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Staff:
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STATE OF MAINE

Citizen Trade Policy Commission

DRAFT AGENDA

Friday, November 15, 2013 at 1 P.M.
Room 214, Burton M. Cross State Office Building
Augusta, Maine

1 PM Meeting called to order

I. Welcome and introductions

II. Review of EU TTIP Position Paper (Lock Kiermaier, Staff)

III. Review of USTR 2013 Report on Technical Barriers to Trade (Lock Kiermaier, Staff)

IV. Articles of interest (Lock Kiermaier, Staff)

V. Discuss topics for CTPC Chairs to bring up with Senator Angus King

3:30 PM Adjourn

2013 REPORT ON TECHNICAL BARRIERS TO TRADE



UNITED STATES TRADE REPRESENTATIVE

2013 Report on Technical Barriers to Trade



Ambassador Demetrios Marantis
Office of the United States Trade Representative

ACKNOWLEDGEMENTS

The Office of the United States Trade Representative (USTR) is responsible for the preparation of this report. Acting U.S. Trade Representative Demetrios Marantis gratefully acknowledges contributions of all USTR staff who contributed to the drafting and review of this report. Thanks are extended to partner Executive Branch agencies, including the Departments of Agriculture, Commerce, Labor, Justice, State, Transportation and Treasury, the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, the U.S. Consumer Product Safety Commission, the U.S. International Trade Commission, and the Office of Management and Budget.

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

April 2013

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I. Foreword

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

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

Since the last TBT Report was released, the United States has significantly advanced its efforts to resolve concerns with standards-related measures that act as unjustifiable barriers to trade and to prevent their emergence. USTR will continue its work to resolve and prevent trade concerns arising from standards-related measures *inter alia* through new and existing cooperative initiatives regarding standards-related issues in the World Trade Organization (WTO), Asia-Pacific Economic Cooperation Forum (APEC), U.S. free trade agreements (FTAs), and other bilateral fora, as well as progress on the negotiation of a modernized Technical Barriers to Trade (TBT) chapter in the Trans-Pacific Partnership (TPP) that will build on and strengthen TBT disciplines contained in the WTO Agreement on Technical Barriers to Trade (TBT Agreement). In addition, on February 13, 2013, President Obama and EU leaders announced that they would initiate the internal procedures necessary to launch negotiations on a comprehensive trade and investment agreement, the Transatlantic Trade and Investment Partnership. As conveyed in the February 2013 U.S.-EU High Level Working Group on Jobs and Growth (HLWG) Final Report, the United States and the EU are committed to working together to open markets in goods, services and investment, reduce non-tariff barriers, and address global trade issues of common concern. Both parties seek to build on the horizontal disciplines of the WTO TBT Agreement, establish ongoing mechanisms for improved dialogue and cooperation for addressing bilateral TBT issues, and pursue opportunities for greater regulatory compatibility with the objective of reducing costs stemming from regulatory differences in specific sectors.

Again in 2013, USTR will engage vigorously with other agencies of the U.S. Government, as well as interested stakeholders, to press for tangible progress by U.S. trading partners in removing unwarranted or overly burdensome technical barriers. We will fully utilize our toolkit of bilateral, regional and multilateral agreements and mechanisms in order to dismantle unjustifiable barriers to safe, high-quality U.S. industrial, consumer, and agricultural exports and strengthen the rules-based trading system. Recognizing that U.S. economic and employment

recovery and growth continue to rely importantly on the strength of U.S. exports of goods, services, and agricultural products, we will be redoubling our efforts to ensure that the technical barriers that inhibit those exports are steadily diminished.

Ambassador Demetrios Marantis
Acting U.S. Trade Representative
April 2013

II. Executive Summary

The *2013 Report on Technical Barriers to Trade (TBT Report)* is a specialized report focused on significant foreign trade barriers in the form of product standards, technical regulations and testing, certification, and other procedures involved in determining whether products conform to standards and technical regulations and actions the United States is taking to address these barriers. These standards-related trade measures, which in World Trade Organization (WTO) terminology are known as “technical barriers to trade” (TBT) when they act as barriers to trade, play a critical role in shaping the flow of global trade.

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

This report describes and advances U.S. efforts to identify and eliminate standards-related measures that act as significant barrier to U.S. trade. The report consists of following key components:

- An introduction to standards-related measures, including the genesis of this report and the growing importance of standards-related measures in international trade (Section III);¹
- An overview of standards-related trade obligations, in particular rules governing standards-related measures under the WTO Agreement on Technical Barriers to Trade (TBT Agreement) and U.S. free trade agreements (Section IV);
- A description of the U.S. legal framework for implementing its standards-related trade obligations (Section V);
- A discussion of standards, including the role of international standards in facilitating trade and fulfilling legitimate public policy objectives and federal agencies’ participation in standards development (Section VI);

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.

- An elaboration on conformity assessment procedures, including federal agencies' use of conformity assessment and the possibility for international systems of conformity assessment to facilitate trade (Section VII);
- A description of how the U.S. Government identifies technical barriers to trade and the process of interagency and stakeholder consultation it employs to determine how to address them (Section VIII);
- An explanation of how the United States engages with its trading partners to address standards-related measures that act as barriers and prevent creation of new barriers through multilateral, regional, and bilateral channels, including the WTO's Committee on Technical Barriers to Trade (TBT Committee) and cooperative activities under the APEC Subcommittee on Standards and Conformance, among others (Section IX);
- A summary of current trends regarding standards-related measures trends relating to standards-related measures (Section X); and
- An identification and description of significant standards-related trade barriers currently facing U.S. exporters, along with U.S. government initiatives to eliminate or reduce the impact of these barriers (Section XI) in 17 countries – Argentina, Brazil, China, Chile, Colombia, India, Indonesia, Japan, Kenya, Korea, Malaysia, Mexico, Russia, South Africa, Taiwan, Turkey, and Vietnam – as well as the European Union (EU).

III. Introduction

Genesis of this Report

Shortly after taking office in 2009, President Obama reaffirmed America's commitment to ensuring the effective implementation and enforcement of the WTO's system of multilateral trade rules. The President vowed to pursue an aggressive and transparent program of defending U.S. rights and benefits under the rules-based trading system as a key element in his vision to restore trade's role in leading economic growth and promoting higher living standards. The President has also recognized that non-tariff barriers have grown in significance for U.S. exporters seeking access to foreign markets. Two kinds of non-tariff measures pose a particular challenge to U.S. exports: sanitary and phytosanitary (SPS) measures and standards-related measures.

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

The *TBT Report* is a specialized report addressing significant foreign barriers in the form of product standards, technical regulations, and conformity assessment procedures (standards-related measures). Prior to 2010, the *National Trade Estimate Report on Foreign Trade Barriers (NTE Report)* addressed standards-related measures.² By addressing significant foreign trade barriers in the form of standards-related measures, the *TBT Report* meets the requirements under Section 181 of the Trade Act of 1974, as amended, to report on significant foreign trade barriers with respect to standards-related measures. A separate report addressing significant foreign trade barriers in the form of SPS measures (*2013 Report on Sanitary and Phytosanitary Measures*) is being released in parallel to this report.

The *TBT Report* includes country reports that identify specific standards-related trade barriers imposed or under consideration by certain U.S. trading partners. The report also includes general information on standards-related measures, the processes and procedures the United States uses to implement these measures domestically, and the tools the United States uses to

² In accordance with section 181 of the Trade Act of 1974 (the 1974 Trade Act) (codified at 19 U.S.C. § 2241), 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.

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

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

Central Focus in 2012

During 2012, the United States succeeded in persuading its trading partners to reduce or eliminate a variety of technical barriers to trade identified in last year's report. The United States also continued to intensify its efforts to help other governments to avoid imposing unwarranted standards-related barriers to trade, particularly with respect to innovative technologies and new areas of regulation, and to strengthen their capacity to regulate properly and to promote good regulatory practices. In 2012, the United States also proposed new initiatives in key trade and economic forums, including in the WTO and the Asia-Pacific Economic Cooperation Forum (APEC), as well as in negotiations to conclude a Trans-Pacific Partnership (TPP) agreement, to encourage governments to eliminate and prevent unwarranted standards-related barriers to trade.

Overview of Standards-Related Measures

Today, standards-related measures (standards, technical regulations, and conformity assessment procedures) play a critical role in shaping the flow of international trade. While tariffs still constitute an important source of distortions and economic costs, the relative role of tariffs in shaping international 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 1947). With these declines in tariffs, the role of non-tariff barriers in international trade has become more prominent.

Broadly speaking, standards-related measures are documents and procedures that set out specific technical or other requirements for products or processes as well as procedures to ensure that these requirements are met. Among other things standards-related measures help:

- ensure the connectivity and compatibility of inputs sourced in different 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;
- achieve 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 conveying information to producers and consumers about the characteristics or performance of components and end products they purchase from a wide variety of suppliers. These measures also enable more widespread access to technical innovations. Standards-related measures can offer particularly pronounced benefits to SMEs from this perspective. Uniform standards and product testing procedures established under a common set of technical requirements that producers can rely on in manufacturing components and end products, can facilitate the diffusion of technology and innovation, contribute to increasing buyer-seller confidence, and assist SMEs to participate in global supply chains.

Conversely, outdated, overly burdensome, discriminatory, or otherwise inappropriate standards-related measures 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.

Thus, while standards-related measures can be an effective and efficient means of achieving legitimate commercial and policy objectives, policy makers, industry officials, and other stakeholders must also confront an important question: how to 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 as a means to facilitate the flow of goods across borders, reduce costs associated with complying with different standards and technical regulations across jurisdictions and markets, and enhance governments' ability to achieve important public policy objectives.

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

A broad and active agenda of U.S. engagement on many fronts is needed to ensure that foreign standards-related measures do not impose unwarranted barriers to trade. USTR leads Federal

government policy deliberations on these measures through the interagency [Trade Policy Staff Committee](#) (TPSC).³ U.S. activities in the WTO are at the forefront of USTR's efforts to prevent and resolve trade concerns arising from standards-related measures. Coordinating with relevant agencies through the TPSC, USTR engages with other governments in many venues, including those established by U.S. FTAs and through regional and multilateral organizations, such as the WTO, APEC and the Organization for Economic Cooperation and Development (OECD). USTR also raises standards-related issues in bilateral dialogues with U.S. trading partners. These efforts are designed to ensure that U.S. trading partners adhere to internationally-agreed rules governing these measures and to reduce or eliminate unnecessary measures of this kind that can create barriers for U.S. producers and businesses.

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

Technical regulation

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

Standard

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

Conformity assessment procedures

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note: Conformity assessment procedures include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation, and approval as well as their combinations.

Source: Annex 1 of the TBT Agreement.

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

³ <http://www.ustr.gov/about-us/executive-branch-agencies-trade-policy-staff-committee-and-trade-policy-review-group>

IV. Overview of Trade Obligations on Standards-Related Measures

WTO Agreement on Technical Barriers to Trade

The WTO Agreement on Technical Barriers to Trade ([TBT Agreement](#)) contains rules that help ensure that standards-related measures serve legitimate objectives, are transparent, and do not create unnecessary obstacles to trade.⁴ The TBT Agreement establishes rules on developing, adopting, and applying voluntary product standards and mandatory technical regulations as well as conformity assessment procedures (such as testing or certification) used to determine whether a particular product meets such standards or regulations. These rules help distinguish legitimate standards-related measures from protectionist measures, and ensure that testing and other conformity assessment procedures are fair and reasonable.

The TBT Agreement recognizes that WTO Members have the right to prepare, adopt, and apply 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 obligations regarding the development and application of those measures. For example, the TBT Agreement requires governments to develop standards-related measures through transparent processes, and to base these measures on relevant international standards (where effective and appropriate). The TBT Agreement also prohibits measures that discriminate against imported products or create unnecessary obstacles to trade. The TBT Agreement contains a *Code of Good Practice for the Preparation, Adoption, and Application of Standards* (Code). The Code applies to the preparation, adoption, and application of voluntary standards and is open to acceptance by any standardizing body located in the territory of any WTO Member, including government and non-governmental bodies. Box 2 outlines the key disciplines of the TBT Agreement.

