (b) set out the criteria and procedures that the Ministry of Commerce uses to approve bodies to test and certify products for the Saudi market; (c) describe the formal process it uses to notify bodies whether they have been approved; (d) set out clear procedures for approved bodies to follow when issuing conformity certificates or marks to convey that a product complies with the relevant requirements; (e) clarify when testing is required (*e.g.*, for each individual shipment or once for each product type); and (f) indicate whether the procedures will change once Saudi Arabia adopts the GCC conformity assessment scheme and if so the duration of any transition period that will ensure suppliers have adequate time to adapt to any such changes.

Saudi and U.S. officials are attempting to resolve this issue on a technical level. The United States believes that the issue can be resolved in the near term if Saudi Arabia is willing to devote sufficient attention to the matter at senior levels.

The GSO is currently developing a conformity assessment scheme that could be adopted by each of the six GCC Member States. (Committee representatives have informed U.S. officials that the GCC intends for the scheme to be implemented in successive stages, beginning with toys in 2010.) Thus, in parallel with efforts to resolve concerns with Saudi Arabia's CoC program, the United States is working to establish a dialogue between U.S. and GCC technical experts to discuss the proposed GCC-wide conformity assessment scheme, with the goal of helping to ensure that it is developed, adopted, and applied in accordance with WTO rules and that it is fully transparent.

India

Bilateral engagement

The United States discusses TBT matters with India during and on the margins of TBT Committee meetings. U.S. government officials also discuss such matters with Indian officials under the U.S.-India Trade Policy Forum (TPF), the TPF's Tariff and Nontariff Barriers and Agriculture Focus Groups, the U.S.-India Commercial Dialogue and the High-Technology Cooperation Group.

Cosmetics – registration requirements

U.S. industry has raised concerns regarding India's "Drugs and Cosmetics (Amendment) Rules, 2007," which would amend the *Drug and Cosmetics Rules, 1945*. Industry contends that the amendment would create an unreasonably costly and burdensome registration system for cosmetics products that would also result in unnecessary delays for cosmetic products being brought to market.

Given that India did not notify this measure to the WTO, the United States requested that India notify the measure promptly, delay enforcement to allow a reasonable time for Members to comment, and afford suppliers a reasonable period to comply with the new requirements. India eventually notified the measure, and the United States submitted comments including concerns raised by U.S. stakeholders through India's TBT Inquiry Point.

In response to these comments, India's Ministry of Health (MoH) made a number of clarifications and modifications to the proposed measure, including that it would: not require companies to list all countries where marketing authorization of a product exists; accept manufacturers' self-certification of compliance supported by laboratory reports issued by foreign laboratories, so long as suppliers provided the required data; provide suppliers with either six months or a year to comply and an exemption for products that had already been imported into India from the new requirements; not require suppliers to obtain separate registrations for individual colors of the same product (*e.g.*, lipstick); and recognize internationally-accepted names for ingredients, as set out in the International Nomenclature of Cosmetic Ingredients (INCI) dictionary.

However, the United States remains concerned that MoH intends to treat all cosmetics, whether low- or high-risk, the same under the new system.

Food and distilled spirits – nutritional labeling

The United States continues to raise concerns regarding MoH's changes to its nutritional labeling requirements. In February 2009, India addressed a major U.S. concern by removing a provision that would have required producers of proprietary foods to list the formulation of their products on the label. MoH also clarified that producers of distilled spirits would be exempt from the requirements to provide nutritional information and the expiration date on labels. The revised measure entered into force in June 2009, after India provided a three-month delay in enforcement at the request of the United States and other stakeholders.

The United States is still concerned that the measure may require the labels of distilled spirits to provide the date of production, which is irrelevant in the case of distilled spirits, since such products have an indefinite shelf life. Other outstanding technical questions and concerns that India has yet to address include: the labeling of proprietary foods; the declaration and calculation of certain nutrient values, especially trans fats; the criteria for labeling a product as "trans fat free;" the allowance of stickering on products; and the rules for front of pack flavoring declarations using the statement "CONTAINS ADDED FLAVOUR."

A recent proposal from the Food Safety and Standards Authority of India (FSSAI) may resolve several of the outstanding labeling issues, including the front of pack flavoring declaration rules, but the United States is awaiting further clarification from India on these points. The United States will continue to press India to resolve the remaining issues, including in forthcoming discussions between U.S. and Indian trade and regulatory officials.

Tires – conformity assessment procedures

Since 2007, the United States has raised concerns, both bilaterally and at the TBT Committee, about a proposed Bureau of Indian Standards (BIS) measure setting out conformity assessment procedures for tires. India published the final version of this measure in November 2009, with an effective date of 180 days from date of publication. The measure requires tire suppliers to

apply for approval for each of their tire plants in order to export tires to India. As part of the application process, suppliers need to identify tire families and send sample tires for each family to India for compliance testing at the Central Institute for Road Transport (CIRT). CIRT is currently the only laboratory authorized by BIS to conduct the testing; given CIRT's limited capacity, industry believes that this could lead to testing backlogs and disrupt trade in tires to India.

The United States supports India's goal of promoting vehicle safety, and notes the positive bilateral discussions between the United States and India on this issue over the years. However, if the BIS procedures are promulgated without BIS authorizing additional laboratories to do the testing or providing a sufficient transition period, trade in tires could be disrupted. BIS has recently indicated that it may recognize foreign laboratories to test the tires as long as such laboratories meet the Indian standard and are accredited by the Indian accreditation agency. The United States has advocated that BIS should provide this information and the relevant application procedures, on the BIS website so that test laboratories know how to apply for recognition and what the BIS criteria are. In response, BIS officials have recently indicated that the criteria for accreditation of laboratories may be found on the National Accreditation Board for Testing and Calibration Laboratories (NABL) website and that the guidelines for recognition of laboratories may be found on the BIS website.

On November 19, 2009, India published Notification SO2953 relating to these procedures in its official journal, setting the implementation date at 180 days from publication.

While these are helpful steps, U.S. officials will continue to seek clarification of the criteria, as well as advocate that India recognize additional test laboratories, such as laboratories that have been accredited by ILAC MRA signatories, wherever they may be located. Additionally, U.S. officials will monitor the transition period to ensure that it is an appropriate period of time for compliance.

Indonesia

Bilateral engagement

The United States discusses TBT matters with Indonesia both bilaterally and during meetings of the TBT Committee. The United States – Indonesia Trade and Investment Framework Agreement (TIFA) Council provides a forum for bilateral discussions on a variety of trade-related issues, including TBT issues. Indonesia participates actively on standards and conformance issues in APEC.

Meat and poultry products – halal certification

Indonesia only allows the sale of meat and poultry products that have been certified halal by certifiers recognized by Indonesia's Council of Ulama ("MUI"). Halal certification involves certifying that the product has been slaughtered and handled in a manner consistent with Islamic law. On March 9, 2009 MUI issued a decree announcing that a new list of MUI recognized halal certifiers would become effective October 1, 2009, superseding all previous MUI recognized

halal certifiers. MUI did not make publicly available or notify to the WTO the new procedures and criteria for recognition and inclusion of certifiers on the new list. MUI published the new list of halal certifiers on October 22, 2009, 21 days after the decree's effective date, causing a twenty-two day disruption in all halal trade to Indonesia. The procedures and criteria for MUI recognition remain unclear, preventing U.S. certifiers from effectively petitioning for recognition and inclusion on the list of recognized halal certifiers. The new halal certifier list does not include any MUI recognized poultry certifiers, which has blocked all U.S. exports of poultry to Indonesia. The new list of certifiers also excluded several U.S. processed food halal certifiers that MUI has historically recognized.

In bilateral and TBT Committee discussions with Indonesia on this matter, U.S. officials emphasized that the United States respects Indonesia's right to regulate halal products and that Indonesia and the United States share the common goal of ensuring that foods labeled "halal" meet Indonesia's requirements. The United States, however, is concerned with the lack of transparency in the development and application of the new halal certifiers list. U.S. officials requested clarification on how Indonesia makes regulatory decisions with respect to halal issues, including which entities are responsible for composing the list of recognized halal certifiers, and for clarification of the scope of Indonesia's halal regime, including whether halal certification is voluntary or mandatory. The United States has also asked Indonesia to clarify an attachment to the final certifiers list, which indicates that the certifiers can only certify raw materials. The United States has pressed Indonesia to notify all halal procedures and criteria in draft form to the WTO for comment. Finally U.S. officials have urged Indonesia to allow U.S. halal certifiers to apply for and receive recognition under transparent procedures and criteria and, until that happens, to allow previously-recognized halal certifiers to continue to certify halal products for the Indonesian market.