Box 2. Key principles and provisions of the TBT Agreement

Non-discrimination: The TBT 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 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 to the applicable requirements. (Art. 5.1.2)

⁴ http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

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

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

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

Acceptance of technical regulations as equivalent: Alongside promoting better alignment of technical regulations, 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 be "at least 60 days" (G/TBT/26), and take comments it receives from other Members into account. (Art. 2.9 and 5.6) The Agreement establishes a Code of Good Practice that is applicable to voluntary standards and directs 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 final technical regulations and conformity assessment procedures be promptly published. (Art. 2.11 and 5.8) In addition, the Agreement requires each Member to establish an inquiry point to answer all reasonable questions from other Members and interested parties and to provide documents relating to technical regulations, standards, and conformity assessment procedures adopted or proposed within its territory. (Art. 10.1)

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

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

provides for disputes under the Agreement to be resolved under the auspices of the WTO Dispute Settlement Body and in accordance with the terms of the WTO's Dispute Settlement Understanding. (Art. 14)

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

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

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

The TBT Agreement requires each WTO Member to provide other Members the opportunity to participate in the development of mandatory standards-related measures, which helps to ensure that standards-related measures do not become unnecessary obstacles to trade.⁵ In particular, the TBT Agreement requires each Member to publish a notice in advance that it proposes to adopt a technical regulation or conformity assessment procedure.⁶ 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.⁷ In 2012 alone, WTO Members notified 1,550 new or revised technical regulations and conformity assessment

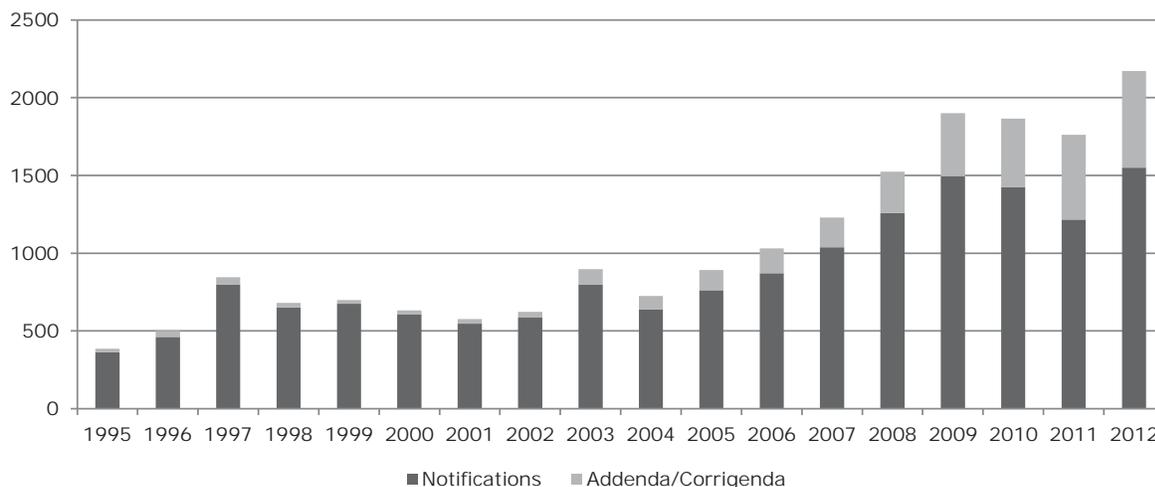
⁵ Depending on the WTO Member's domestic processes, interested parties may participate directly in that Member's process for developing new standards-related measures, for example, by submitting written comments to the Member, or indirectly by working with their own governments to submit comments.

⁶ WTO 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.

⁷ 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.

procedures, as well as submitted 575 addenda and 45 corrigenda to previous notifications. Since entry into force of the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement)⁸ on January 1, 1995, up to December 31, 2012, 15,736 notifications along with 2,684 addenda and 485 corrigenda to these notifications have been made by 116 members. Box 3 shows the number of notifications yearly since 1995.⁹

Box 3. Number of TBT Notifications since 1995¹⁰



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 159 WTO Members. The TBT Committee is one of over a dozen standing bodies (others include the Committees on Import Licensing, Antidumping Practices, and Rules of Origin, for example) that report to the WTO Council for Trade in Goods. The activities of the TBT Committee are described in detail below.

Operation of the TBT Agreement

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

⁸ The TBT Agreement is one of several agreements, understandings and decisions comprising the WTO Agreement.

⁹ 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).

¹⁰ Number of TBT Notifications since 1995 found in “Eighteenth Annual Review of the Implementation and Operation of the TBT Agreement (G/TBT/33).”

the relevant provisions. 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.¹¹

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. Sound mechanisms for internal coordination among a WTO Member’s trade, regulatory, and standards officials are critical to ensuring that the Member effectively implements the TBT Agreement. When interested agencies and officials coordinate their efforts in developing standards-related measures, it makes it more likely that the government will consider alternative technical specifications that may reduce any adverse effects on trade while still fulfilling the measure’s objective.

Further, when governments take account of how the products they propose to regulate are traded in foreign markets, it can actually make the measures they adopt more effective in fulfilling their objectives. The effectiveness of a WTO Member’s internal coordination also often determines the extent to which it is able to resolve specific trade concerns raised by other Members. Accordingly, 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.

The TBT Committee conducts triennial reviews of systemic issues affecting WTO Members’ policies and procedures for implementing specific obligations.¹² In the course of these reviews, Members adopt specific recommendations and decisions, and lay out a forward-looking work program to strengthen the implementation and operation of the TBT Agreement. To advance their understanding of systemic issues, Members share experiences and participate in special events and regional workshops to explore topics in depth. In recent years, Committee events have covered good regulatory practice, conformity assessment, transparency, the role of international standards in development, and regulatory cooperation.

In addition to its triennial reviews and the related special events and workshops, the TBT Committee also meets three times a year. At these meetings, Members may raise any specific trade concern regarding standards-related measures that other WTO Members have proposed or adopted. The Committee’s discussion of these concerns can help to clarify the technical aspects of the measures concerned, promote greater understanding of how the measures might affect trade, and perhaps even help to resolve the concerns. In 2012, WTO Members raised over 94 specific trade concerns in the TBT Committee, including, for example, concerns regarding measures relating to managing hazards arising from use of chemicals, labeling and other non-safety requirements relating to food products, and duplicative or redundant testing requirements on a wide variety of goods such as toys and medical devices. WTO Members have underscored

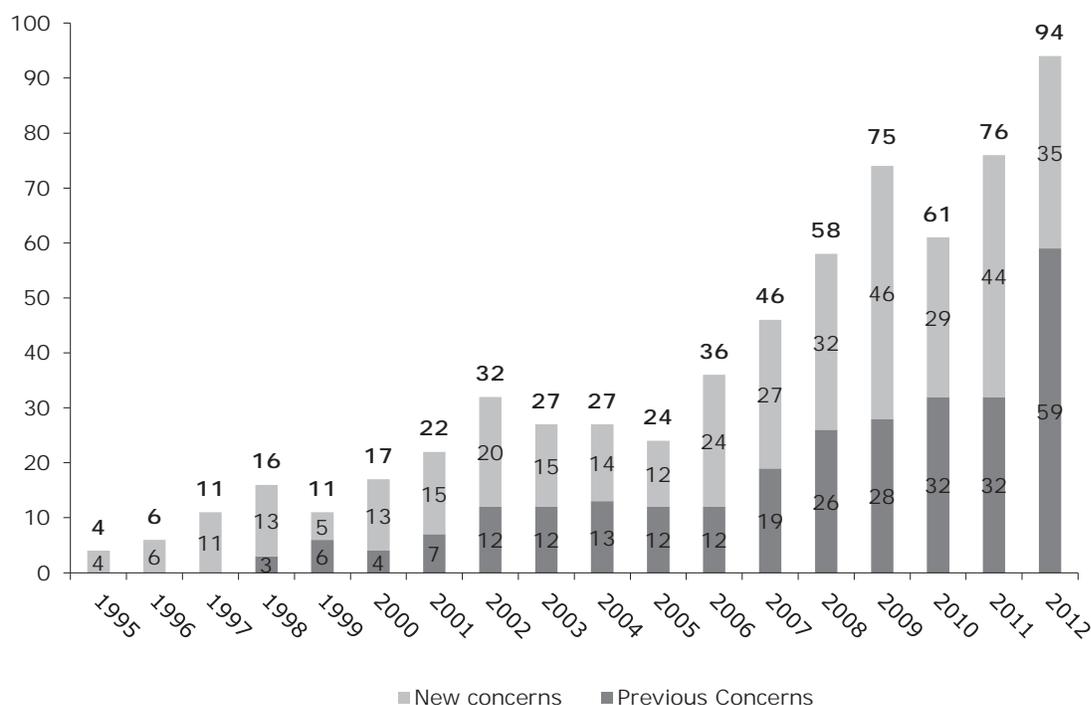
¹¹ See [G/TBT/GEN/1/Rev.11](#) for a list of Members’ submissions on the measures they have taken to implement and administer the TBT Agreement.

¹² The Committee’s work on the outcome of the most recent triennial review is discussed in Section IX.

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.¹³

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

Box 4. Number of specific trade concerns raised per year¹⁴



In recent years, the Committee has implemented procedures to streamline the discussion of specific trade concerns during its meetings and avoid unnecessary repetition. While addressing specific trade concerns is core to the Committee’s responsibility in monitoring how well WTO Members are implementing the TBT Agreement, some exchanges on unresolved issues have become protracted, leaving less time for the Committee to address the cross-cutting or systemic

¹³ 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](#).

¹⁴ Number of specific trade concerns raised since 1995, found in “*Eighteenth Annual Review of the Implementation and Operation of the TBT Agreement (G/TBT/33)*.”

issues needed to prevent and resolve trade issues. In 2012, the Committee agreed to use informal “thematic” discussions on the margins of its meetings in 2013, in order to sharpen focus and make progress on key systemic issues. In 2013, the Committee held thematic discussions on standards and good regulatory practices in March and will hold thematic discussions on Transparency and Inquiry Point operations in June and conformity assessment in November.

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

In U.S. FTAs, the parties reaffirm their commitment to the TBT Agreement. 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.”¹⁵ For example, recent FTAs require each party to allow persons of the other Party to participate in the development of standards, technical regulations and conformity assessment procedures. Moreover, each party is required to permit persons of the other party to participate in the development of these measures on terms no less favorable than it accords its own persons.

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

By enhancing understanding of each Party’s respective rulemaking processes and standards and conformance processes, 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.¹⁶ The provisions in U.S. FTAs that provide for more timely and robust consultations and participation, enhance the notifications process, and provide for direct bilateral engagement on notified measures are particularly important in this regard. These consultative mechanisms can provide a channel for peer-to-peer capacity building activities with FTA partners whose standards and conformance processes may be underdeveloped or otherwise in need of improvement.

Like the TBT Agreement, the TBT provisions of U.S. FTAs recognize that FTA partners should

¹⁵ 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](#)).

¹⁶ 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.

not be prevented from taking measures necessary to protect public health and safety or the environment. At the same time, U.S. FTAs provide mechanisms through which FTA partners can reduce the negative effects on their bilateral trade stemming from unnecessary differences in their 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*.¹⁷ The U.S. experience with the *2000 Committee Decision* is described at length in [G/TBT/W/305](#). These issues are discussed in more detail in Section VI below.

In 2012, the United States made significant progress with ten Asia Pacific trading partners through the Trans-Pacific Partnership (TPP) negotiations towards concluding a TBT chapter and several sectoral annexes addressing standards-related measures. Further details on the TPP are provided in Section IX below.

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

The United States has concluded FTAs with a number of countries. While each agreement is unique, many of these FTAs 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, Colombia, Korea, Morocco, Oman, Panama, and Peru.

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 expand upon transparency obligations provided for in the TBT Agreement. For example, US FTAs with Colombia, Peru and Korea provide 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 and require parties (1) to notify proposed technical regulations even where those regulations are based on relevant international standards; (2) to notify proposals for technical regulations or conformity assessment procedures directly to the other Party; (3) to include in notifications of proposed technical regulations and conformity assessment procedures the objectives of the proposed measure and the proposed measure's rationale or how the measure meets those objectives; (4) to provide interested parties as well as the FTA partner a meaningful opportunity to comment on the proposed measure; (5) to allow at least 60 days for comment; (6) to provide responses to significant comments received no later than the time a final measure is published; and (7) to provide

¹⁷ Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement, contained in document [G/TBT/1/Rev.10](#).

additional information about the objectives when requested.

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

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

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

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

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

The United States maintains a robust system to support implementation of its trade obligations on standards-related measures through strong central management of its regulatory regime, an effective interagency trade policy mechanism, and public consultation. The legal framework for implementing U.S. obligations under the TBT Agreement and standards-related provisions in U.S. FTAs includes the [Administrative Procedure Act of 1946](#) (APA) and the [Trade Agreements Act of 1979](#) (TAA).¹⁸ The APA establishes a process of public participation in rulemakings by U.S. agencies through a system of notice and comment. The TAA prohibits Federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade and directs them to consider the use of international standards in rulemaking.

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

The APA provides the foundation for transparency and accountability in developing Federal regulations. The APA requires agencies to undertake a notice and comment process open to all members of the public, both foreign and domestic, for all rulemakings, and to take these comments into account in the final rule.¹⁹ In accordance with the APA, agencies publish proposed technical regulations and conformity assessment procedures in the *Federal Register* and solicit comments from the public through notices published in the *Federal Register*. To fulfill WTO obligations to notify proposed technical regulations and conformity assessment procedures, the National Institute of Standards and Technology (NIST) in the Department of Commerce serves as the U.S. notification authority and inquiry point for purposes of the TBT Agreement. The U.S. inquiry point reviews the *Federal Register* and other materials on a daily basis and notifies the WTO of technical regulations and conformity assessment procedures that agencies propose to adopt.

¹⁸ The standards-related provisions of the TAA are codified at [United States Code, Title 19, Chapter 13, Subchapter II, Technical Barriers to Trade \(Standards\)](#).

¹⁹ The term “rule” refers to “an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy....” 5 U.S.C. § 551(4). “Rule making” means the “agency process for formulating, amending, or repealing a rule....” 5 U.S.C. § 551(5). These definitions include rules or rulemakings regarding technical regulations and conformity assessment procedures. The APA makes exceptions for urgent matters, allowing Federal agencies to omit notice and comment, for example, where they find that notice and public procedures are impracticable or contrary to the public interest. 5 U.S.C. § 553(b)(3).

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 regulatory philosophy, principles, and actions that guide federal agencies in planning, developing, and reviewing Federal regulations. E.O. 12866 and Circular A-4 are the primary basis on which good regulatory practice (GRP) has been integrated into the Federal regulatory structure. These practices ensure openness, transparency, and accountability in the regulatory process, and, as a result, help ensure that the United States fulfills key TBT Agreement and U.S. FTA obligations. GRP,²⁰ such as that embodied in E.O. 12866 and Circular A-4, enables government agencies to achieve their public policy objectives efficiently and effectively. GRP is also critical in reducing the possibility that governments will adopt standards-related measures that create unnecessary obstacles to trade.

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

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

²⁰ 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.

On May 12, 2012, President Obama issued [*Executive Order 13610 - Identifying and Reducing Regulatory Burdens*](#) (E.O. 13610), which requires agencies to conduct retrospective analyses of existing rules to examine whether they remain justified and whether they should be modified or streamlined in light of changed circumstances, including the emergence of new technologies.

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 use²¹ voluntary consensus standards²² in their regulatory activities wherever possible and to avoid using "government-unique" standards.²³ The purpose is to discourage Federal agencies from developing their own standards where suitable voluntary consensus standards already exist. OMB will revise A-119, and will seek comments from the public on the changes in 2013.

Voluntary consensus standards can often effectively achieve an agency's regulatory objectives. The NTTAA and the TAA are complementary: the NTTAA directs Federal agencies to look to voluntary consensus standards to meet their regulatory objectives, while the TAA directs them to consider using relevant international standards. As elaborated in Section VI, international standards are those that recognized bodies, either intergovernmental or non-governmental, develop in accordance with principles such as openness, transparency, and consensus.

For additional information on the laws, policies, and interagency processes through which the United States implements the TBT Agreement, see [G/TBT/2/Add.2](#), [G/TBT/W/285](#), and [G/TBT/W/315](#). See also the [*Report on the Use of Voluntary Standards in Support of Regulation in the United States*](#) presented to the High Level Regulatory Cooperation Forum of the United States – European Union Transatlantic Economic Council (TEC) in October 2009. For additional information on the relationship between technical barriers to trade and GRP, see [G/TBT/W/287](#) and USITC Working Paper No ID-24, [*The Role of Good Regulatory Practice in Reducing Technical Barriers to Trade*](#). In 2012, APEC published two related studies. The first study, "[Good Regulatory Practices in APEC Member Economies - Baseline Study](#)," reviews the application of selected GRPs across the 21 APEC members. The report focuses on several procedures that promote good regulatory practices particularly important to trade and investment such as accountability, consultation, efficiency, and transparency. The second study, "[Supporting the TBT Agreement with Good Regulatory Practices](#)," explores the relationship between TBT obligations and current GRPs used around the world. These recommended GRPs demonstrate choices available to WTO Members for implementation of practices that support trade-friendly regulation and implementation of their WTO commitments.

²¹ Circular A-119 defines "use" as the inclusion of a standard in whole, in part, or by reference in a regulation.

²² 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.

²³ Circular A-119 defines "government-unique standards" as standards developed by the government for its own uses.

VI. Standards

Voluntary standards serve a variety of functions and their use supports world trade, for example, by promoting the connectivity and compatibility of inputs sourced in global markets. The TBT Agreement defines “standard” as:

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 competition²⁴ 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 objectives 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.²⁵

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. The TBT Agreement also strongly discourages standardizing bodies from developing standards where international standards already exist.

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

The TBT Agreement 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.²⁶ The 2000

²⁴ See [Standards & Competitiveness: Coordinating for Results: Removing Standards-Related Trade Barriers Through Effective Collaboration](http://www.trade.gov/td/standards/pdf%20files/Standards%20and%20Competitiveness.pdf), International Trade Administration, 2005, available at <http://www.trade.gov/td/standards/pdf%20files/Standards%20and%20Competitiveness.pdf>.

²⁵ 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.

²⁶ Decision on Principles for the Development of International Standards, Guides and Recommendations with

Committee Decision is designed to clarify the concept of “international standard” and to advance objectives such as greater harmonization of technical requirements across markets. The six 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.²⁷ 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*.²⁸ WTO Members’ central government standardizing bodies are required to comply with the *Code*, and WTO Members are required to take reasonable measures to ensure that local government bodies and 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](#).²⁹ For more information on the ANSI system, see [Overview of the U.S. Standardization System](#).

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

Relation to Articles 2, 5 and Annex 3 of the TBT Agreement are contained in document [G/TBT/1/Rev.10](#).

²⁷ The U.S. experience with the *2000 Committee Decision* is described in [G/TBT/W/305](#).

²⁸ Available at http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

²⁹ Available at http://www.ansi.org/standards_activities/nss/usss.aspx.

OMB Circular A-119 contains guidance for Federal agencies in participating in the development of voluntary standards.³⁰ *Circular A-119* directs Federal agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. The Circular also provides guidance for Federal agencies participating in voluntary consensus standards bodies. 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 organizations³¹ 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.

³⁰ Available at http://www.whitehouse.gov/omb/circulars_a119/.

³¹ Source: NIST, 2008.

VII. Conformity Assessment Procedures

The TBT Agreement defines “conformity assessment procedures” as: “Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.” Outside the TBT Agreement, conformity assessment procedures may also encompass a broader set of procedures, for example, good manufacturing practices that are not related to product characteristics.

Conformity assessment enables buyers, sellers, consumers, and regulators to have confidence that products sourced in domestic and foreign markets meet specific requirements.³² 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.³³

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.³⁴ Indeed, many specific trade concerns that the United States has raised in the TBT Committee with respect to other WTO Members’ measures center on difficulties associated with the Member’s conformity assessment requirements. Governments can reduce or minimize such difficulties by taking into account the risks associated with a product’s failure to conform to an underlying standard or requirement when choosing the type of conformity assessment procedure to apply with respect to that standard or requirement. Governments can also reduce or minimize costs associated with conformity assessment by adopting approaches that facilitate the acceptance of the results of those procedures (*e.g.*, approaches that allow products to be tested or certified in the country of export). The TBT Committee’s list of approaches that facilitate this acceptance is contained in [G/TBT/1/Rev.10](#).

In the United States, the NTTAA directs NIST to coordinate the conformity assessment activities of Federal, state, and local entities with private sector technical standards activities and conformity assessment activities. The goal is to eliminate any unnecessary duplication of these activities. Pursuant to this statutory directive, NIST published a notice in the *Federal Register*

³² 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.

³³ For an introduction to conformity assessment, see Breitenberg, Maureen, [The ABC’s of the U.S. Conformity Assessment System](#), NIST, 1997.

³⁴ See Johnson, Christopher, [Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures](#), U.S. International Trade Commission Working Paper, 2008.

in 2000 providing [guidance to Federal agencies on conformity assessment](#).³⁵ This notice calls for Federal agencies to provide sound rationales, seek public comments, look to the results of other government and private sector organizations, and use international guides and standards when incorporating conformity assessment procedures in their regulations and procurement processes. Today, the conformity assessment standards and guides published by ISO and IEC are known as the “CASCO toolbox.”³⁶

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](#).³⁷ The TBT Agreement, NIST’s guidance, and ANSI’s principles all emphasize the importance of the development and use of international conformity assessment standards and participation in international accreditation systems in facilitating international trade.

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

Examples of international accreditation systems include the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). ILAC and IAF have established voluntary mutual recognition arrangements (MRAs). Under these MRAs, accreditation bodies agree to adhere to international standards and other procedures and criteria when accrediting testing and certification bodies and subject themselves to a system of peer-to-peer review to ensure that they continue to meet MRA requirements. U.S. 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.

³⁵ http://gsi.nist.gov/global/docs/FR_FedGuidanceCA.pdf

³⁶ ISO/CASCO is the standards development and policy committee on conformity assessment of ISO.

³⁷ <http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf>

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

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

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

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

To disseminate information to U.S. stakeholders on proposed foreign notifications of standards-related measures, the U.S. Inquiry Point operates a web-based service, [Notify U.S.](#), which automatically notifies registered stakeholders of measures proposed and adopted by other WTO Members in sectors of interest.³⁸ 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 so provide, or through the U.S. Inquiry Point, which works with relevant Federal agencies to review, compile and submit comments to the WTO Member. By providing comments through the U.S. Inquiry Point, U.S. stakeholders alert Federal agencies to their concerns and enable advocacy by Federal agencies on their behalf.

In 2012, the U.S. TBT Inquiry Point distributed 2,176 WTO TBT notifications to registered stakeholders, including 248 U.S. notifications. The U.S. TBT Inquiry Point processed 450 requests for information on standards and technical regulations and fulfilled 728 requests for full-text documents associated with TBT notifications. The U.S. TBT Inquiry Point distributed

³⁸ Available at <https://tsapps.nist.gov/notifyus/data/index/index.cfm>

190 U.S. Government and industry comments to other WTO Members and circulated 26 WTO Member comments on U.S. measures, as well as 27 WTO Member replies to U.S. comments, to relevant Federal agencies. U.S. stakeholders monitor notifications of new or revised measures of other WTO Members in sectors of interest through *Notify U.S.* (which added more than 400 new subscribers in 2012), 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 U.S TBT Inquiry Point hosted or participated in training for eight U.S. and foreign visiting delegations interested in learning how a WTO inquiry point operates.

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

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

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

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

practical realities that producers face in complying with technical regulations and conformity assessment procedures. USTR and Commerce officials meet at least quarterly with the ITAC on Standards and Technical Trade Barriers (ITAC 16), which is composed of cleared advisors from manufacturers, trade associations, standards developers, and conformity assessment bodies.³⁹ USTR also meets with other ITACs and advisory committees to receive advice on TBT issues affecting specific industry sectors, such as steel, chemicals, automobiles, processed foods, and textiles, or specific regulatory areas, such as labor and the environment.

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

Engagement in Voluntary Standards Activities

In the United States, standards development is led by the private sector and highly informed by market needs. However, in limited circumstances, in areas relevant to their agency objectives, Federal government agencies also actively engage or play a convening role in standards development. In January 2012, USTR, OIRA, and OSTP released a joint memorandum to agencies entitled “[Principles for Federal Engagement in Standards Activities to Address National Priorities](#)”⁴⁰ to clarify principles guiding Federal agencies’ engagement in standards activities. The memorandum emphasizes the strengths of the U.S. standards model of private sector leadership but notes that where a national priority has been identified in statute, regulation, or Administration policy, active engagement or a convening role by the Federal Government may be needed to accelerate standards development and implementation to spur technological advances, promote market-based innovation, and encourage more competitive market outcomes. The memorandum establishes five “fundamental strategic objectives” for Federal Government engagement in standards activities:

- produce timely, effective standards and efficient conformity assessment schemes that are essential to addressing an identified need;
- achieve cost-efficient, timely, and effective solutions to legitimate regulatory, procurement, and policy objectives;

³⁹ See http://www.ustr.gov/Who_We_Are/List_of_USTR_Advisory_Committees.html.

⁴⁰ Available at <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf>.

- promote standards and standardization systems that promote and sustain innovation and foster competition;
- enhance U.S. growth and competitiveness and ensure non-discrimination, consistent with international obligations; and
- facilitate international trade and avoid the creation of unnecessary obstacles to trade.

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

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

The United States pursues a broad agenda and active engagement with foreign governments to prevent unnecessary obstacles to trade and to resolve specific trade concerns arising from standards-related measures. As noted above, the TBT Committee is the principal multilateral forum for engagement on trade issues relating to standards-related measures. The mechanisms for cooperation on these measures in U.S. FTAs also play a vital role in facilitating U.S. efforts to prevent and resolve standards-related trade concerns. In addition, U.S. agencies seek to prevent potential standards-related trade 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 other countries can assist firms in complying with standards-related measures. As producers increase their participation in global supply chains, they need a better understanding of technical requirements of countries, including the United States, and strategies to meet those requirements consistently. 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), the Commerce Department's Commercial Law Development Program (CLDP) and Market Development Cooperator Program (MDCP), and NIST's Standards in Trade Program. USDA's FAS also provides technical assistance on standards-related to food trade. These agencies have broader missions and generally provide standards-related capacity building assistance as a component of a specific project or mission.

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

NIST maintains a complete inventory of the government-to-government [MRAs to which the United States](#) is a party.⁴¹ It also maintains a listing of the accreditation requirements for conformity assessment bodies under each of these MRAs and a list of conformity assessment bodies that NIST has designated pursuant to each MRA as competent to perform tests or certify products to ensure they conform to the other MRA party's technical requirements. (The [Federal Communications Commission \(FCC\) website](#) provides useful background information on U.S. MRAs in the telecommunications sector and examples of how they work.)⁴²

The United States also seeks to reduce foreign technical barriers to trade by concluding equivalency arrangements with other governments. In 2009, the United States exchanged the first equivalency determination with Canada on organic agricultural products. On February 15, 2012, the United States signed a second organics equivalence arrangement with the European Union.

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

WTO TBT Committee and Related Engagement

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

Specific Trade Concerns

In 2012, the United States raised specific trade concerns regarding on average 20 to 30 foreign TBT measures at each TBT Committee meeting and in the informal meetings it held with individual or groups of WTO Members. The details and status of many of the specific trade concerns that the United States raised in, and on the margins of, the TBT Committee sessions are described in Section XI of this report. As elaborated in Section XI, U.S. interventions in the TBT Committee, and on its margins, have helped resolve a number of standards-related concerns affecting U.S. trade. The Committee's annual review of its activities is contained in [G/TBT/29](#), which includes a thumbnail description of the specific trade concerns that WTO Members raised and identifies the Members that raised them.

⁴¹ Available at <http://gsi.nist.gov/global/index.cfm/L1-4/L2-16>.

⁴² Available at <http://transition.fcc.gov/oet/ea/mra/>.

Systemic Issues

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

In November 2011, the TBT Committee initiated its *Sixth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade under Article 15.4*. In the review, which concluded in November 2012, the Committee agreed to exchanges of information on (1) voluntary mechanisms and related principles of Good Regulatory Practices to guide members in efficient and effective implementation of the TBT Agreement; (2) approaches to, recognition of, and use of international standards for conformity assessment; (3) implementation of the *Code of Good Practice* by local governments and non-governmental bodies; and (4) the six principles of international standards development set out in the *2000 Committee Decision*, with particular focus on the development dimension and transparency.

The United States also launched a new U.S.-sponsored assistance facility called the “Standards Alliance” to help build capacity among developing countries to implement the TBT Agreement. The new Standards Alliance will help developing countries strengthen implementation of the TBT Agreement, including by improving their notification practices, by improving domestic practices related to adopting relevant international standards, and in clarifying and streamlining their regulatory processes for products. This program aims to reduce the costs and bureaucratic hurdles U.S. exporters face in foreign markets, and increase the competitiveness of American products, particularly in developing markets.