Food, supplements, drugs, and cosmetics – distribution license requirements

On August 31, 2009, Indonesia's National Agency of Drug and Food Control announced new requirements for the distribution of food, food supplements, drugs, and cosmetics. These requirements state that no food, food supplements, drugs, or cosmetics may be distributed in Indonesia without first obtaining a distribution license. The criteria that must be met to receive a license differ by product type and are based on several factors, including whether certain ingredients are halal. For instance, in the case of pharmaceutical products, drugs sourced from, containing, or manufactured using certain animal substances cannot be awarded a distribution license unless there is an "emergency."

In emergencies, a Cross Sector Team for Legality and Emergency, comprising officials from the Health Ministry, the National Agency of Drug and Food Control, MUI, and relevant expert physicians, determines which drug products will receive a license. Once awarded a license, drug products sourced from swine must bear a label indicating "Swine Content." Further, drug products manufactured using substances sourced from swine in the production process must bear a label indicating that: "The manufacturing process involves a substance that [is] sourced from swine and has been purified so that [it is] not detected on final product." Food sourced from swine is subject to a separate set of emergency procedures. Distribution licenses also cannot be awarded for products containing alcohol, such as certain pharmaceuticals, cosmetics, and food flavorings. Indonesia did not publish the draft measure in advance or notify it to the WTO.

The new requirements could disrupt U.S. exports to Indonesia of foods (many flavorings contain alcohol, sometimes in *de minimis* amounts); drugs (many products, such as cough syrups and other over-the-counter drugs, contain alcohol and others, such as gelatin capsules and vaccines, are sourced from swine); and cosmetics (many products contain alcohol). The United States is particularly concerned that the new requirements may disrupt trade in critical medicines, such as vaccines, as well as trade in many other products. For example, vaccines developed to address a pandemic can be sourced from swine and thus could be banned in Indonesia under the new requirements. In addition, because the decree indicates that the use of traditional drug products, cosmetics, and food supplements are “in general not emergency,” it appears that Indonesia will generally not award a distribution license for products sourced from, containing, or derived from, certain animal substances.

While the United States respects Indonesia’s right to regulate halal products, Indonesia should have developed and applied its requirements affecting trade in halal products in a transparent manner that does not disrupt trade. Because the measure entered into force on the date of publication, and Indonesia did not notify it to the WTO in proposed form, stakeholders did not have an opportunity to comment on, or a reasonable period to comply with, the new requirements. In addition, many of the operational details of the licensing system are unclear.

U.S. officials have posed several questions to Indonesia to better understand the new requirements. In particular, U.S. officials raised questions about the basis for Indonesia’s decision to create separate procedures for halal products to receive distribution licenses, as well as a number of questions regarding the operation of the new requirements including: the criteria and procedures used to determine whether an emergency exists and who makes that determination; the procedures to apply for a distribution license; the criteria and procedures the Cross Sector Team will use to evaluate whether to grant a distribution license; and any avenues for appealing application denials.

The new requirements raise further concerns. Because there is currently no test for detecting porcine (swine) materials in drugs, it may not be feasible for producers to label drugs manufactured using porcine (swine) content (and awarded distribution licenses under the emergency provision) and thus Indonesia is asking drug manufacturers to certify to something that they may not be able to confirm readily.

The United States has raised this issue with Indonesia bilaterally and in the TBT Committee and has requested technical talks with Indonesia to try to resolve the matter. The United States has requested that Indonesia suspend enforcement of the measure until it notifies it to the WTO and takes comments from trading partners into account. The United States believes that additional transparency and clarification of Indonesia’s distribution licensing regime is needed, and that Indonesia can meet its regulatory objectives while ensuring that trade in food, food supplements, cosmetics, and drugs (including critical products such as medicines) is not disrupted.

Israel

Bilateral engagement

The United States and Israel engage on TBT issues in a variety of venues. The United States discusses TBT matters with Israel during, and on the margins of, TBT Committee meetings and at Joint Committee meetings of the U.S.-Israel FTA. The United States and Israel also convene an annual Working Group on Standards and Technical Regulations to discuss outstanding bilateral issues, as well as achieve greater cooperation in the areas of standards and conformance. During the most recent Working Group meeting in Jerusalem in March 2009, U.S. officials met with numerous officials from Israeli trade and regulatory agencies, including the Standards Institute of Israel (SII), to discuss their countries' respective standards systems and ways that the two sides can work together more closely on standards-related issues. U.S. officials have forged a constructive relationship with SII, which has generally been responsive to U.S. concerns, notifies draft measures to the WTO for comment and takes WTO Member comments into account, and engages with U.S. officials to find solutions to bilateral challenges.

Distilled spirits – quality and identity requirements

On January 12, 2009, Israel notified to the WTO proposed amendments to its alcoholic beverages identity requirements that, if implemented, would restrict exports of certain U.S. spirits to Israel. The United States submitted comments on March 5, 2009, requesting that Israel: (1) clarify that Bourbon and Tennessee whiskey are distinctive U.S. products that may be produced only in the United States in accordance with U.S. laws and regulations; (2) eliminate the mandatory aging requirement for blended whiskey; and (3) ensure the proper use of the term “straight” whiskey. U.S. officials have discussed these concerns with Israel bilaterally including on the margins of TBT Committee meetings as well as in Working Group and Joint Committee meetings.

In May 2009, the SII Technical Committee – Alcoholic Beverages indicated that it would accept requests (1) and (3) above, and these changes were incorporated into the final measure. However, the SII Technical Committee denied the U.S. request to eliminate the minimum aging requirement for “General kinds of whiskies” (*e.g.*, whiskies whose labeling is not based on the geographical site of production).

The United States continues to have concerns regarding Israel's decision to maintain the mandatory aging requirement for whiskey because that decision will adversely affect exports to Israel of certain U.S. whiskey products (though not Bourbon and Tennessee whiskey). The problem arises with respect to blended whiskeys, which are defined as mixtures that contain straight whiskey or a blend of straight whiskeys at not less than 20 percent on a proof gallon basis, together with other whiskeys (*i.e.*, not straight whiskeys) or neutral spirits. Neutral spirits are almost never aged and therefore, if neutral spirits are added to straight whiskeys, the resulting blended whiskey will not meet any minimum aging requirement.

There is no international standard for “whiskey” including none pertaining to maturation requirements for whiskey. Depending on climactic conditions, whiskey does not need to be aged

three years in certain parts of the world (*e.g.*, in some U.S. States) in order for the product to obtain the characteristics of whiskey. Given that Israel does not produce whiskey, it is surprising that Israel would choose to retain such restrictive requirements for the identity of whiskey that will prohibit certain U.S. blended whiskeys from entering the Israeli market.

U.S. officials have urged Israel to create an exception from the three-year aging requirement for “blended whiskeys” that conform to the exporting country’s origin requirements. This would allow the importation of U.S. blended whiskey without undermining the three-year aging requirements for Scotch whisky and Irish whiskey. SII has indicated that the U.S. proposal has been sent to the SII Technical Committee for its consideration. The United States is prepared to provide additional information to the SII Technical Committee as it considers the proposal.

Infant formula – requirements for approval, labeling, and conformity assessment

In March 2007, U.S. industry began raising concerns about the lack of clear, consistent, and publicly available information on Israel’s requirements for issuing import approvals or licenses, conformity assessment procedures, and labeling requirements for infant formula.

The United States raised this issue with Israel, both bilaterally and during TBT Committee meetings, on several occasions, including in written communications to Israel’s Ministry of Health (MoH). In particular, the United States sought to obtain additional information about Israel’s requirements for infant formula and requested that Israel notify these requirements to the WTO so that other Members could comment on them.

In December 2009, Israel published a document setting forth its technical requirements governing infant formula, which appears to apply equally to domestic and imported formula, for instance: how frequently testing must be conducted (every batch); which laboratories are authorized to test for particular vitamins, minerals, or other substances; and procedures for inspection of domestic facilities. U.S. officials are analyzing this document and in 2010 will follow up with Israel on any remaining technical issues. The United States will continue to urge Israel to indicate the specific quality and health requirements that infant formula must meet to be sold on the Israeli market.