From October 30 through November 1, 2012, the U.S. Inquiry Point, in partnership with its Brazilian partner INMETRO and Standards Council Canada, hosted the first ever Inquiry Point of the Americas conference in Rio de Janeiro. The conference, a product of the U.S.-Brazil Commercial Dialogue, brought together nearly 200 TBT experts from thirty Western Hemisphere countries and the WTO in a workshop to exchange best practices regarding implementing transparency provisions of the WTO TBT Agreement and working with the private sector to improve the use of this valuable tool.

Total Economic Engagement Program

The Department of Commerce’s Total Economic Engagement (TEE) Program provides technical assistance and capacity building to advance a more collaborative and open process to foster greater regulatory harmonization and convergence. TEE works with foreign governments, trade associations, and standards setting bodies on key public-private partnerships.

For example, in 2012, the TEE program sought to improve market access for U.S. certification bodies in China’s compulsory certification (or CCC mark) testing regime. Through this program the Commerce Department urged China’s Certification and Accreditation

Administration (CNCA) and China's Quality Certification Centre (CQC) to increase transparency, foster more predictable administrative processes, and develop more appropriately designed verification procedures for China's CCC program in accord with China's WTO commitments.

With the Russian Federation's recent membership in the WTO, Russia offers U.S. producers and exporters a potentially significant export market for high-quality products. To assist Russia in meeting its WTO commitments, the Commerce TEE program is conducting a series of outreach events across the United States and Russia to raise awareness of the new trade opportunities that will be afforded to U.S. companies.

Asia Pacific Economic Cooperation

APEC is the Asia-Pacific region's premiere inter-governmental economic organization. Its core mission is to strengthen regional economic integration by addressing barriers to trade and investment. APEC's twenty-one member economies comprise nearly half the world's population and more than half of the global economy. These member economies account for 55 percent of global GDP, purchase 58 percent of U.S. goods exports, and comprise a market of 2.7 billion customers. In fact, seven of the top 15 trade partners of the United States are members of APEC. In 2012, APEC focused on four areas: trade and investment liberalization and regional economic integration; strengthening food security; establishing reliable supply chains; and intensive cooperation to foster innovative growth.

As part of these efforts, the United States furthered work to prevent and eliminate unnecessary technical barriers related to emerging green technologies, such as those related to commercial green buildings and Smart Grid technology.⁴³ Additionally, the United States encouraged APEC economies to adopt standards and conformity assessment procedures that promote greener growth through the alignment of energy efficiency standards and conformity assessment procedures for information and communication technology (ICT) products. The areas of focus for 2012 with respect to green technologies included regional economic integration, product safety, supply chain integrity, and environmental protection. These green technology efforts with respect to Smart Grid, green buildings, and solar and ICT technologies, are further elaborated below. The United States also worked with APEC to advance regulatory cooperation dialogues regarding food and wine. APEC economies further recognized the importance of good regulatory practices and addressing unnecessary technical barriers to trade by advancing regulatory convergence and coherence.

Good Regulatory Practices

In 2012, APEC economies also re-affirmed their 2011 commitment to strengthen implementation of good regulatory practices, including through capacity building. In 2013, the United States will advance Good Regulatory Practices by updating the 2011 APEC Baseline

⁴³ The U.S. Department of Energy defines Smart Grid as an electrical grid that uses information and communications technology to gather and act on information, such as information about the behaviors of suppliers and consumers, in an automated fashion to improve the efficiency, reliability, economics, and sustainability of the production and distribution of electricity.

Study on member practices, developing a self-funded study on good regulatory practices with respect to conformity assessment, and participating in the 7th APEC Conference on Good Regulatory Practice, to be held in Medan, Sumatra in June 2013.

Smart Grid

Building on the success of the intensive dialogue and suggested trade-related principles on Smart Grid interoperability standards developed through the 2011 APEC Regulatory Cooperation Advancement Mechanism (ARCAM), the United States conducted a second workshop for energy regulators, entitled, “Regulatory Approaches to Smart Grid Investment and Deployment,” on the margins of the World Forum on Energy Regulation held on May 16-17, 2012, in Quebec City, Canada. The conference sought to facilitate collaboration and information sharing between key stakeholder groups involved in the development of Smart Grid interoperability standards. The workshop responds to the APEC Committee on Trade and Investment (CTI) call for APEC economies to “implement mechanisms for internal coordination within APEC member economies among regulatory authorities, standards developing bodies and trade officials to advance interoperability of Smart Grid requirements.”

The workshop recommended that regulators and standardization bodies continue and enhance discussion of developments and experiences regarding implementation of Smart Grid programs.

Green Buildings

Green buildings provide opportunities for U.S. companies to export a wide range of “green” products in which they have a competitive advantage, such as products related to plumbing, lighting, flooring, HVAC systems, and fixtures. The world imported \$70 billion in U.S. building products in 2009, with APEC economies accounting for fully 70 percent of this total (\$50 billion).

In addition, greening the commercial building sector can also yield significant energy savings, given that the sector accounts for between 30 and 40 percent of energy usage in most industrialized economies. These energy savings contribute to meeting greenhouse gas emissions targets, and improve energy security.

To advance these objectives, the United States supported two APEC studies on the subject of green buildings. The [first study](#) addressed green building rating systems in APEC economies. The [second study](#) addressed the trade impact of life cycle analysis for flooring materials and plumbing fixtures.

APEC Support Fund (ASF) has awarded the U.S. Department of Commerce \$830,000 to serve as the project sponsor of a new APEC multi-year project on the relationship between standards and conformity assessment and energy efficient performance in commercial buildings. The project consists of a series of interrelated workshops and data gathering, which will occur from 2013-2015. These workshops and data gathering activities will aim to build the capacity of APEC economies to implement green building measures that are consistent, transparent, and appropriate, thus avoid creating unnecessary obstacles to trade. In 2013, Peru and the United States are working together to organize a workshop on “Sharing Experiences in the Design and Implementation of Green Building Codes” (March 2013). For this workshop, the United States will present a study on the use of building codes and green codes in the Asia Pacific region. The

other workshop topics in the series include: Building Information Modeling (BIM) (June 2013); best practices in the testing and rating of products in the building envelope; and mapping of building product testing requirements. The United States is working together with the ASEAN Consultative Committee on Standards and Quality (ACCSQ) on these workshops.

Solar Technologies

The United States plans to introduce a project on solar technology and Smart Grid integration in 2013-2014. The goal of this project is to identify common goals, best practices, and strategies among APEC member economies that can facilitate Smart Grid and solar technology deployment as well as trade.

Information and Communication Technologies

Following the first successful dialogue in APEC on Information and Communication Technology (ICT) Energy Efficiency Standards, the United States organized a second workshop on the same subject in Seoul, Korea on July 18, 2012. Building on agreed principles from the first workshop, participants discussed the adoption and application of the ECMA383/IEC62623 standard.⁴⁴

In 2013, the United States will suggest that APEC form a limited term working group of regulators to facilitate transition of personal computer energy efficiency programs to the new international standard.

APEC Food Safety Cooperation Forum (FSCF) and Partnership Training Institute Network (PTIN)

Trade in food and agricultural products in the Asia Pacific is vital to U.S. interests, yet concerns about food safety in the region spiked in recent years following a series of high-profile food safety incidents. These prompted APEC economies to agree to strengthen food safety standards and practices in the region and encourage adherence to international science-based standards to facilitate trade in the region and enhance food safety. In response, the APEC Subcommittee on Standards and Conformance (SCSC) established the Food Safety Cooperation Forum (FSCF) in 2007 with the goal of improving food safety regulatory systems in APEC economies in line with WTO Members' rights and obligations under both the SPS and TBT Agreements. In 2008, APEC economies called for increased capacity building to improve technical competence and understanding of food safety management among stakeholders in the food supply chain through the public-private partnership initiative, the Partnership Training Institute Network (PTIN).

Since 2007, over \$4 million of public and private sector funds have been contributed for FSCF and PTIN activities. The FSCF and PTIN have identified priority capacity building needs and delivered over 30 programs in key areas (supply chain management, food safety incident management, laboratory competency, risk analysis, food safety regulatory systems) since their inception.

⁴⁴ ECMA383/IEC 62623:2012 covers personal computing products. It applies to desktop and notebook computers. This standard specifies a test procedure to enable the measurement of the power and energy consumption.

In 2012, the U.S. convened experts from the public and private sectors to develop a strategy to improve laboratory capacity in the APEC region. Funding for two to three pilot projects may be available for 2013. This work builds on previous PTIN efforts on laboratory capacity building, including three U.S.-led training sessions in 2012 on laboratory practices. In addition, the PTIN developed a supply chain management training module, which is now freely available on the PTIN website.

APEC awarded the United States \$1.8 million to serve as the project sponsor for an APEC multi-year project: Building Convergence in Food Safety Standards and Regulatory Systems for 2013-2015 encompassing priorities that include food safety standards and best practices for small- and medium-sized enterprise, incident management, laboratory capacity, food inspection based on risk analysis, and proficiency testing. FSCF and PTIN Steering Group meetings are scheduled to occur in April 2013 at the second APEC Senior Officials Meeting (SOM 2) in 2013 to address a first suite of activities relate to these priorities.

Lastly, the PTIN continued to work closely with the World Bank through the newly established Global Food Safety Partnership (GFSP), including developing a three-year plan of coordinated activities on food safety with the GFSP.

Wine Regulatory Forum

In 2008, the SCSC created a Wine Regulatory Forum (WRF) to promote trade-facilitating regulation of wine. Wine exports are critically important to several APEC economies, with their wine product export market totaling \$3.6 billion in 2010. Following the success of the first-ever regional meeting of wine regulators and industry representatives in 2011, New Zealand hosted the second meeting of the APEC WRF. On November 5-6, 2012, the APEC Wine Regulators Forum meeting entitled, “Risk Management & Certification in Wine Trade: Public-Private Dialogue,” was held in Auckland, New Zealand. This was a follow-up to the highly successful meeting in San Francisco, in September 2011. The key themes of the meeting were risk management and certification in the APEC wine trade. Participants exchanged views on the issues of wine as a low food safety risk product and multiple certification requirements. In 2013, the United States has proposed a multi-year project, which includes a pilot for electronic certificates for wine.

Global Food Safety Partnership

In 2012, the United States and the food industry contributed an initial \$1 million in start-up funds to launch the World Bank GFSP. The objective of the GFSP is to improve food safety systems. The GFSP is undertaking a five-year program for training and capacity building in food safety. GFSP held a training program on food safety prerequisites and hazard analysis and critical control points (HACCP) in Beijing in June 2012 and will expand this program in 2013. A HACCP aquaculture module will be ready by April 2013. An assessment of laboratory capacity in the APEC economies is also under way. Other initial training programs will be supported by a \$1.8 million APEC funding commitment for 2013-2015.

Trans-Pacific Partnership

In November 2009, President Obama announced that the United States would participate in negotiations to conclude a comprehensive Asia-Pacific trade agreement: The Trans-Pacific

Partnership (TPP) Agreement. Through the TPP, the United States seeks to advance U.S. trade and investment opportunities in the Asia-Pacific by negotiating an ambitious, 21st century regional trade agreement. The TPP negotiations began with an initial group of countries comprising: Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam. In October 2012, Canada and Mexico joined the negotiations and participated in the round of negotiations held in Auckland, New Zealand in December 2012.

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

In 2012, the TPP Working Group on Technical Barriers to Trade (TBT) made substantial progress to advance negotiations of the TBT chapter, including several sector-specific annexes. The TBT chapter includes obligations that build upon the WTO TBT Agreement (referred to as “TBT plus”), including obligations on transparency, conformity assessment and international standards, and sets a framework for addressing trade concerns and for advancing cooperative activities on standards-related measures. These obligations seek to prevent and reduce unnecessary costs and barriers to trade in the region. The sector-specific annexes include obligations regarding the development and implementation of standards-related measures to address unnecessary barriers to trade in products in specific sectors, such as cosmetics, pharmaceuticals, medical devices, information and communications technology products, wine and spirits, and food formulas.

In 2013, the TBT Working Group will press to conclude the TBT chapter and its annexes.

Free Trade Agreement – TBT Committee Meetings

The inaugural meeting of the United States-Colombia Trade Promotion Agreement’s Committee on Technical Barriers to Trade (TBT Committee) was held in Washington, DC, on October 23-24, 2012. The two governments discussed their respective systems as well as particular issues such as biologics, diesel emissions, baby clothing, food safety standards, appliances, and cosmetics. The Colombian delegation also visited NIST for training on Inquiry Point operations.

Other FTA TBT Chapter meetings that were held in 2012 included the TBT Chapter meeting under the United States-Chile FTA in November 2012, and two meetings of the NAFTA Committee on Standards Related Measures in February and October.

Regulatory Cooperation Fora

Executive Order 13609

On May 1, 2012, President Barack Obama signed Executive Order (E.O.) 13609 entitled “[Promoting International Regulatory Cooperation](#)” to help reduce, eliminate, and prevent unnecessary differences in regulatory requirements imposed by U.S. and foreign regulators, which can limit the ability of American businesses to export and compete internationally. The E.O. calls for the Regulatory Working Group established by E.O. 12866, and reaffirmed by E.O. 13563, to serve as a forum to discuss, coordinate, and develop a common understanding among agencies of

U.S. Government positions and priorities with respect to: international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions; efforts across the Federal Government to support significant, cross-cutting international regulatory cooperation activities; and promotion of good regulatory practices internationally, as well as the promotion of U.S. regulatory approaches, as appropriate.

USTR continues to lead on the coordination and development of standards-related trade policies. The United States participates in three bilateral regulatory cooperation forums aimed at promoting regulatory best practices and aligning regulatory approaches in economically significant sectors with the European Union, Canada, and Mexico.