Spare parts – labeling requirement

The United States has serious concerns regarding Israel’s country of origin labeling requirement for automotive products and heavy equipment. On December 9, 2008, Israel’s Ministry of Transportation (MoT) finalized Regulation 31/08, the “Regulation for Labeling of Imported and Locally Produced Automotive Products – Name of Manufacturer and Country of Origin Requirements.” The apparent objective of the regulation is to help ensure that suppliers are complying with the existing country of origin labeling requirement on spare parts.

The United States does not object to Israel’s country of origin labeling requirements for these products, which have existed for many years. However, the new measure appears to treat U.S. products differently from Israeli and third-country products by requiring the label to indicate the U.S. State, and possibly the city, in which those products are manufactured, in addition to the

country of origin. This requirement has generated significant concern among U.S. manufacturers of auto parts and heavy equipment. In particular, sections 8 and 9 of the regulation state that the markings such as “Made in Japan,” “Made in India,” and “Made in China,” are acceptable, but “Made in the USA” is not. Instead, spare parts from the United States – and the United States alone – must also indicate the State of production, and possibly even the city or town (*e.g.*, “Made in the USA-Detroit, Michigan”).

WTO rules generally do not permit a Member to treat another Member’s products less favorably with regard to marking requirements than it treats like products of other WTO Members. Regulation 31/08 appears to treat certain U.S. products differently from similar products manufactured elsewhere. Israel has not provided a plausible justification for such disparate treatment. The reasons for this disparate treatment are particularly difficult to discern given that U.S. producers must also provide a Certificate of Origin for these goods to Israeli Customs on importation in order to qualify for duty-free treatment pursuant to the U.S.-Israel FTA, and are required to provide a detailed declaration upon request to substantiate any origin claim. Israel also failed to notify the measure to the WTO for comment in its proposed form.

Given that Regulation 31/08 was not developed in a transparent manner and appears to treat U.S. automotive products and heavy equipment differently from like products that are manufactured in other countries, the United States has urged Israel both bilaterally and in the TBT Committee to repeal the regulation’s additional marking requirements for U.S. products so that U.S. spare parts receive treatment that is comparable to like products from Israel and other WTO Members.

In January 2010, Israeli authorities indicated that Israeli Customs would no longer enforce the additional marking requirements for U.S. products and that they would pursue a change in the applicable regulation within the next few months.

Vehicle headlights – replacement requirement

Section 351A of MoT Regulation 262 requires that all vehicles intended for civilian use manufactured in North America that enter the Israeli market be re-fitted with headlights that meet the UNECE headlight standard (EEC 756/76).

U.S. industry is concerned that the additional cost of replacing the headlights on imported U.S. vehicles puts them at a competitive disadvantage in the Israeli market. While cars built to U.S. Federal Motor Vehicle Safety Standards (FMVSS) specifications may be imported and sold in Israel, industry believes that considerably more U.S. vehicles would be shipped to Israel if this requirement were eliminated. According to Israeli distributors of certain U.S. vehicles, converting a vehicle’s headlights from FMVSS to UNECE adds approximately \$1,300 to the price of every U.S.-made car sold in Israel, putting such cars at a disadvantage against other imported cars. One company states that, if this measure were eliminated, the company would import approximately 3,500 additional cars into Israel annually, which would result in an additional \$70 million in sales.

The United States supports Israel’s right to regulate in the area of automobile safety, but has indicated U.S. interest in learning more from MoT about the scientific and technical basis for its headlight requirement. The U.S. government is seeking discussions on this issue with Israeli

auto regulators so that the U.S. Department of Transportation's National Highway Traffic Safety Administration can provide additional information on the FMVSS for headlights and better understand MoT's safety concerns.

Japan

Bilateral engagement

The United States discusses TBT matters with Japan during, and on the margins of, TBT Committee meetings. In addition, the U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) has served as one important forum for engagement between the United States and Japan on market access and business environment issues, including some with a potential TBT component. Four working groups and a high-level officials group have been addressing issues in areas such as telecommunications, transparency, agriculture, medical devices and pharmaceuticals, information technologies, and cosmetics and nutritional supplements. The Regulatory Reform Initiative has been led by USTR and Japan's Ministry of Foreign Affairs, and has involved a broad array of U.S. and Japanese departments and agencies.

The July 2009 Regulatory Reform Initiative's Report to the Leaders outlines the steps that Japan has either taken, or will take, across a number of areas. In the area of pharmaceuticals and medical devices, Japan is setting clearer performance measures for reviewers involved in approving new products. For nutritional supplements, Japan will continue efforts to improve transparency at its quarantine stations to streamline import procedures. Japan will also continue an exchange of views with consumers and industry groups, including from the United States, on ways to improve the Foods for Specified Health Uses (FOSHU) system, use of which allows health claims to be made about nutritional supplements, and on industry proposals for a system allowing ingredient-specific health claims that is science-based and transparent. Japan also explained its classification criteria for drugs, foods, and food additives and the process it uses to determine whether ingredients qualify as drugs, as well as the process it uses to provide opportunities for industry to exchange views and ask questions about the classification criteria for new ingredients and the application process for health foods.

Regarding cosmetics, Japan indicated that it had published a list of active ingredients from previously approved medicated cosmetics applications to increase transparency in the approval process. Japan reported it will continue to engage in consultations with U.S. industry concerning Japan's "quasi-drug" regulations, the appropriate labeling of cosmetics, and the regulation of manufacturer claims on the effectiveness of cosmetics. Moreover, Japan will devise ways of streamlining the import process for cosmetics, including publishing additional regulatory information and continuing to discuss the issue with industry, including U.S. industry.

Lastly, Japan will continue to take steps to encourage its ministries and agencies to increase the number of public comment periods in administrative rulemaking that are longer than thirty days, as well as to take other steps to promote more effective implementation of the public comment procedure, including allowing sufficient time for agencies to consider comments where possible, and to provide responses as efficiently as possible. The United States has continued to press

Japan regarding the importance of taking additional steps to ensure that the private sector has sufficient information on regulations and interpretations and commentaries of laws and regulations are published and made easily available to the public.

Organic product requirements

Despite close cooperation between U.S. and Japanese officials, U.S. organic exports to Japan continue to be hindered due to several factors.

First, U.S. organics exports to Japan are limited by Japan's ban on alkali extracted humic acid, a substance that USDA permits for use on U.S. organic crops. After examining scientific data provided by the United States on lignin sulfonate, potassium bicarbonate, and humic acid, Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) announced in October 2008 that it would permit only (1) potassium bicarbonate and (2) some uses of lignin sulfonate for binding and anti-caking. Japan explained what information it needed to re-assess the use of humic acid in organic production. The United States subsequently requested that Japan allow the use of lignin sulfonate as a floatation device for cleaning fresh fruits in the organic production process, but MAFF rejected the request on the grounds that there was a lack of research on the subject. However, Japan conveyed its willingness to re-examine the issue if U.S. officials could provide data supporting the need to use lignin sulfonate for this purpose.

In addition, Japan's zero tolerance policy for pesticide and herbicide residues on organic products is problematic. While such substances may not have been applied to organic crops, they are present in the natural environment, so a zero percent residue is rarely achievable. Mandating zero tolerance for pesticide and herbicide residues would appear to go beyond the Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods. The Codex Guidelines apply to the process by which organic foods are produced. They do not require organically produced foods to comply with specific safety or quality criteria and do not mandate specific maximum residue levels for pesticides and contaminants. In fact, paragraph 6 of the "Forward" to the Guidelines notes that organic production practices do not ensure products are completely free of residues.

In March 2002, Japan granted equivalence to the U.S. National Organic Program (NOP), meaning that products that are certified organic under the NOP can be marketed as organic in Japan. In January 2007, Japan requested that USDA recognize the MAFF organic requirements as equivalent to the NOP and submitted a side-by-side comparison of MAFF and NOP requirements. In May 2008, U.S. officials recognized MAFF to be the competent authority to accredit Japanese certifiers to certify domestic organic production to the NOP requirements. However, U.S. officials cannot deem the Japanese requirements to be equivalent to the NOP unless Japan eliminates its zero tolerance policy on pesticide residues.

On April 8, 2009, MAFF announced that it would begin the process of revising Japan's requirements for organic plants, organic processed foods, organic livestock products and organic feeds. It indicated that during the revision process, which is scheduled for completion by 2011, MAFF will discuss with stakeholders the question whether to ensure that organic foods are free from pesticide residues.

Korea

Bilateral engagement

Korea and the United States hold regularly scheduled bilateral consultations to address potential bilateral trade issues, including technical barriers, as they emerge. These bilateral consultations, led by USTR with participation from the full range of relevant 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 2009, bilateral trade consultations were held on three occasions: in March, July, and December, leading to the resolution of a number of TBT issues. A similar slate of meetings will be held in 2010. In addition, USTR and other agency officials meet with their counterparts in the Korean government on a regular basis to discuss trade-related issues, for example, in the context of the TBT Committee or WTO NAMA negotiations.

Cell phones – WIPI

Prior to April 2009 Korea required manufacturers to install the Wireless Internet Protocol for Interoperability (WIPI) software platform on all cell phones sold in Korea. The WIPI software platform is a Korea-unique standard, and is technologically incompatible with the open network architecture used on Internet-capable smartphones. (Please refer to the National Trade Estimate reports from 2003-2009 for more information on WIPI and U.S. Government efforts to address concerns with this requirement.) This requirement expired on April 1, 2009, following years of U.S. Government engagement on the issue. Subsequently, a number of smartphone models have been launched in the Korea market.

Conformity assessment

The pending United States – Korea Free Trade Agreement addresses conformity assessment issues in several ways, most notably by committing Korea to provide national treatment in its recognition of conformity assessment bodies, to recognize conformity assessment bodies on the basis of published criteria, and to take steps to implement Phase II of the APEC Telecomm MRA with respect to the United States as soon as possible. At the current time, however, Korean laws and regulations generally limit the bodies that may test and certify products for compliance with Korean electrical safety requirements to “domestic nonprofit organizations equipped with suitable testing equipment and qualified testing personnel...” U.S. industry has argued that the inability of U.S. testing and certification bodies to test and certify products for the Korean market disadvantages U.S. manufacturers on account of the fact that U.S. manufacturers must have their products tested and certified in Korea, which can be inconvenient, time consuming, and costly and cause delays to market. However, there were positive developments on this front in 2009 with respect to lithium ion batteries and energy efficiency testing as noted below.

Energy efficiency testing

U.S. appliance manufacturers had raised concerns about Korean measure requiring that their products be tested for energy efficiency only in designated Korean laboratories. Following U.S. engagement on this issue (together with engagement on related issues regarding energy

efficiency testing for refrigerators discussed below), in December 2009 Korea amended its certification requirements for refrigerators to allow manufacturers to use laboratories accredited by ILAC MRA signatories, including non-Korean laboratories, to test their products for compliance with Korea's energy efficiency requirements.

Lithium ion battery testing

Prior to September 2009, U.S. consumer electronics producers had also expressed concerns about new Korean safety regulations for lithium ion batteries, in particular the requirement that the batteries used in their products (*e.g.*, laptops and cell phones) destined for the Korean market be tested at one of four Korean laboratories, which could lead to bottlenecks and resulting delays to market. U.S. officials raised this issue with Korea and, in September 2009, Korea published final measures that will allow non-Korean laboratories to test lithium-ion batteries for conformity with Korean safety requirements. The measures provide that the Korean Agency for Technology and Standards (KATS) will accept test results issued by laboratories that have been accredited by an ILAC-MRA signatory and that have been designated by KATS as having the Korean battery standard (which is based on IEC 62133) within the scope of their accreditation. This decision benefits U.S. consumer electronics producers as it enables them to use batteries in their products destined for the Korean market that have been tested outside of Korea (*e.g.*, in the United States).

While welcoming this development, U.S. officials are also urging the Korean government to use the decision in this instance to allow foreign laboratories to test products for the Korean market as a precedent for other such products for which testing is required.

Cosmetics – approval of active ingredients and testing requirements

In 2009, the United States raised industry concerns that the Korean Food and Drug Administration's (KFDA) process for adding new active ingredients to its list of "approved active ingredients" for functional cosmetics (*e.g.*, facial creams containing sunscreen), and its process for providing notice of such additions, lacked transparency. The list of approved active ingredients is important, as products that use such ingredients are not required to undergo the full testing and approval regimen required of products containing other active ingredients. The lack of transparency led to concerns that KFDA may have been informing Korea's domestic industry of new approved ingredients sooner than U.S. industry was able to obtain this information. To resolve such concerns, KFDA clarified its process of updating its list of approved active ingredients for functional cosmetics, providing a notice and comment period for proposals to add new approved active ingredients to the list and publishing the list on its web site.

U.S. cosmetics manufacturers have also raised concerns about KFDA's quality control testing requirements. Korea allows foreign cosmetics manufacturers to export cosmetics to Korea without additional quality control testing in Korea, if their manufacturing plants have been certified by KFDA through an audit and inspection process. A lack of clarity regarding whether KFDA would certify a plant that uses testing processes different from those used in Korea led many manufacturers to not pursue this option. U.S. officials discussed this issue with Korea on several occasions in 2008-2009.

In March 2009, KFDA approved the application of a major U.S. cosmetics manufacturer to ship non-functional cosmetics to Korea from all of its U.S. facilities without requiring those products to undergo quality control testing in Korea. Korea indicated that it would also approve applications of U.S. cosmetics manufacturers to ship functional cosmetics without requiring them to undergo quality control testing in Korea. However, for functional cosmetics, Korea indicated that under its Cosmetics Act it could only certify U.S. manufacturing facilities that implement Korean testing requirements – in particular, testing the final product for presence of heavy metals. As the more common international practice is to test a product’s ingredients – rather than the final product – for heavy metals, U.S. companies have been unable to obtain certification of their plants with respect to functional cosmetics. The United States will continue to work with Korea to increase opportunities for U.S. manufacturers to use this manufacturing facility certification process if they choose, including for functional cosmetics.

Motor vehicles – proposed fuel efficiency and emissions requirements

In 2009, Korea proposed to strengthen its fuel efficiency requirements and introduce carbon dioxide emissions limits for automobiles. (See the Korea section of the 2010 National Trade Estimate report for a discussion of this issue.)

Organic products – requirements and conformity assessment issues

In June 2008, Korea published its new Processed Organic Foods Regulation, with an original implementation date of January 1, 2010, which would require all products claiming to be organic to be certified as organic by a certification body accredited by Korea’s Ministry of Food, Agriculture, Forestry and Fisheries (MIFAFF). Many U.S. producers and certifiers have been reluctant to attempt to seek certification and accreditation under the new regulation, in part because no provisions exist in Korean regulations that allow for negotiating agreements for equivalence or mutual recognition, and in part due to Korea’s zero-tolerance policy on biotechnology presence in organic products. As a result, the regulation could significantly impede, or even stop, U.S. organics exports to Korea. In response to several requests by the United States and other exporting countries, in December 2009 MIFAFF agreed to allow foreign organic products to be sold in Korea until January 1, 2011 without having to be certified by a MIFAFF-accredited certifier.

While Korea’s decision to extend the implementation date of the regulation to January 1, 2011 is a positive development, longer-term solutions will be necessary. The U.S. Government intends to address all outstanding its concerns by seeking Korea’s recognition of USDA as the U.S. organic accreditation body – so that USDA-accredited certifiers can certify products to both U.S. and Korean requirements – and eventual equivalence between the two countries’ organic systems. The United States will also continue to urge Korea to re-consider its zero-tolerance policy on biotechnology presence in organics.

Processed food products – mandatory biotechnology labeling

In October 2008, KFDA proposed expanding its mandatory biotechnology labeling for food products containing bioengineered ingredients to include processed products such as vegetable oils and distilled spirits. Under this proposal, certain processed products with ingredients

derived from biotechnology commodities, such as corn and soybeans, would require a label indicating that they are derived from biotechnology products. A decision from the Korean government on whether to adopt the proposed requirements remains pending.

As noted in the Trends section, the United States has concerns with the negative effect on trade that results from the mandatory labeling of food products containing or derived from biotechnology. By expanding the scope of products covered by its mandatory labeling regime, Korea's proposal would result in an even greater disruption of trade in food products. U.S. officials have continued to urge Korea to reconsider the need for expanding the regime.