European Union

The EU's approach to standards-related measures (as described in the 2012 TBT Report), and its efforts to encourage governments around the world to adopt its approach, presents a strategic challenge for the United States in the area of standards-related measures. In 2013, U.S. officials will continue to encourage systemic changes in the EU approach in existing bilateral fora, such as the Transatlantic Economic Council (TEC) and the United States – European Union High-Level Regulatory Cooperation Forum (HLRCF). The TEC is designed to give high-level political direction to bilateral initiatives aimed at promoting increased bilateral trade, job creation, and economic growth through deeper transatlantic economic integration. The HLRCF, comprising U.S. and EU regulatory and policy officials and oversees a program of bilateral cooperation on regulatory issues. The group has convened in advance of each of the previous four TEC meetings to identify projects for the TEC to consider.

In November 2011, the Leaders of the United States and the EU launched the U.S.-EU High Level Working Group on Jobs and Growth (HLWG) with the objective of identifying new ways to increase transatlantic trade and investment in support of job creation, economic growth, and international competitiveness. Leaders directed the HLWG to examine options in specific areas (including possible trade agreements) *inter alia* to reduce and prevent non-tariff barriers.

On February 13, 2013, President Obama and EU leaders announced that they would initiate the internal procedures necessary to launch negotiations on a Transatlantic Trade and Investment Partnership (TTIP). President Obama and EU leaders' announcement followed issuance of the HLWG's final report to leaders (<http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/final-report-us-eu-hlwg>) in which it recommended that the United States and the EU pursue a comprehensive agreement that would include ambitious, reciprocal market opening in goods, services and investment, make substantial progress on reducing non-tariff barriers, and address global trade issues of common concern. The report's specific recommendations for negotiations on "regulatory issues and non-tariff barriers" include that a comprehensive agreement pursue: SPS and TBT issues; regulatory coherence and transparency; sector-specific outcomes and regulatory cooperation; and the development of a framework for future U.S.-EU progress on the regulatory issues.

Mexico

In May 2010, President Obama and Mexican President Calderón committed to enhance significantly the economic competitiveness and the economic well-being of the United States and Mexico through improved regulatory cooperation. The Presidents directed the creation of a

United States – Mexico High-Level Regulatory Cooperation Council (HLRCC), comprising senior-level regulatory, trade, and foreign affairs officials from each country.

In February 2012, the HLRCC released its first work plan, which outlines cooperative activities on food safety, electronic import and export certificates, oil and gas development, nanotechnology, motor vehicle safety, and e-health and conformity assessment.⁴⁵ On October 15, 2012, the HLRCC met to review progress on the seven work plans. It is expected a new consultation schedule will commence in 2013 to update the activities of the HLRCC.

Canada

In February 2011, President Obama and Canadian Prime Minister Harper directed the creation of a United States – Canada Regulatory Cooperation Council (RCC), composed of senior regulatory, trade, and foreign affairs officials from each government. The RCC has a two-year mandate to promote economic growth, job creation, and benefits to U.S. and Canadian consumers and businesses by enhancing regulatory transparency and coordination, with a focus on sectors characterized by high levels of integration, significant growth potential, and rapidly evolving technologies. The [United States – Canada Regulatory Cooperation Council \(RCC\) website](#) provides information on specifics for the 29 initiatives and work plans, including cooperation on topics such as, agriculture, personal care products, pharmaceuticals, and motor vehicles.

The RCC issued a [Progress Report to Leaders](#) on December 14, 2012. The report highlighted that work is also underway on the development of Memoranda of Understanding, discussion papers, initial statements of work on regulatory changes, and various assessment activities.

North American Leaders Summit – Trilateral Regulatory Cooperation

The outcomes of the 2012 North American Leaders Summit (“NALS”) provide for opportunities for Mexico, Canada, and the United States to promote trilateral regulatory cooperation. Benefits of trilateral regulatory cooperation will include increased economic growth in the three countries; lower costs for their citizens, businesses, producers, governments, and consumers; increased trade in goods and services across borders; and greater protection of health, safety, and the environment.

In 2013, the four sectors that Mexico, Canada, and the United States have agreed upon for trilateral regulatory cooperation are: (1) Regulatory Approach to Nanomaterials; (2) Transportation Railroad Safety; (3) Transportation Emissions; and (4) Globally Harmonized Standards for workplace chemicals.

Doha Round Negotiations

The U.S. Government’s longstanding objective in the WTO Non-Agricultural Market Access (NAMA) negotiations – which cover manufactured goods, mining, fuels, and fish products – has been to obtain a balanced market access package that provides new export opportunities for U.S. businesses through liberalization of global tariffs and non-tariff barriers. The NAMA

⁴⁵ The U.S.-Mexico HLRCC work plan can be found at <http://www.whitehouse.gov/sites/default/files/omb/oira/irc/united-states-mexico-high-level-regulatory-cooperation-council-work-plan.pdf>.

negotiations have included discussions of several proposals addressing standards-related measures, including U.S. proposals covering textiles labeling, electronic products, and automobiles.

However, despite continued, intensive efforts by USTR negotiators to engage with key trading partners since the launch of the negotiations, the NAMA negotiations reached an impasse in 2011. In 2012, a new Chairman for the NAMA Negotiating Group was chosen. However, there were no substantive meetings or other activities related to either the tariff or non-tariff elements of the NAMA negotiations, and negotiations on the standards-related non-tariff barrier proposals did not advance.

In 2013, the United States intends to work with other WTO Members to pursue fresh and credible approaches to meaningful multilateral trade liberalization.

X. 2012-2013 Trends Regarding Standards-Related Measures

This section reviews trends that appear across various U.S. trading partners' markets, as well as standards-related systemic issues, that can significantly affect, both positively and negatively, the ability of U.S. businesses and producers to access foreign markets.

Nutritional Labeling and Advertising

In 2011, Thailand became the first country to introduce mandatory front of package (FOP) stop light labeling on food products for five snack categories. In a stop light labeling system, certain nutritional content values are depicted using colors analogous to traffic lights – i.e., red for high, amber for moderate, and green for low. After receiving comments from several WTO members concerning stop light labeling, Thailand opted to implement the Guideline Daily Amount (GDA) system, a guidance system which provides information on to how many calories and nutrients people can consume each day for a healthy, balanced diet. Voluntary schemes are also taking hold in other countries, with South Korea being the first to press ahead with a voluntary scheme for stop light labels on children's foods in January 2011, and reports from the United Kingdom industry indicate that supermarkets will introduce a voluntary, FOP labeling scheme in 2013.

In 2012, several countries in the Western Hemisphere proposed measures related to nutritional labeling and advertising. The most restrictive to date has been Chile's proposed implementing regulations for Law No. 20,606. The Chilean Congress adopted this law on July 6, 2012.

The stated objective of Chile's draft regulation is to provide the public with information about food products in order to prevent obesity and non-communicable diseases. It sets limits for fat (trans fat, saturated fat), calories, sugar, and salt, that if exceeded trigger a requirement to place a stop sign shaped FOP label on the product indicating that the product is "high in" fat, sugar, calories, or salt. The draft regulation requires that the label cover up to 20 percent of the FOP. The draft regulation also imposes certain limits on television advertising of particular foods and restricts the inclusion of promotional toys and related materials in or attached to products.

The mandatory nature of Chile's draft regulation, along with its FOP stop sign labeling requirements, makes it the most far-reaching nutritional labeling requirement of its kind to date. Both Ecuador and Peru are considering similar mandatory and related "high in" claims for prepackaged foods and prepackaged food advertising.

The United States will continue to monitor developments regarding each of these measures and engage in follow-up actions, as appropriate.

EU Agreements on Conformity Assessment and Acceptance (ACAA)

The EU is currently pursuing Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs) with several governments in the Mediterranean region, in particular with Algeria, Egypt, Israel, Jordan, Lebanon, Morocco, Palestinian Authority, and Tunisia, as well as Ukraine. Jordan and Israel have already adopted ACAAs with the EU as part of their Euro-Mediterranean Association Agreements with the EU.

The EU ACAAs cover machinery, electrical products, construction products, pressure

equipment, toys, medical appliances, gas appliances, and pharmaceuticals. Under these agreements, parties agree to adopt EU standards and regulations in exchange for eased conformity assessment procedures into the EU for certain product sectors.

U.S. manufacturers have expressed concern that the EU ACAAs will create additional export barriers in these regions.

“Voluntary” Measures as Trade Barriers

In various product sectors, certain governments are developing and implementing so-called “voluntary” standards in a manner that effectively makes compliance with them mandatory. In addition, many truly voluntary standards that governments have developed (such as voluntary labeling programs related to energy efficiency or agricultural products) have nonetheless created substantial trade barriers. Further, oftentimes voluntary standards may solely reflect domestic stakeholder interests rather than also those of the larger global trading community.

Examples of “voluntary” standards that have raised trade concerns include:

- China’s standards related to information security: The Chinese Government is finalizing several draft “voluntary” standards related to information security for ICT products. The United States is concerned China will make compliance with these voluntary standards mandatory, either through incorporation into technical regulations, or through integration into the certification and type approval schemes of the Ministry of Industry and Information Technology (MIIT) and the CNCA. One such standard, Information Security Technology – Requirement for Office Devices Security, appears to restrict the use of computer chips in ink cartridges. U.S. and other foreign companies consider that this design restriction reduces the functionality of printers, and they question how the measure relates to the protection of national security. U.S. industry and the U.S. Government are concerned that China may effectively mandate the use of this standard by incorporating it by reference into one of China’s various certification regimes, for example, the CCC Mark or the MIIT telecom type approval process. U.S. industry is also concerned that various versions of the draft standard, including prohibitions of certain chips as components of printer cartridges, have diverged from the relevant international standard (IEEE 2600).
- Korea’s standards for solar panels: Korea’s Energy Management Corporation (KEMCO) only certifies one type of thin film solar panel – the type that Korean producers manufacture – as meeting its version of the International Electrotechnical Commission standard. While compliance with that standard is not technically required for sale of solar panels in the Korean market, a company will not be commercially viable in Korea without KEMCO certification. As a result, U.S. solar panel producers that make different kinds of thin film panels find themselves unable to access the Korean market.

As with the other issues identified in this section of the report, the United States works to resolve issues concerning voluntary standards through the TBT Committee and regional and bilateral engagement as they arise in individual markets. The United States is also seeking to

address these issues on a systemic basis because many of the specific trade concerns that WTO Members raise in the TBT Committee continue to be related to standards. Currently, U.S. officials are seeking opportunities to tackle the trade issues associated with voluntary standards in the APEC Subcommittee on Standards and Conformance and the TPP negotiations.

Mandatory Labeling of Foods Derived from Genetic Engineering

In May 2011, following twenty years of discussions and negotiations, the Codex Alimentarius Commission (Codex) adopted a “Compilation of Codex Texts Relevant to Labeling of Foods Derived from Modern Biotechnology.” The compilation summarizes existing Codex texts and confirms that many Codex labeling guidance documents developed for foods generally also apply to foods derived from modern biotechnology. Most importantly, the compilation confirms that foods derived from modern biotechnology are not necessarily different from other foods simply as a result of the way they are produced. Consistent with that view, the U.S. FDA applies a science-based approach to food labeling, which requires labeling of foods derived from modern biotechnology only if such labeling is necessary to reveal any material information that differs significantly from conventionally produced food in order to avoid misbranding. Such information includes proper use of the food, nutritional properties, and allergens.

The United States continues to be concerned about the European Court of Justice (ECJ) ruling that honey containing pollen with genetically engineered (GE) material should be considered an “ingredient” rather than a natural constituent. As a result, honey with pollen from GE plants would have to be approved under the EU’s laws for “genetically modified organisms” and labeled for GE content when sold in the EU. The United States has raised this matter in bilateral meetings with the European Commission. During the March 2012 WTO Sanitary and Phytosanitary Committee meeting, Argentina and Uruguay objected to the ECJ’s ruling as creating uncertainty in the markets, which has led to declines in their exports. The United States, Mexico, Brazil, Canada, and Paraguay supported the objections. The Codex standard, upon which the EU based Directive 2001/110/EC, does not treat pollen as an ingredient and the EU was urged to act to withdrawal the measure. In September 2012, the EU Commission proposed an amendment to Directive 2001/100/EC to clarify that pollen is not an ingredient of honey, but it has not been finalized. In addition, the European Food Safety Authority issued an opinion that pollen from the genetically engineered corn approved for cultivation in the EU was equivalent to pollen from conventionally bred varieties of corn. The United States most recently raised this issue during the TBT Committee meeting of March 2013.

The United States is also concerned by a measure proposed by Peru with regards to labeling of foods derived from genetic engineering. Peru renewed its efforts to finalize a regulation mandating that all GE ingredients must be included on the labels of processed products. Peru notified its Draft Supreme Decree Approving the Regulations Governing the Labeling of Genetically Modified Foods to the WTO on June 27, 2011. The regulation requires mandatory labeling of all GE foods even though such products may not differ from non-GE products in terms of safety or quality. The United States submitted comments to Peru on September 14, 2011, but Peru has not responded, and has raised concerns with this measures in several bilateral meetings in 2012 and 2013. The United States (and other WTO Members) raised this issue during the TBT Committee March 2013 meeting as well as during previous meetings.

XI. Country Reports

Background on Specific Trade Concerns Contained in the Country Reports

This section contains individual country reports detailing TBT barriers encountered by U.S. stakeholders. The measures and practices the country reports identify raise significant trade concerns, and, in some instances, give rise to questions concerning whether a trading partner is complying with its obligations under trade agreements to which the United States is a party.⁴⁶

The decisions on which issues to include resulted from an interagency process that incorporated the expertise of a variety of government agencies.

While the tools used to address TBT barriers vary depending on the particular circumstances, in all instances, USTR's goal remains the same: to work as vigorously and expeditiously as possible to resolve the issue in question. As reflected in the country reports, in many instances

USTR seeks to resolve specific concerns through dialogue with the pertinent trading partner – either bilaterally or through multilateral fora – and working collaboratively to obtain changes that result in improved market access for U.S. exporters.