Refrigerators – energy efficiency requirements

Building on agreements reached in 2007 and 2008, U.S. officials continued in 2009 to address remaining issues related to Korea's energy efficiency regulations, particularly with respect to refrigerators. To address U.S. industry concerns that the previous standard resulted in underreporting of actual energy consumption that provided unfair advantages to Korean domestic manufacturers, Korea expedited adoption of ISO 15502 (Household refrigerating appliances – Characteristics and test methods). Adoption of ISO 15502 in April 2008 reduced the ability of Korean companies to circumvent Korean energy efficiency requirements. Korea also agreed to require that manufacturers attach energy efficiency rating labels based on the new test standard. This requirement applied to new models and existing models whose energy efficiency label may have been flawed on account of the previous test method. (See the 2008 and 2009 National Trade Estimate reports for more details on the history of this issue.)

However, when the final amended energy efficiency regulation went into effect on April 30, 2008, a key industry request – inclusion of a complaint mechanism – was not granted. U.S. officials continue to press the issue of including a challenge mechanism in the amended energy efficiency regulation. In February 2009, Ministry of Knowledge Economy amended relevant regulations to include provisions allowing a manufacturer to challenge a competitor's test results, and to clarify that a subsequent finding of non-compliance with the energy efficiency regulation would result in penalties. Nevertheless, concerns remained with the challenge procedure as initially implemented, and U.S. officials worked closely with their Korean counterparts in 2009 to enhance the effectiveness of the challenge mechanism and stakeholders' confidence in Korea's enforcement system.

As a result of ongoing discussions, Korea is moving forward with additional amendments to the challenge mechanism to ensure that a case is assessed within a specific period. Korea is also positively considering a mechanism that would allow manufacturers to provide test results from foreign laboratories as a reference point for Korean authorities to use in initiating their own investigations and enforcement actions. U.S. officials have indicated that the United States and U.S. industry would like to engage in further discussions with Korea regarding amendments to the challenge mechanism to ensure that it is an effective tool that fully accomplishes its objectives. Among other things, the United States has stressed that Korea should ensure that penalties for fraudulent claims (and labels) that a product has a higher energy efficiency ranking than actual performance would merit are equivalent to penalties for fraudulent claims that a product meets Korea's minimum energy efficiency requirements.

Solar panels – design requirements

U.S. officials raised concerns in 2009 that certain types of thin-film solar panels (TFSP) manufactured by U.S. industry cannot be placed on the Korean market. Since July 2008, Korea has required solar panels to be certified by the Korea Management Energy Corporation (KEMCO) in order to be sold in Korea. In 2007, Korea issued a mandatory Korean standard (KS) for TFSP (KS61646:2007 Thin film terrestrial photovoltaic (PV) modules – Design qualification and type approval). The Korean standard is based on IEC 61646 (thin-film terrestrial photovoltaic (PV) modules – design qualification and type approval), except that the Korean standard applies only to amorphous silicon (A-Si) type thin film solar panels. Korea has not adopted a standard for other types of TFSP.

As a result, other leading types of panels, including Cadmium Telluride (CdTe) and Copper Indium (di) Selenide (CIS), cannot be tested or certified under the Korean standard and accordingly cannot gain the necessary certification to be placed on the Korean market. The lack of an applicable standard will also affect other types of thin film panels, such as Gallium arsenide (GaAs), which are emerging as commercially proven technologies. According to U.S. industry, Korea is the only country in the world that specifically restricts application of the IEC standard to only one of the three leading types of thin film panels.

U.S. officials have raised this issue with Korea throughout 2009, and will continue to do so, in order to press Korea to allow the use of IEC 61646 for thin film panels other than A-Si TFSP.

Malaysia

Bilateral engagement

The United States discusses TBT matters with Malaysia during, and on the margins of, TBT Committee meetings. Malaysia also participated actively in the APEC Toy Safety Initiative.

Toys and children’s articles – conformity assessment procedures

On November 6, 2008, Malaysia notified a proposed toy safety measure to the WTO. Originally scheduled to take effect on January 30, 2010, the “Consumer Protection (Certificate of Approval and Conformity Mark of Safety Standards) Regulations 2009” would establish new conformity assessment procedures for toys and children’s articles sold in Malaysia. The proposed procedures set out several requirements, including review and approval of test reports (involving possibly redundant testing), and submission of toy samples to determine placement of a new Malaysian mark of conformity.

Under the proposal, in order for a toy to qualify for the Malaysian mark of conformity, its manufacturer would be required to have the product tested for compliance with Malaysian toy safety standards by an accredited laboratory and obtain a “Conformity Assessment Report” (CAR) and a “Certificate of Approval” (COA) from the Malaysian government. To obtain a CAR, the manufacture would need to file an application with SIRIM QAS International Sdn.

Bhd – a subsidiary of SIRIM Berhad, which is a wholly-owned company of the Malaysian Government under the Ministry of Finance. A separate application would need to be filed for each “set” of products that are similar in function and material. If, based on its assessment, SIRIM determines that the products comply with applicable Malaysian safety requirements, SIRIM will issue a CAR.

To secure a COA, the measure would require the manufacturer to submit application showing that the manufacturer complies with the requirements established by the Companies Commission of Malaysia as well as submit extensive documentation on the company itself. Once the manufacturer obtained the COA, the company would be permitted affix the new Malaysian conformity assessment mark on the “set” of toys covered by the application. The manufacturer would also have to obtain approval from SIRIM regarding the position of the mark on the product.

Malaysia proposed to begin enforcement of these requirements on January 30, 2010. As of that date, toys that had not received a CAR and COA and marked in accordance with the procedures could not be introduced into commerce, and any products on store shelves or in inventory that had not been tested, certified, and marked would have to be withdrawn from commerce.

U.S. industry raised three primary concerns with the proposed measure. First, it was concerned that Malaysia appeared to be imposing a government certification system for toys and expressed its preference that Malaysia adopt a system similar to the one used in the United States – a self-certification system based on third party testing. Second, many of the details of the procedures were unclear. Third, the proposed measure would apply retroactively to all toys in the supply chain, with enforcement set to begin after a very short period.

The United States discussed the issue with Malaysia bilaterally on the margins of the TBT Committee. The United States noted its strong support for Malaysia’s objective to protect children from exposure to potentially dangerous toys and children’s articles. The United States also sought clarification on several aspects of the proposed regime to gain a better understanding of how the system would work. In addition, U.S. officials noted the importance of Malaysia’s engagement in the regulator-to-regulator discussions as part of the ongoing APEC Toy Safety Initiative. Malaysian officials participated actively in the APEC Toy Safety Initiative Regulator Dialogue in August 2009 in Singapore. Subsequently, a Malaysian regulatory official also participated as a speaker at the “Open Dialogue for All Stakeholders on Toy Safety” in Hong Kong in January 2010. In Hong Kong, Malaysia indicated in its presentation that it would not implement the system it had notified to the WTO in November 2008 and would switch to a system based on suppliers’ declaration of conformity.

Under the system announced in Hong Kong, manufacturers and importers will need to provide a Certificate of Conformity with every shipment and provide a test report to Malaysian authorities upon request. Further, Malaysia reported more streamlined requirements for the placement of its mark of conformity. Lastly, Malaysia extended the implementation date from January 30, 2010 to July 1, 2010. U.S. industry has not raised any concerns with the new Malaysian measure. The United States appreciates the efforts of Malaysia and looks to Malaysia to notify these changes to the WTO. U.S. officials plan to review that notification.

Mexico

Bilateral engagement

The United States discusses TBT matters with Mexico during and on the margins of TBT Committee meetings. The United States also discusses specific trade concerns and systemic issues with Mexico together with Canada in the NAFTA CSRM and subordinate TWGs established to address particular standards-related issues. For example, the NAFTA TWG established to address food labeling and packaging led to enhanced cooperation among the three NAFTA parties regarding food laboratories and nutritional labeling. The NAFTA parties also address standards-related measures in the context of the NAFTA RCF. For details on these fora and other trilateral cooperation regarding standards-related measures between the NAFTA parties, see Section VIII.

Conformity assessment body recognition

Under Article 908.2 of the NAFTA, Mexico is required to accredit, approve, license, or otherwise recognize conformity assessment bodies (*e.g.*, certification bodies or testing laboratories) in the United States on terms no less favorable than those applied to conformity assessment bodies in Mexico.