In response to USTR's outreach in compiling this report, stakeholders raised a number of new standards-related concerns. In several cases, USTR lacked sufficient information about those concerns at the time of publication to include them in this report. For purposes of this report, USTR included measures and practices about which USTR is well informed; USTR continues, however, to gather information about others. Accordingly, the omission of any issue in this report should not be taken to mean that USTR will not pursue it, as appropriate, with the trading partners concerned, in the same manner as those listed below. An analysis of the country sections of the 2013 TBT Report demonstrates that numerous issues were recently resolved or are on a path to resolution. Despite these successes, U.S. exporters still face a variety of specific trade concerns as a result of measures adopted or proposed in numerous countries and the EU, as described in the pages that follow.

Argentina

Bilateral Engagement

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

Testing of All Graphic Products for Lead (Resolution 453)

As previously reported in the 2012 TBT report, the United States continues to be concerned with Argentina's Resolution 453/2010, which requires all inks, lacquers and varnishes used in producing printed materials, such as package labeling and inserts, to undergo testing for lead

⁴⁶ 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).

content. Prior to adoption of an amendment in March 2012 (see below), Resolution 453/2010 required the testing to be conducted in one of two designated laboratories in Argentina. The United States expressed concern during TBT Committee meetings in November 2011 and March 2012 that this regulation appeared to apply to foreign producers only, and that Argentina's testing capacity was insufficient to perform all the required testing. The United States asserted that the situation, coupled with the inability to test these products in the country of production, would lead to significant delays, cost and burdens for industry.

In March 2012, Argentina notified an amendment to Resolution 453/2010. Under this amendment, Argentina will temporarily accept a sworn declaration from the producer or importer that states that the product, or group of similar products, complies with the applicable norm, ASTM D 3335-85a in lieu of testing at the designated laboratories in Argentina. This alternative procedure, however, will be phased out in stages, ending November 12, 2013.

Both the U.S. and the European Union raised this issue during the March and June 2012 TBT Committee meetings. The United States indicated that it continue to question whether mandatory third party certification should be required for these products since they are low risk, and whether it is necessary for the testing to be performed in Argentina itself or by any accredited laboratory. The United States will continue to press Argentina on this issue in 2013.

Electrical and Electronic Products – Conformity Assessment Procedures

Argentina's new requirements for conformity assessment for electrical and electronic products, modifying Resolution 92/98, came into force January 1, 2013, but have not been notified to the WTO. Resolution 92/98 specifies the process by which foreign manufacturers and importers obtain the S-mark safety certification from local certification bodies. This certification is required to market electrical and electronic products between 50 and 1000 Vac in Argentina.

According to U.S. industry, Resolution 92/98 imposes repetitive testing and associated delays, resulting in costs for U.S. exporters that outweigh the purported safety benefits. In addition, industry reports that the requirements disproportionately impact foreign manufacturers and importers and favor domestic manufacturers. Failure to follow Resolution 92/98 will result in the inability of products to clear customs and enter Argentina's market.

The United States will continue to press Argentina on this issue in 2013.

Brazil

Bilateral Engagement

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

Health Products

As discussed in previous *TBT Reports*, the United States continues to be concerned with the timeliness of the registration of medical devices in Brazil. Resolutions 24 and 25, notified to the WTO in May 2009 and also known as Public Consultation 11, establish the requirements for manufacturers to submit a Certificate of Good Manufacturing Practice for registration of health products. According to Resolutions 24 and 25, a health product is defined as a product that fits into one of two categories, either a medical product or a product for *in vitro* use diagnosis. As of May 2010, applicants have had to submit to ANVISA a Good Manufacturing Practices (GMP) certificate with their application for registration of health products in Brazil. ANVISA issues a GMP certificate only after it has inspected the manufacturing premises. The United States is aware that Brazil intends to accelerate GMP inspections. However, according to discussions in the 2012 TBT Committee meetings, the average waiting time from submission of the inspection request until completion of the inspection is twenty months, while U.S. industry reports a wait time of up to 3 years. This is significantly longer than the average time of 3 months for similar inspections by other accredited auditing bodies. This delay hinders medical device exports to Brazil.

The United States and other WTO members raised this issue with Brazil in 2012 at meetings of the TBT Committee. The United States pressed ANVISA to accept existing GMP certificates without inspection or to consider subcontracting overseas inspections to accredited auditing bodies. In 2013 the United States will continue to raise this issue with Brazil.

Telecommunications – Acceptance of Test Results

As discussed in the 2012 TBT Report, the United States continues to be concerned about Resolution 323 (November 2002) promulgated by Brazil's National Telecommunications Regulatory Agency (ANATEL). Resolution 323, Standard for Certification of Telecommunications Products, only allows testing of products to be performed within Brazil, except in cases where the equipment is too large or too costly to transport. As a result, U.S. suppliers must present virtually all of their information technology and telecommunications equipment for testing at laboratories located in Brazil before that equipment can be placed on the Brazilian market. This requirement causes redundant testing, higher costs and delayed time to market. Brazil did not notify Resolution 323 to the WTO.

The United States has urged Brazil to implement the CITELE (Inter-American Telecommunication Commission) MRA with respect to the United States. Under the CITELE MRA, two or more CITELE participants may agree to provide for the mutual recognition of conformity assessment bodies and mutual acceptance of the results of testing and equipment certification procedures undertaken by those bodies in assessing the conformity of telecommunications equipment to the importing country's technical regulations. The United States and Brazil are both participants in CITELE. If Brazil implemented the CITELE MRA with respect to the United States, it would benefit U.S. suppliers seeking to sell telecommunications equipment into the Brazilian market by enabling them to have their products tested and certified in the United States to Brazil's technical requirements, eliminating the need for U.S. suppliers to have their products tested and certified in Brazil. The United States will continue in 2013 to encourage Brazil to implement the CITELE MRA with respect to the United States.

Chile

Bilateral Engagement

The United States and Chile discuss TBT-related matters in the context of the United States – Chile Free Trade Agreement, during annual Free Trade Commission and TBT Chapter Committee meetings, as well as during the TBT Committee meetings. The last United States – Chile FTA TBT Chapter Committee meeting was held November 14, 2012.

Food Labeling

The Chile's Congress adopted Law No. 20,606 on nutrition and composition of food and food advertising on July 6, 2012, and according to the Law, it will be implemented on July 6, 2013. Chile notified draft implementing regulations and accompanying guidance on advertising for Law No. 20,606 to the WTO in January 2013. These measures were open for comment until March 2013, and April 2013 respectively. The stated objective of Law No. 20,606 and its implementing regulations is to communicate information to the public about alleged obesity and other non-communicable disease risks in certain food. The proposed regulation requires manufacturers to place a stop sign-shaped icon on the front of the package (FOP) that covers up to 20 percent of the product, if it exceeds limits for fat (trans fat, saturated fat), calories, sugar, and salt. The icon will carry a warning from the Ministry of Health indicating the food is "high in" fat, sugar, calories, or salt. Industry has encouraged Chile to consider existing voluntary programs instead. Trade in processed and packaged foods to Chile amounts to \$255 million annually.

The Chilean Ministry of Health responded to requests from and met with domestic and foreign industry members prior to Chile's WTO notification of the measures. Chilean officials also met with U.S. representatives during the November 2012 United States – Chile Free Trade Agreement TBT Chapter Committee meeting, and then again bilaterally in March 2013. The United States raised concerns that the draft regulation is unclear and omits information such as an explanation of how the regulation applies to foods served in restaurants and to existing commercial inventory and whether imports can comply through the use of supplemental labels or stickers. The United States also raised concerns that the labeling scheme as proposed would take up a significant portion of the packaging for some products, that the stop sign shape is unnecessary to communicate the fat, sugar and salt content of the product.

The United States submitted written comments to the Government of Chile on February 26, 2013 through its WTO Inquiry Point regarding the proposed measures, citing similar concerns, including that the draft regulation could have a significant trade impact, that the draft regulation sets out a mandatory labeling requirement when voluntary labeling schemes could address Chile's stated objective, and that the timetable for implementation (July 2013) does not leave sufficient time for industry to comply or address trading partner concerns.

The U.S. Government will continue to monitor the situation and seek opportunities to work with the Chilean government both bilaterally and in the TBT Committee to ensure adequate consideration of comments from stakeholders, a constructive discussion of the rationale, details and potential impact of this proposed regulatory approach, and full consideration of less trade restrictive alternate approaches.

China

Bilateral Engagement

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

Food Additives – Formula Disclosure Requirements

In April, 2011, China’s General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released its “Specification for Import and Export of Food Additives Inspection, Quarantine and Supervision (2011 No. 52)” (“Specification”) The Specification, effective July 1, 2011, appears to require U.S. and other foreign food producers to disclose their proprietary food additive formulas by mandating that food product labels list the precise percentage of each food additive. As a result of this requirement, a competitor would have access to information that it can use to replicate proprietary formulas and compromise an innovator’s legitimate commercial interests. The requirement to disclose product formulas appears to apply only to imported food additives.

In addition, China developed and implemented the Specification without notifying the TBT or SPS Committees in advance. As a result, neither the United States nor U.S. industry stakeholders were aware of, or provided the opportunity to comment on, the proposed Specification before AQSIQ issued it. Finally, the measure appears to have taken effect less than six weeks after AQSIQ announced it, which did not provide suppliers with adequate time to comply.

In a May 31, 2012 letter to China, the United States raised concerns regarding the serious impact on legitimate commercial interests caused by the required disclosure of formulas on labels and the apparent application of the Specification only to imported products. The United States observed that the Specification requirements appeared to diverge from the applicable standards in the Codex Alimentarius Commission. The United States also noted that the Specification appeared to conflict with China’s own National Food Safety Standard for the Labeling of Prepackaged Foods, which China notified to the WTO in April 2010. China’s labeling measure requires only the listing of all ingredients in descending order of in-going weight, and provides that ingredients used in small amounts for the purpose of flavoring need not be declared on the label. The United States emphasized that the regulatory incoherence raised by the Specification created uncertainty in the trading community.

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

China Compulsory Certification (CCC) Requirements – Conformity Assessment Procedures

As previously reported, China's CNCA requires a single safety mark – the CCC mark – to be used for both Chinese and foreign products. U.S. companies continue to report, however, that China is applying the CCC mark requirements inconsistently and that many Chinese-produced goods continue to be sold without the mark. In addition, U.S. companies in some sectors continue to express concerns about duplication of safety certification requirements, particularly for radio and telecommunications equipment, medical equipment, and automobiles.

To date, China has authorized 153 Chinese facilities to perform safety tests and accredited 14 Chinese firms to certify products as qualifying for the CCC mark, as reported in the 2012 USTR Report to Congress on China. When it joined the WTO, China committed to provide non-discriminatory treatment to majority foreign-owned conformity assessment bodies seeking to operate in China. Despite this commitment, China so far has accredited only six foreign-invested conformity assessment bodies. It is not clear whether these six bodies play any appreciable role in testing or certifying products sold in China. China rejected suggestions that it recognize laboratories that have been accredited by ILAC MRA signatories or develop other procedures to recognize foreign conformity assessment bodies. It insists that it will accept conformity assessment bodies domiciled abroad only if the governments of ILAC MRA signatories negotiate MRAs with China. Moreover, China has not developed any alternative, less trade-restrictive approaches to third-party certification, such as recognition of a supplier's self-certification.

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

In 2012, as in prior years, the United States raised its concerns about the CCC mark system and China's limitations on foreign-invested conformity assessment bodies with China both bilaterally and during TBT Committee meetings. At the December 2012 JCCT meeting, China confirmed that eligible foreign-invested testing and certification entities registered in China can participate in CCC mark-related work and that China's review of applications from foreign-invested entities will use the same criteria as those applicable to Chinese domestic entities. The United States will continue to press China on this issue in 2013.

Mobile Devices – WAPI Encryption Standards

The United States continues to have serious concerns regarding China's 2009 unpublished requirement that its WAPI wireless local area networks (WLAN) standard be used in mobile handsets, despite the growing commercial success of computer products in China that comply with the internationally recognized WiFi standard developed by the Institute of Electrical and

Electronics Engineers (IEEE).

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

A new trade concern related to WiFi standards arose in 2011 when China published a proposed voluntary wireless LAN industry standard known as the "UHT/EUHT standard" to be used in wireless networks. China's UHT/EUHT standard appears to be an alternative to the internationally recognized IEEE 802.11n standard. MIIT released the UHT/EUHT standard for a 15-day public comment period on September 20, 2011 and approved it in February 2012. U.S. industry groups commented that the UHT/EUHT standard may not be compatible with either WAPI or the IEEE 802.11 standard. Separately, the United States expressed its concern to China that the integration of the UHT/EUHT standard into certification or accreditation schemes would make the standard effectively mandatory. This could restrict market access for U.S. producers. The United States will vigorously pursue a resolution of this issue in 2013.

Mobile Devices – Draft Regulatory Framework

China's MIIT issued the "Draft Mobile Smart Terminal Administrative Measure" ("Measure") on April 10, 2012. The Measure established a new regulatory framework for the mobile device market. The United States raised concerns about the Measure with China in April and May 2012. The United States expressed concern that the Measure imposed numerous new obligations, technical mandates, and testing requirements on information technology and telecommunications hardware, operating systems, applications, app stores, and other related services. The scope and mandatory nature of these requirements appear unprecedented among the major global markets for mobile smart devices.

On June 1, 2012, MIIT published a draft of the Measure on its website, soliciting public comment for 30 days. In addition, in November 2012, China notified the draft measure to the TBT Committee and indicated that it would accept comments for a 60-day period. Both the United States and affected industry submitted written comments on the Measure. The United States and U.S. industry are concerned that the top-down government-mandated requirements contained in the Measure are overly burdensome and could create significant trade barriers. Furthermore, the United States and U.S. industry are concerned that inclusion in the Measure of numerous voluntary standards and testing requirements relating to smart terminals could create additional trade barriers if these voluntary standards become mandatory through MIIT's testing and certification process. At the December 2012 JCCT meeting, China confirmed that it will take the views of all stakeholders into full consideration in regard to the regulation of information technology and telecommunications hardware, operating systems, applications, app stores, and other related services. The United States and China will continue to discuss this issue as China revises the current draft.

4G Telecommunications - ZUC Encryption Algorithm Standard

At the end of 2011 and into 2012, China unveiled an encryption algorithm (known as the ZUC standard), which was developed by a quasi-governmental Chinese research institute for use in 4G Long Term Evolution (LTE). The European Telecommunication Standards Institute (ETSI)

3rd Generation Partnership Project (3GPP) had approved ZUC as one of three voluntary encryption standards in September 2011. According to U.S. industry reports, MIIT, in concert with the State Encryption Management Bureau (SEMB), informally announced in early 2012 that only domestically-developed encryption algorithms, such as ZUC, would be allowed for the network equipment (mobile base stations) and mobile devices comprising 4G TD-LTE networks in China. In addition, industry analysis of two draft ZUC-related standards published by MIIT suggests that burdensome and invasive testing procedures threatening companies' sensitive intellectual property could be required.

In response to U.S. industry concerns, the United States urged China not to mandate any particular encryption standard for 4G LTE telecommunications equipment used on commercial networks, in line with its bilateral commitments and the global practice of allowing commercial telecommunications service providers to work with equipment vendors to determine which security standards to incorporate into their networks. The United States stated that any mandate to use a domestic encryption standard such as ZUC would appear to contravene a commitment that China made to its trading partners in 2000, which clarified that China would permit the use of foreign encryption standards in IT and telecommunication hardware and software for commercial use and that it would only impose strict "Chinese-only" encryption requirements on specialized IT products whose "core function" is encryption. Additionally, a ZUC mandate would appear inconsistent with China's 2010 JCCT commitment on technology neutrality. In 2010, China had agreed to take an open and transparent approach that allowed commercial telecommunication operators to choose which telecommunications equipment and encryption technologies and standards to use for their networks and not to provide preferential treatment to domestically-produced standards or technology used in 3G or successor networks, so that operators could choose freely among whatever existing or new technologies might emerge to provide upgraded or advanced services.

The United States pressed China on this issue throughout the run-up to the December 2012 JCCT meeting. At that meeting, China agreed that it will not mandate any particular encryption standard for commercial 4G LTE telecommunications equipment. In 2013, the United States will continue to closely monitor developments in this area.

IT Products – Multi-Level Protection Scheme

Beginning in 2010 and continuing through 2012, both bilaterally and during TBT Committee meetings, the United States has raised concerns with China about its framework regulations for information security in critical infrastructure known as the Multi-Level Protection Scheme (MLPS), issued in June 2007 by the Ministry of Public Security (MPS) and MIIT. The MLPS regulations put in place guidelines to categorize information systems according to the extent of damage a breach in the system could pose to social order, the public interest, and national security. The MLPS regulations also appear to require buyers to comply with certain information security and encryption requirements that are referenced in the MLPS regulations.

MLPS regulations bar foreign products from being incorporated into Chinese information systems graded level 3 and above. (China grades an information system with respect to its handling of national security information, with the most sensitive systems designated as level 5). Systems labeled as grade level 3 and above, for instance, must solely contain products developed by Chinese information security companies and their key components must bear

Chinese intellectual property. Moreover, companies making systems labeled as grade level 3 and above must disclose product source codes, encryption keys, and other confidential business information. To date, government agencies, firms in China's financial sector, Chinese telecommunications companies, Chinese companies operating the domestic power grid, educational institutions, and hospitals in China have issued hundreds of request for proposals (RFPs) incorporating MLPS requirements. These RFPs cover a wide range of information security software and hardware. By incorporating level-3 requirements, many RFPs rule out the purchase of foreign products.

Currently, China applies the MLPS regulations only in the context of these RFPs. If China issues implementing rules for the MLPS regulations to apply the rules broadly to commercial sector networks and IT infrastructure, those rules could adversely affect sales by U.S. information security technology providers in China. The United States urged China to notify the WTO of any MLPS implementing rules promulgating equipment-related requirements. At the December 2012 JCCT meeting, China indicated that it would begin the process of revising the MLPS regulations. It also agreed to discuss concerns raised by the United States during the process of revision. The United States will continue to urge China to refrain from adopting any measures that mandate information security testing and certification for commercial products or that condition the receipt of government preferences on where intellectual property is owned or developed.

Medical Devices – Conformity Assessment Procedures

The United States has expressed concerns over the past years regarding China's medical device registration requirements. China has not notified proposed revisions to Order 276 "Regulation on Supervision and Administration of Medical Devices" to the WTO. Amendments to Order 276 have been under consideration by the Legislative Affairs Office of the State Council and significant revisions were released in 2007, 2010, and in 2012.

The most recent 2012 revision (third draft) of Decree 276 continues to mandate country-of-origin registration, a requirement that prevents foreign manufacturers of medical devices from registering their products in China without prior marketing approval in the country of origin or country of legal manufacture. According to U.S. industry, this requirement has blocked or inordinately delayed sales of safe, high-quality medical devices to the Chinese market because some manufacturers did not apply for marketing approval for certain products in the countries in which they were produced or in their home countries for reasons unconnected with product quality or safety. 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. China continues to defend this requirement despite concerted efforts to resolve this issue. The United States will continue to press the issue in 2013.

Draft revisions to Order 276 also continue to reflect: 1) problematic product type testing (or "sample testing") requirements; 2) a burdensome re-registration process; and 3) the requirement that clinical trials be repeated in China in order to register products there. Industry continues to advocate for the transition from end-product type testing to a Quality Management System

approach, as outlined in ISO standard 13485. Furthermore, while the latest draft increases the validity of a registration from four to five years, China's re-registration process continues to require fees and submissions comparable to the initial registration process.

With respect to the issue of in-country clinical trials, at the 2010 JCCT Subgroup meeting, China's State Food and Drug Administration (SFDA) committed to accept clinical evidence from outside China and that China would not automatically mandate in-country clinical trials for Class II and Class III devices. However, the latest revision of Decree 276 proposed a waiver of in-country clinical trials for Class I (lowest risk) devices only and remains unclear on potential waivers of clinical trials for Class II and Class III devices. In bilateral discussions with China in 2012, the United States urged China to meet with stakeholders to discuss their concerns. The United States will continue to monitor the development of revisions to Order 276 in 2013.

Imaging and Diagnostic Medical Equipment – Classification

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

During the 2011 JCCT meeting, the United States urged China to place certain imaging and diagnostic medical equipment into a lower risk category. China's SFDA committed to issue, by June 2012, a complete list of x-ray equipment to be placed in a lower risk category and agreed to endeavor to release a draft for an *in vitro* (e.g., test tube) diagnostic equipment catalog for public comment by June 2012. Subsequently, in August 2012, SFDA revised and lowered the classification for four sub-categories of imaging and diagnostic medical equipment under the "Classification Catalogue of Medical Devices," including certain medical ultrasonic instruments and related equipment, medical x-ray equipment, medical x-ray ancillary equipment and components, and medical radiation protective equipment and devices. The United States will work in 2013 to ensure that China fully implements its commitment.

Patents Used in Chinese National Standards

In the State Council's Outline for the National Medium to Long-Term Science and Technology Development Plan (2006-2020) and in the 11th Five Year Plan (2006-2010) for Standardization Development of the Standardization Administration of China (SAC), China prioritized the development of national standards.

In November 2009, SAC circulated for public comment proposed "Provisional Rules Regarding Administration of the Establishment and Revision of National Standards Involving Patents." The provisional rules indicated that in principle a mandatory national standard should not incorporate patented technologies. The draft provisional rules also indicated that when the use of patented technologies was needed a compulsory license could result if the relevant government entity was unable to reach agreement with the patent holder. The United States provided comments opposing this and other aspects of the draft provisional rules, which did not take effect. In December 2012, SAC circulated new draft interim measures, omitting certain troubling aspects of the earlier draft, such as the compulsory license provision, but raising other

concerns, including in its definition of the responsibilities and potential liabilities of individuals and organizations that participate in the formulation of revision of national standards. In early 2013, the United States provided comments to SAC on these and other concerns. The United States will continue to engage with China on this issue in 2013.

Electronic Information Products – Certification of Pollution Control

The United States continues to be concerned by China's Administrative Measures for Controlling Pollution Caused by Electronic Information Products, issued by MIIT and several other Chinese agencies effective March 2007. This measure (known as "China RoHS") is modeled after existing European Union regulations. While the regulations of both China and the EU seek to ban lead and other hazardous substances from a wide range of electronic products, there are significant differences between the two regulatory approaches.

China's original RoHS regulations were developed without any formal process for interested parties to provide input to MIIT and were not timely notified to the TBT Committee. As a result, stakeholders outside China had limited opportunity to comment on proposals or to clarify MIIT's implementation intentions. The regulations omitted basic information, such as the specific products subject to mandatory testing and the applicable testing and certification protocols. Industry in the United States and other countries expressed concern that producers would have insufficient time to adapt their products to China's requirements and that in-country testing requirements would be burdensome and costly. China circulated subsequent proposed revisions to its RoHS regulations in 2010 and in 2012. U.S. industry submitted comments on the July 2012 draft revision.

Concurrent with these developments, China issued the catalog of electronic information products subject to hazardous substance restrictions and mandatory testing and conformity assessment under the China RoHS regulations. The final version of the catalog included mobile phones, other phone handsets, and computer printers. Information on the applicable testing, certification, and conformity assessment regime was not included in either the draft or final catalog. MIIT and CNCA also introduced a voluntary program in November 2011 to certify electronic information products to the China RoHS limits established for six substances. The United States will carefully monitor developments in this area in 2013.

Cosmetics –Approval Procedures and Labeling Requirements

SFDA initiated a series of changes to China's cosmetics regulation after obtaining jurisdiction over the industry in 2008. SFDA imposed additional requirements on "new ingredients" in April 2010, and promulgated guidance on the application and evaluation of new cosmetic ingredients in 2011. These actions stalled the approval of cosmetics containing new ingredients. In fact, SFDA has approved only a handful of new ingredients since 2010. The United States, along with EU and Japan, continue to raise concerns regarding the application requirements at TBT Committee meetings.

In December 2012, China notified "Cosmetics Label Instructions Regulations" and "Guidance for the Cosmetics Label Instructions," which propose new labeling requirements that are in addition to the two existing labeling requirements that apply to cosmetic products. In January 2013, industry submitted comments through the U.S. TBT Inquiry Point, arguing that the proposed regulation overlaps and conflicts with existing Chinese regulations, as well as creates

an undue burden for the industry.

The United States is also monitoring possible implications of SFDA's efforts to create an inventory of "existing ingredients" that have been approved for use in cosmetics products in China. In September 2012, SFDA released for comment the "SFDA Notification: List of Raw Materials Already in Use in Cosmetics (Third Batch)." The first and second lists of materials were released in April and July 2012, respectively.

The United States will urge China to continue dialogue with all interested parties regarding these measures and to take into account the comments received. China should also consider alternative measures that are more commensurate with the risks involved, such as post-market surveillance and reliance on internationally-recognized good manufacturing practices (GMPs). These alternatives would meet China's legitimate regulatory objectives with fewer disruptive effects on international trade.

Colombia

Bilateral Engagement

The United States discussed TBT matters with Colombia during and on the margins of TBT Committee meetings, and in the TBT Chapter Committee of the United States – Colombia FTA. The first meeting of this committee was held October 23-24, 2012.

Distilled Spirits – Identity Requirements

Prior *TBT Reports* outlined U.S. industry's concerns over the quality and identity requirements that Colombia proposed in 2009 for distilled spirits, including gin, rum, vodka, and whiskey.

On August 24, 2012, Colombia notified to the WTO a final version of its alcoholic beverage regulation, which contained standards of identity for distilled spirits based on analytical parameters, such as a limit on congeners and other naturally occurring constituents of gin, vodka, and rum. The regulation provides for a 12-month transition period. Unlike Colombia's approach, the standards of identity for distilled spirits sold in the United States, the European Union, Canada, and nearly every other major spirits market bases their standards of identity on the raw materials and processes used to produce distilled spirits. In response to Colombia's notification, the United States submitted written comments expressing concern about Colombia's approach of basing identity requirements on chemical composition rather than raw materials and processes used to produce the distilled spirits. The United States will continue to monitor this issue in 2013.

Commercial Vehicles – Diesel Emissions

As raised in prior *TBT Reports*, the United States remains concerned about the Ministry of the Environment and Sustainable Development's draft resolution amending Resolution No. 910 of 2008. On December 14, 2012, the Government of Colombia notified this proposed measure to the WTO. Amended Resolution No. 910, which is proposed to go into effect August 5, 2013, indicates that the current commercial vehicles emission standards in Colombia, EPA 98 (a U.S. standard) and EURO III (an EU standard), will not be valid for new commercial vehicles seeking registration for sale in Colombia and that EPA 04 and EURO IV emission standards will

be accepted for long haul semitrailers until December 2014. The draft resolution further provides that by January 2015, all commercial vehicles seeking registration for sale in Colombia must meet EURO IV emission standard requirements. Given the design of some U.S.-manufactured diesel truck engines, industry has expressed concern that use of this EU standard would effectively exclude many U.S. heavy duty trucks from the Colombian market. Further, according to EcoPetrol, the Colombian state-run oil company, the fuel necessary to comply with the standard will not be available nationwide until 2017. This situation is exacerbated by the fact that engines designed to meet EPA 04 standard, which is more stringent than the EURO IV standard, already face restricted access to the Colombian market, because Colombia does not maintain adequate supplies of the high-quality fuel needed for these high technology engines.