Applications by two U.S. conformity assessment bodies for accreditation by the *Entidad Mexicana de Acreditación* (EMA), the body responsible for accrediting conformity assessment bodies to test products for compliance with Mexican Official Standards (NOMs), were delayed for years because of resistance from Mexican conformity assessment bodies. However, in 2006 Mexico announced that it would create a “trust fund” into which accredited bodies would contribute 10 percent of the revenue from conformity certificates issued for standards development in Mexico. The two U.S. conformity assessment bodies signed an accord agreeing to contribute to the trust fund. Mexico accredited one U.S. body in December 2007 and another in January 2008 to perform conformity assessments for certain electrical and electronics products. These two accreditations could significantly increase U.S. exports to Mexico of electrical and electronics goods because U.S. producers will no longer need to re-certify their products in Mexico, acquire multiple certifications, and experience certification delays.

The United States hopes to see Mexico clarify its conformity assessment process and to ensure non-discriminatory treatment for all conformity assessment bodies. In this regard, the United States asked Mexico to clarify its accreditation procedures. In particular, the United States has urged Mexico to clarify whether an application for a new accreditation or an expansion of an existing accreditation can be submitted at any time or only in response to a specific call to certifiers. The United States also urged Mexico to set a reasonable period for evaluating accreditation requests. The United States has asked Mexico to clarify these issues so that U.S. conformity assessment bodies can avoid long delays in the accreditation process. In addition, the United States believes Mexico should fulfill its commitment to modify its accreditation rules to incorporate the required contributions to Mexican standards development as part of a formal accreditation fee in order to provide the necessary transparency for this process.

Food products – nutritional labeling

In 2009, Mexico proposed to amend its nutrition labeling rules, notifying to the WTO for comment the “*Draft Mexican Official Standard PROY-NOM-051-SCFI/SSA1-2009: General Specifications for the Labeling of Pre-packaged Food and Non-alcoholic Beverages - Commercial and Health Information.*” The United States submitted comments to Mexico on the proposal in which it posed technical questions and expressed concerns about the possible trade implications of the proposed rules.

Specifically, the United States requested that Mexico: clarify certain definitions and regulatory objectives, as well as requirements for irradiated foods, compound ingredients, and quantitative ingredient disclosure; provide information on the scientific basis for its Recommended Daily Allowance (RDA) values, including how Mexico took Codex RDA values into account; explain its energy calculations, including how soluble fiber is accounted for; clarify its policy on the use of voluntary claims (*e.g.*, “natural”, “pure”, “fresh”, “homemade”, “kosher”, “halal”, “organic”, and “biological”); set out clear guidance for companies to make claims on labels regarding nutrient content and health benefits; and establish an adequate period for compliance.

The United States seeks to arrange a technical discussion between U.S. and Mexican regulators in 2010 to discuss the proposed measure and share experiences and best practices for dealing with common regulatory issues involving nutritional labeling.

Medical devices – re-registration requirement

In 2005, the Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) issued a decree requiring medical device manufacturers to re-register by February 24, 2010, any medical device or medical equipment (regardless of class) that COFEPRIS had approved prior to 2005. Where re-registration was necessary, companies were initially required to re-submit complete product dossiers and clinical evidence in order for their products to remain on the market. U.S. industry estimates that this re-registration requirement covers 30,000 products.

COFEPRIS was unable to process applications before the deadline for all of the 30,000 products covered by re-registration requirement by the February deadline. Shortly before the deadline, COFEPRIS issued a clarification in writing to Mexican Customs authorities indicating that if a foreign company establishes a “re-registration plan” with COFEPRIS, or if it has already submitted its re-registration applications, it can continue to send its products for placement on the Mexican market after the deadline. U.S. industry contended that, because of insufficient staff and resources at COFEPRIS, trade in medical devices with a prior COFEPRIS registration could have been interrupted if COFEPRIS had not issued the clarification. Trade in medical devices with a prior COFEPRIS registration appears to be continuing without interruption.

However, industry is reporting that the backlog of re-registration requests has led to substantial delays in processing registration requests for new medical devices.

Nutritional supplements – local plant requirement

Prior to August 2008, Mexico maintained a “local plant requirement” for foreign companies that sought to sell pharmaceutical and dietary supplements in Mexico. Specifically, Mexican Health Ministry regulations required the inspection and approval of an applicant’s manufacturing facility as a prerequisite for obtaining a sanitary license to sell these products, yet Mexican authorities refused to inspect U.S.-based supplement and pharmaceutical manufacturing facilities. As a result, companies seeking to sell these products in Mexico could not receive the required licenses unless they established production facilities in Mexico or contracted with a Mexican competitor. The United States and other trading partners repeatedly protested this plant requirement in a variety of fora.

In August 2008, Mexico issued a decree reforming its regulations and lifting the local plant requirement in phases over a two-year period.

As follow-up, U.S. officials have urged Mexico to clarify the decree’s documentation requirements. With respect to pharmaceutical products, Mexican officials clarified that Mexican regulations allow suppliers to provide COFEPRIS with a Certificate of Free Sale, or its equivalent, and a Certificate of Good Manufacturing Practices (GMP) issued by the ministry or competent authority in the country of origin. Reportedly, Mexican health authorities have been accepting such documents, which U.S. pharmaceutical suppliers have obtained from the U.S. FDA and submitted as part of their applications to obtain a sanitary registration in Mexico.

U.S. officials are now requesting Mexico clarify its compliance requirements for vitamin products and other products marketed as dietary supplements in the United States. Because the FDA does not issue export certificates to confirm compliance with GMPs for vitamin products, the United States has asked whether COFEPRIS would accept either a manufacturer’s self-statement of GMP compliance or a GMP certificate issued by a third-party certifier.

Telecommunications equipment – acceptance of U.S. test results

Under Article 1304.6 of the NAFTA, Mexico committed to adopt, as part of its conformity assessment procedures for telecommunications equipment, provisions necessary to accept test results from test laboratories in the United States. Mexico could meet this commitment by implementing the CITELECOM MRA or the APEC Telecom MRA with respect to the United States. These MRAs contain procedures for each party to recognize laboratories located in the other party’s territory as competent to test or certify equipment for compliance with the party’s technical requirements. If Mexico implemented the CITELECOM or APEC Telecom MRA with the United States with respect to testing of telecommunications equipment, U.S. laboratories could test telecommunications equipment for the Mexican market, saving U.S. producers the expense and burden of having to send their products to Mexico for testing.

The United States has raised this issue with Mexico on a number of occasions. In particular, in their June 2009 meeting, Ambassador Kirk urged Mexican Secretary of Economy Ruiz Mateos to move quickly to implement the CITELECOM MRA with respect to testing of telecommunications equipment. Secretary Ruiz Mateos subsequently reported in a June 11, 2009, letter that he had

asked COFETEL, the Mexican telecom regulator, to work quickly to resolve the issue. At the July 2009 meeting of the NAFTA CSRM, U.S. officials made clear that U.S. experts were ready to meet with their Mexican counterparts to move forward on implementing the CITELE MRA. Since then technical discussions between U.S. and Mexican regulators have intensified, including a trilateral meeting of experts from the United States, Canada, and Mexico to discuss technical issues in February 2010. In addition, during his February 2010 trip to Mexico, Ambassador Kirk again urged Secretary Ruiz Mateos to encourage Mexico's telecommunications authorities to work expeditiously with U.S. authorities to implement the CITELE MRA.

Russia

Bilateral engagement

The United States engages with Russia regarding its technical regulations, standards, and conformity assessment procedures both on a bilateral basis as well as in the context of negotiations over Russia's accession to the WTO. (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 – labeling requirement

Russia's United Federal Automated Information System requires importers and domestic manufacturers of alcoholic beverages to print Universal Product Code data on small paper excise stamps attached to each bottle.

Importers are required to report individual sequentially-numbered stamps, whereas domestic producers may report stamps by batches of products. U.S. producers also contend that this requirement is costly and burdensome.

The Government of Russia has indicated its intention to impose the requirements, which currently applicable only to importers, on domestic producers as well, but that regulatory step has not yet been taken. In addition, the government announced its plan to allow product data to be filed electronically with Customs, which may reduce the burden on importers. However, the system for e-reporting has not yet been developed.

The United States will ask Russia to clarify this issue in 2010.

Encryption technology – testing requirements

Russia requires that any product containing encryption technology be imported under an import license; those encryption products that are subject to non-automatic licenses must be tested and approved by Russia's Federal Security Service before they can be imported into Russia. The United States is continuing to work with Russia to address concerns leading U.S. technology

companies have raised with respect to these requirements. For further discussion of this issue see the 2010 National Trade Estimate.

Taiwan

Bilateral engagement

The United States discusses TBT matters with Taiwan during, and on the margins of TBT Committee meetings. In addition, in September 2009 the United States and Taiwan held a successful Total Economic Engagement (TEE) event in Taiwan under the auspices of the U.S.-Taiwan Competitiveness Forum. The “Leveraging the WTO TBT Agreement and Standards” workshop, co-hosted by the U.S. Departments of Commerce and State through the American Institute in Taiwan (AIT), provided a forum for information exchange and technical discussions between U.S. and Taiwan authorities to initiate greater cooperation on respective regulatory and standards systems. The event also brought together U.S. and Taiwan industry experts and officials to discuss the TBT Agreement, its role in facilitating trade in safe, high quality products, and the implementation of standards and conformity assessment regimes in both economies. TBT issues are also discussed in the bilateral Trade and Investment Framework Agreement (TIFA) process.

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 test method that Taiwan mandates for determining whether those materials meet applicable incombustibility requirements. Industry asserts that Taiwan’s test method, which appears to be derived from ISO 5660-1, is unsuitable for products such as ceiling tiles since it does not provide a consistent and accurate measure of the extent to which these materials are incombustible. 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, which makes it more difficult for U.S. producers to sell their ceiling tiles in Taiwan’s market.

Industry has urged Taiwan to lift its requirements for producers to use Taiwan’s version of ISO 5660-1 as their test method and allow them to use other test methods until a new ISO standard, ISO 5660-3, has been completed. In the interim, industry has suggested Taiwan accept an alternative testing method, such as that contained in ASTM-E84, which is an international standard, or rely on type testing and Underwriters Laboratories (UL) plant certifications instead of batch testing. (Currently, producers can only use type testing if their plants are ISO 9001 certified.)

At a September 2009 meeting at the Bureau of Standards, Metrology, and Inspection (BSMI) in Taiwan, BSMI confirmed that it would consider adopting ISO 5660-3 when it is released in twelve to eighteen months. In the interim, BSMI indicated that it was open to accepting, as an alternative to ISO 9001 certification, UL certification of ceiling tile manufacturing plants if the United States provides additional information on the UL certification process and BSMI can visit the U.S. plants in question. U.S. and industry officials are working to provide this information to BSMI.

Chemical substances – management system

In September 2009, Taiwan's Council on Labor Affairs (CLA) confirmed plans to establish a national registration and management system for chemical substances that includes a voluntary Existing Chemical Substance Nomination (ECN) program and a mandatory New Chemical Substance Notification (NCN) program. The CLA began the voluntary program on October 31, 2009 and it will run through December 2010. Reportedly, chemical manufacturers may continue their existing chemical exports to Taiwan during this time period. However, despite the fact that the ECN program is ostensibly voluntary, chemical exporters that fail to register under the ECN, during this period will be required to register those chemicals under the NCN, when it takes effect and pay the associated registration fee. Taiwan has confirmed that it intends to include the NCN regulation in its Labor Safety and Health Act in 2010, and to implement the new system in June 2011.

The United States supports a robust science-based chemical management system and has indicated to Taiwan that U.S. officials would like to gain a better understanding of Taiwan's chemical registration process, including through an opportunity to review proposed measures and provide comments through the WTO notification process. To this end, in a bilateral meeting on the margins of the November 2009 TBT Committee meeting, the United States provided a list of technical questions to Taiwan officials regarding the operation of the ECN and NCN programs.

U.S. officials have also urged CLA and the Safety and Health Technology Center (SAHTECH) officials to organize a workshop with industry representatives to explain the details of the ECN program, including the application process, data requirements, and the treatment of confidential business information. Taiwan and the United States have indicated a mutual interest in setting up a dialogue to discuss their respective chemicals management regimes.

Product multipacks – labeling requirements

The U.S. retail industry has reported that Taiwan's Ministry of Economic Affairs MOEA has re-interpreted its Commodity Inspection Act and Commodity Labeling Act to require all units included in a retail multipack to be labeled, even if the retailer will not divide up the multipack for sale as single units. For example, the new rules will require a country of origin label for each pair of socks included within a sock multipack, even when the socks are sold as a six-pack. U.S. suppliers assert that this imposes unnecessary additional costs as they will be forced to add additional labels on their products to continue exporting to Taiwan.

Commodity goods – labeling requirements

In 2009, U.S. industry also raised concerns that Taiwan is requiring all "commodity goods" to be labeled with the manufacturer's or producer's name, telephone number, and address. Industry notes that some commodity goods may be produced by several different manufacturers, and product labels may not be large enough to contain each name, address, and phone number. U.S. industry also contends that inspectors in Taiwan visit their warehouses and require expiration dates to be placed on non-food items, such as furniture and electronic goods. U.S. industry would like to see a more definitive list for goods – in place of the ambiguous "commodity

goods” designation – that require an expiration date label, as well as the rationale behind the new requirement. The United States will seek additional clarification from Taiwan on these issues in 2010.

Thailand

Bilateral engagement

The United States discusses TBT matters with Thailand during, and on the margins of, meetings of the TBT Committee as well as in bilateral dialogues such as the Thailand TIFA Council and the Bilateral Consultative Mechanism. Thailand participates actively in APEC on standards and conformity assessment issues, particularly those related to food.

Alcoholic beverages – labeling requirements

Thailand has proposed to modify its warning label requirements for alcoholic beverages to require manufacturers to include images of the potential adverse effects of drinking alcohol. No international consensus exists on the use of warning labels on alcoholic beverages. Fifteen countries, including the United States and Thailand, have implemented some form of warning statement for alcoholic beverages. However, U.S. industry has sent several letters of concern to the Thai government opposing the size of the warning statements and their graphic nature, and questioning the scientific research supporting the need for such statements.

The United States requested information from the Thai government in late 2009 about the status of the proposal, including whether Thailand intended to notify the proposal to the WTO so that WTO Members and stakeholders would have an opportunity to comment. The United States also proposed that the two governments’ regulatory agencies engage in a technical discussion to share relevant experiences. Thailand notified the proposed measure to the WTO in January 2010, and the United States is in the process of reviewing it.

“Snack Food” – labeling requirement

In October 2006, Thailand proposed to adopt a labeling requirement that would have instituted "traffic light" labeling (*i.e.*, red, yellow, and green lights) on five categories of foods: potato chips, corn chips, extruded snack foods, biscuits/crackers, and assorted wafers. While Thai and U.S. regulators share the goal of reducing childhood obesity, the United States and other countries raised concerns about the Thai proposal because it deviated from the prevailing scientific and technical information on health and nutrition (*e.g.*, by not focusing on total diet and portion size) and had the potential to tarnish in the minds of Thai consumers the reputation of all products within certain food groups (even variations with lower salt, fat, and sugar) and to distort trade in these products.

In August 2007, the Thai Ministry of Public Health withdrew the proposal. The Thai government then proposed a new requirement that snack foods be labeled with a message stating: “Should consume small amounts, and exercise for a better health.” For new products, suppliers would have to comply within 90 days of the measure’s effective date, but suppliers were given

one year to modify the labels for products already on the marketplace. While this warning label requirement is a significant improvement over the original “traffic light” proposal, the new measure nonetheless raises some of the same concerns.

In March 2009, U.S. and Thai regulators discussed the labeling issue, including U.S. concerns about targeting specific food groups for special labeling treatment and current best practices in nutritional labeling, including front of pack labeling. U.S. officials also discussed ongoing work in Codex Food Labeling subcommittees and invited Thailand to participate in those fora.

Subsequently, Thailand conducted a public survey on its labeling requirements. U.S. officials have asked Thailand to provide information on the survey’s design and findings. The United States will continue to discuss this requirement and other food labeling regulations with Thai authorities with a view toward ensuring that Thai requirements are based on relevant scientific and technical information on diet and nutrition and adopt an approach that encourages better health and avoids creating unnecessary obstacles to trade.

Turkey

Bilateral engagement

The United States discusses TBT matters with Turkey during, and on the margins of, the TBT Committee meetings and in meetings of the Council established under the U.S.-Turkey TIFA.

Food and feed products – mandatory biotech labeling

On October 26, 2009, Turkey’s Ministry of Agriculture published a regulation governing biotechnology in food and feed that did not have to be approved by the Parliament. The measure was neither made public nor notified to the WTO in advance, and contained no phase-in period. Turkey published an amended regulation on January 20, 2010. This amended regulation is nearly identical to the original regulation and likewise contained no phase-in period (*i.e.*, it became effective on the date of publication. Turkey has not notified this amended regulation to the WTO.

Among other things, the regulation mandates the labeling of bio-engineered ingredients in all food and feed, provided the content is greater than 0.9 percent. As noted in the Trends section, the United States has concerns with the negative effect on trade that results from the mandatory labeling of food products containing or derived from biotechnology.

Moreover, Turkey’s regulation goes beyond mandatory method-of-production labeling by requiring that “GMO” labels on food should contain health warnings if the biotechnology food differs from the non-biotechnology food. This labeling provisions raises additional concerns because it appears to presume that food containing biotechnology products that is different from its non-biotechnology food counterpart raises a health risk beyond that of its non-biotechnology counterpart. In fact, however, the biotechnology food might be different from non-biotechnology food in ways that do not convey health risks; consequently, such health warnings would unnecessarily cause public alarm while providing no additional public health protection. For example, changes in oil composition could lead to health benefits, and the oil could still be

as safe for consumption as similar oils. Thus, the use of health warnings in the absence of a legitimate health concern could misinform the public about the safety of the food.

The total value of U.S. biotech crop exports to Turkey was over \$1 billion in 2008. The United States has raised concerns about this measure to Turkey in the TBT Committee and with the appropriate officials of the Turkish government, and will continue to do so in 2010.

Conformity assessment requirements

Starting on December 31, 2008 Turkey has published a series of communiqués in its Official Gazette, requiring that prior to entry specific classes of products to obtain certificates of conformity and undergo product safety inspections conducted by the Foreign Trade Undersecretariat. The list of products subject to the requirement is revised each year. The communiqués now in force, issued on December 31, 2009, include No. 2010/8 – radios and telecommunications equipment; 2010/10 – toys; 2010/11 – personal protective equipment; 2010/14 – building materials; 2010/15 – batteries; and 2010/16 – medical equipment. A similar communiqué, 2010/9, covers a broad range of “high risk products” to be inspected by the Turkish Standards Institute. None of these measures was notified to the WTO; all took effect the day after publication.

The measures, which do not apply to domestically-manufactured products or products originating in the European Union, do not explain their rationale or the applicable requirements against which the products are being inspected, nor do they explain how the lists of products to which the measures apply (and which are set out in Annexes to the measures) were compiled. U.S. industry has reported that the measures are affecting numerous U.S. exporters, contending that customs clearance time has increased from a few days to several weeks or longer once the new measures were implemented.

The United States has raised this issue with Turkey both bilaterally and in the TBT Committee. While the customs clearance time for U.S. origin products included under the above measures has reportedly dropped from 30 days or more to between 8-12 days – a vast improvement – this is still a longer period than prior to the original implementation of these measures. U.S. officials will continue to press Turkey on what steps it intends to take to reduce the clearance time, and to ensure that in the future it notifies any related measures to the WTO and provides an opportunity for comment and a reasonable time period for implementation. U.S. suppliers also contend that the paperwork requirements are redundant, costly, and burdensome – for example, Turkish Customs has reportedly applied different inspection regimes to the same product from the same manufacturer, and is requiring importer information to be marked on the product rather than supplied in the shipping documentation, which companies find to be unduly burdensome. The United States will continue to explore these concerns with Turkey in 2010.

Notification of proposed measures to the WTO

Turkey has a poor track record of notifying WTO Members of its proposed technical regulations and conformity assessment procedures, having notified just three such measures to the WTO since its accession in 1995. Among the measures that Turkey has failed to notify are registration

requirements for cotton and textile imports, restrictions on products containing bio-engineered ingredients, inspection requirements for medical equipment, and a stamp requirement for alcoholic beverages. In 2007, Turkey and the United States resolved the stamp issue when Turkey agreed to charge foreign and domestic bottlers the same price for a stamp and allowed foreign bottlers to apply the stamp at their warehouses in Turkey, rather than requiring them to send their products to one of two designated facilities in Turkey, which would have imposed unnecessary costs and delays on imported alcoholic beverages. However, this problem, like many of the problems suppliers encountered regarding Turkish measures, could have been resolved prior to implementation if Turkey had notified the draft measure and allowed stakeholders to comment.

In addition, most changes in Turkey's measures become effective immediately upon publication, with little or no notice to the public. Coupled with Turkey's need to improve its notification of its measures to the WTO, this has resulted in significant trade disruption in several instances that might have been avoided.

Vietnam

Bilateral engagement

The United States discusses TBT matters with Vietnam at the WTO as well as through the bilateral TIFA Council, which meets regularly and serves as a forum for raising and resolving trade and investment issues and for promoting increased technical cooperation activities. The United States has also partnered with Vietnam in advancing standards and conformity assessment issues in APEC.

Biotechnology – mandatory labeling

Vietnam is in the process of developing a legal and regulatory framework for foods derived from agricultural biotechnology. The United States and Vietnam have worked closely on these issues, and the United States remains encouraged by many aspects of the proposed regime. However, the Vietnamese proposals include mandatory biotechnology labeling provisions. As noted in Section IX (Trends), the United States has concerns with the negative effect on trade that results from the mandatory labeling of food products containing or derived from biotechnology.

The United States has provided extensive comments to Vietnam on its draft proposals both directly and in the WTO SPS Committee. The United States has urged Vietnam to notify its proposed biotechnology measures to the TBT Committee.

Telecommunications – conformity assessment procedures

U.S. industry has raised concerns with conformity assessment procedures for certain information and communication technology products that are administered by the Vietnamese Ministry of Communications (MIC). Specifically, companies have asked MIC to give them greater flexibility in fulfilling the requirement to submit test reports demonstrating that their products conform with Vietnam's requirements for electromagnetic compatibility (EMC), and to

recognize foreign laboratories that conduct the testing. In 2009, USTR and the Department of State held technical discussions with MIC in Hanoi, as did U.S. industry representatives.

Subsequent to those discussions, MIC indicated that it would allow a foreign manufacturer to submit one test report on behalf of all of its importers of the same product, rather than requiring each importer to submit an original, notarized test report for the same product. This accommodated a key industry concern. MIC has also begun recognizing test reports issued by foreign laboratories, pursuant to its commitments under the APEC Telecom MRA. Lastly, MIC has indicated that it will review its regulations in 2010 and is receptive to receiving additional stakeholder input during the review process.

VIII. Appendices

Appendix A

List of Commenters

Public comments received from:

1. AgBiotech Planning Committee
2. American National Standards Institute
3. American Potato Trade Alliance
4. California Table Grape Commission
5. Council for Responsible Nutrition
6. Distilled Spirits Council of the United States
7. Grocery Manufacturers Association
8. Herbalife International of America, Inc.
9. Information Technology Industry Council
10. National Confectioners Association
11. National Electrical Manufacturers Association
12. National Milk Producers Federation, U.S. Dairy Export Council
13. Novartis Corporation
14. Outdoor Power Equipment Institute, Inc.
15. Pharmaceutical Research and Manufacturers of America
16. Public Citizen Global Trade Watch
17. Ranchers-Cattlemen Action Legal Fund—United Stockgrowers of America
18. Society of the Plastics Industry, Inc.
19. Telecommunications Industry Association
20. Tobacco Industry
21. Toy Industry Association, Inc.
22. U.S. Wheat Associates
23. USA Poultry & Egg Export Council
24. Wine Institute, WineAmerica, California Association of Winegrape Growers
25. Yum! Restaurants International

Appendix B

List of Frequently Used Abbreviations and Acronyms

APEC	Asia Pacific Economic Cooperation
CITEL	Inter-American Telecommunication Commission
EU	European Union
IAF	International Accreditation Forum
FTA	Free Trade Agreement
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
MRA	Mutual Recognition Agreement
NAFTA	North American Free Trade Agreement
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
SME	Small and Medium Size Enterprise
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
TIFA	Trade and Investment Framework Agreement
TPSC	Trade Policy Staff Committee
URAA	Uruguay Round Agreements Act
TTB	U.S. Alcohol and Tobacco Tax and Trade Bureau
USDA	U.S. Department of Agriculture
USITC	U.S. International Trade Commission
USTR	Office of the United States Trade Representative
WTO	World Trade Organization