The United States has encouraged Colombia to focus efforts on removing older trucks from the road to achieve the most immediate and significant emissions reductions. In 2012, the United States raised concerns during the first meeting of the United States – Colombia FTA TBT Committee meeting, engaged in technical exchanges, and raised the issue on the margins of the March and June TBT Committee meeting.

In 2013, the United States will respond to the WTO notification of the draft resolution, and will continue to raise concerns about the measure bilaterally and in the WTO.

The European Union

Bilateral Engagement

The United States has actively engaged the EU on TBT-related matters in the TBT Committee, the WTO Trade Policy Review of the EU, and in bilateral meetings. The United States also raises concerns and encourages reform in EU approaches to key TBT issues in the Transatlantic Economic Council (TEC) and the United States – European Union High-Level Regulatory Cooperation Forum (HLRCF).

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

The announcement by President Obama and EU leaders that the United States and the EU intend to pursue a comprehensive trade and investment agreement will provide new opportunities to address TBT-related issues with the EU.

Honey – Biotechnology Labeling

EC Regulation No. 1829/2003 addresses GE crops for food use and for animal feed. The United States, along with other WTO Members, has expressed concerns in TBT Committee meetings, most recently in March 2013, regarding the requirement in Regulation No. 1829/2003 that honey containing pollen derived from GE plants must be labeled as such in accordance to EU regulations. This requirement was the result of the ECJ 2011 decision in Case C-442/09 that interpreted EC Regulation No. 1829/2003. The United States will continue to monitor this issue in 2013. In September 2012, the EU Commission proposed an amendment to Directive 2001/100/EC to clarify that pollen is not an ingredient of honey, but it has not been finalized. In

addition, the European Food Safety Authority issued an opinion that pollen from the genetically engineered corn approved for cultivation in the EU was equivalent to pollen from conventionally bred varieties of corn. The United States raised this issue during the March 2013 TBT Committee meeting.

In addition, industry has raised concerns on several occasions about the impact the EU's restrictive stance on biotechnology has had on U.S. exports of soy, grains, corn, and other crops. The United States have repeatedly raised concerns and objections with the EU regarding the EU's biotechnology regulations and legislation and their detrimental effect on U.S. exports. With respect to SPS issues arising from the EU's policy regarding food and agricultural products derived from modern biotechnology, please refer to the SPS Report.

Accreditation Rules

As noted in previous *TBT Reports*, the United States has serious concerns regarding the EU's accreditation framework set out in EC Regulation No. 765/2008. The regulation, which became effective in January 2010, 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.

Under the regulation, Member States can recognize non-European accreditation bodies at their discretion. Member States may refuse to recognize non-European accreditation bodies and refuse to accept conformity assessments issued by these bodies. The regulation raises market access concerns for U.S. producers, whose products may have been tested or certified by conformity assessment bodies accredited by non-European accreditation bodies.

The United States will continue to press the EU on these issues in 2013.

Foods - Quality Schemes

New framework legislation for quality schemes in agriculture, EU No. 1151/2012, became effective in January 2013. The quality schemes provide for (1) "certification" procedures, in which detailed specifications are checked periodically by a competent body and (2) "labeling" systems to communicate information regarding product quality to the consumer, and which are subject to official controls. The United States is concerned with an element of the legislation that establishes a new framework for the development and protection of optional "quality terms." For example, it creates and protects the term "mountain product."

In particular, the United States is concerned that the legislation incorporates commonly used terms into the EU's quality schemes and subjects them to registration requirements. The United States is concerned that, as result, the legislation will negatively impact U.S. producers' ability to export and market their products in the EU. The United States will seek to work with the EU to address these concerns in 2013.

Chemicals – REACH Regulation

The EU's REACH regulation imposes extensive registration, testing, and data requirements on tens of thousands of chemicals. REACH also subjects certain chemicals to an authorization

process that would prohibit them from being placed on the EU market except for specific uses. U.S. industry is concerned that REACH requires polymer manufacturers and importers to register reacted monomers in many circumstances. This is problematic because reacted monomers no longer exist as individual substances in polymers and would not create exposure concerns in the EU. In addition, EU polymer manufacturers generally can rely on the registrations of their monomer suppliers and do not need to be individually registered. Since U.S. monomer suppliers are generally not located in the EU, U.S. polymer producers cannot likewise rely on 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. The United States has pressed the EU to eliminate the registration requirement.

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 procedures. Differing interpretations between the Commission and several Member States regarding when these obligations apply has created uncertainty among industry over how to comply. The Commission has indicated that notification and communication 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. However, Member States have stated that these obligations should apply when a substance on the Candidate List is present in concentrations above 0.1 percent of the weight of the article's components or homogenous parts. In 2010, these Member States pushed the Commission to reverse its position as part of what may have been an effort to seek to protect the EU market from imports. Departure from the Commission's interpretation would present a much more difficult compliance problem for U.S. industry since it would require companies to perform an analysis of individual component concentration levels in their products, which would be extremely time-consuming and burdensome. Given that an alteration of the EU's approach could substantially disrupt U.S. exports, the United States has asked the EU to ensure that all Member States follow the Commission's current interpretation.

Other problematic issues with the EU's REACH regime include inadequate transparency and differing registration requirements for EU and non-EU entities. In general, the European Commission regularly publishes notices of draft EU measures in the Official Journal of the European Union and sends notifications to the WTO Secretariat. However, U.S. and other non-EU interested persons allege such notifications occur far too late in the process for them to familiarize themselves with the new requirements and submit timely comments. In advance of these notifications, European Commission trade and regulatory officials consult primarily with EU stakeholders.

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

In addition, the United States registered concerns with the EU during the November 2011 TBT Committee meeting regarding a costly REACH requirement, applied only to manufacturers

outside the EU, to appoint “Only Representatives” (ORs). An OR is a natural or legal person established in the EU authorized to carry out the obligations that REACH imposes on importers. REACH bars U.S. producers from registering substances for use in the EU and thus they must engage an OR for this purpose.

The United States also encouraged the EU to address in its 2012 REACH review data compensation issues in connection with the operation of Substance Information Exchange Forums (SIEFs). Specifically, U.S. industry has raised concerns that the “lead registrant” for each SIEF may take commercial advantage of its position in dealing with other SIEF members, particularly SMEs. Because other SIEF members must negotiate with the lead registrant to register their chemicals, a lead registrant could unfairly charge members registration fees at a level that would reduce competition in the EU market. The United States urged the EU to consider issuing guidance for cost-sharing that would place limits on what lead registrants can charge other SIEF members, thus preventing undue financial burdens on those members, especially SMEs.

The United States will continue to monitor closely REACH implementation in 2013, and will raise trade concerns, as appropriate, in the TBT Committee and other pertinent fora.

Wine – Traditional Terms

The EU continues to seek exclusive use of so-called “traditional terms” such as tawny, ruby, reserve, classic, and chateau on wine labels, but may allow third-country producers to use such terms if their governments enter into an agreement with the EU regulating use of the terms in their markets. Regulation EC No 607/2009 implements EU protections on designations of origin and geographical indication, traditional terms, labeling, and presentation of certain wine products.

The EU’s regulation of traditional terms severely restricts the ability of non-EU wine producers to use common or descriptive and commercially valuable terms to describe their products sold in the EU. While no shipments have been blocked, U.S. industry reports that the regulation has deterred exporters from seeking to enter the EU market. The EU’s efforts to expand the list of so-called “traditional terms” to include additional commercially valuable terms are also problematic because some of these terms do not have a common definition across all EU Member States. Additionally, the United States remains concerned about the EU’s decision to withdraw permission to use certain “traditional terms” under the United States – EU agreement on trade in wine, as well as the EU’s limitation on the use of traditional expressions in trademarks.

The EU justifies these above-mentioned efforts to limit use of traditional terms on the ground that misuse of the terms may confuse consumers. However, these terms have been used without incident on U.S. wines in the EU market for many years. Moreover, the EU has allowed the use of the terms by other countries, including Chile, South Africa, Canada, and Australia. Although the EU recently approved the use by U.S. industry of the terms “cream” and “classic” it has not issued a decision with respect to use on U.S. products of the terms “chateau,” “clos,” “ruby,” and “tawny.” During 2013, the United States will continue to coordinate with U.S. wine exporters on how best to address and resolve concerns regarding the EU’s wine policy, and will engage with EU officials at the TBT Committee and in bilateral meetings.

Distilled Spirits – Aging Requirements

The EU requires that for a product to be labeled “whiskey” it must be aged a minimum of three years. U.S. whiskey products that are aged for a shorter period cannot be marketed as “whiskey” in the EU market or other markets such as Israel and Russia that adopt EU standards. The United States views a mandatory three-year aging requirement for whiskey as unwarranted. In fact, recent advances in barrel technology enable U.S. micro-distillers to reduce the aging time for whiskey. Variations in climate can also shorten aging time. In 2013, the U.S. will continue to urge the EU and other trading partners to end whiskey aging requirements that serve as barriers to U.S. exports.

Biofuels – Renewable Energy Directive

The EU’s renewable energy directive (RED) provides for biofuels (such as biodiesel and ethanol) and biofuel feedstocks (such those derived from soybeans or canola) to be counted toward fulfilling Member State biofuel use mandates. It also provides for biofuels and biofuels feedstocks to benefit from RED tax incentives but only if they qualify for a sustainability certificate. However, to qualify for a sustainability certificate biofuel or biofuel feedstock must meet a patchwork of standards or be subject to a bilateral agreement with the EU. The use of varying approaches and sustainability standards has disrupted U.S. trade in soybeans.

To find alternative approaches to address U.S. concerns with the EU’s certification scheme, the United States and the EU began discussions to explore a possible bilateral agreement that would recognize that longstanding U.S. conservation programs correspond to RED sustainability criteria. In July 2011, a high-level delegation from the U.S. Government met with officials from the EC Directorate-Generals for Trade and Energy to address U.S. concerns. Additional discussions were held in September, November, and December 2011, leading to the creation of a working group to explore the possibility of a bilateral agreement as provided for under the RED. The working group met in February, April and June 2012, but did not reach agreement on the basis for a bilateral agreement. In the November 2012 TBT Committee meeting, the United States continued to urge the EU to show flexibility and openness in recognizing different approaches that could provide equivalent outcomes when it comes to sustainable energy feedstocks. In 2013, the United States will continue to work with the EU and push for resolution of U.S. concerns.

India

Bilateral Engagement

The United States discusses TBT matters with India in various fora including the TBT Committee, the United States – India Trade Policy Forum (TPF), the United States – India Commercial Dialogue, and the High-Technology Cooperation Group. The United States and India also engage in ad hoc bilateral discussions. For example, the United States and India conducted a digital video conference on standards and conformity assessment on December 12, 2012. Similar conferences are planned for 2013.

In addition, the Confederation of Indian Industry (CII) and ANSI have added India-specific content on relevant standards, conformity assessment, and technical regulations in India to [ANSI’s standards portal](#).

Cosmetics – Registration Requirements

In April of 2008, India notified to the WTO an amendment to its “Drugs and Cosmetics (Amendment) Rules of 2007” that introduced a new registration system for cosmetics products that U.S. industry believes to be overly burdensome and costly, and lead to unnecessary delays to market for companies’ products.

In 2009 and 2010, U.S. industry sought clarifications in a number of areas, and India made a number of modifications to the measure and developed implementing guidelines. The United States raised the issue at the June 2012 TBT Committee meeting. In particular, the United States expressed concern that under the guidelines the registration certificates and import licenses for foreign producers must be renewed every three years, while the certificates and licenses for domestic producers are valid for five years.

India has not yet addressed these concerns and has indicated that the guidelines will enter into force on March 31, 2013. In 2013, the United States will continue to monitor the implementation and changes to the guidelines and press for changes that address U.S. concerns.

Foods Derived from Biotech Crops

India’s biotechnology regulatory and approval system prohibits the importation of food and agricultural products containing ingredients derived from biotech crops such as corn and soybeans, with soybean oil being the sole exception.

On June 5, 2012, India’s Department of Consumer Affairs proposed an amendment to the Legal Metrology (Packaged Commodities) Rules, 2011 that would require, *inter alia*, that the term “GM” be placed on the principal display panel of packages containing genetically engineered foods.

The United States will continue to monitor this issue in 2013.

Telecommunications Equipment – Information Security Regulations

In 2009 and 2010, India imposed new requirements in telecommunications service licenses, including mandatory transfer of technology and source codes as well as burdensome testing and certification for telecommunications equipment. Following extensive engagement with trading partners including the United States, India eliminated most of these requirements in 2011. In doing so, however, India adopted new telecommunications license amendments that continue to require, among other things, that as of April 2013, testing of all telecommunications equipment deemed to raise security concerns take place in India. The U.S. Government and industry continue to press India to reconsider the domestic testing policy and to adopt the international best practice of using international common criteria and accepting products tested in any accredited lab, whether located in India or elsewhere.

The United States will continue to monitor this issue in 2013.

Toys and Toy Products – Registration and Testing Requirements

The United States continues to be concerned about the proposed “Toys and Toy Products (Compulsory Registration) Order” being considered by the government of India. As noted in the *2012 TBT Report*, the registration order, if implemented, would impose onerous and time consuming registration obligations on U.S. toy companies and conformity assessment burdens that are dramatically higher than those found in any other country.

The proposed manufacturer’s self-declaration provisions require an extremely detailed and onerous level of information, including submission of a registration form that contains information concerning management composition, raw materials, components, machinery (including the serial numbers for all equipment on the factory floor and notification whenever a piece of equipment is removed from the factory, even for maintenance), factory layout, production processes, packing/storage, inspection, and quality control staff for each plant at which the imported toys are manufactured. Much of this information is unnecessary as it does not demonstrate anything about the quality or safety of the toy nor the quality of the manufacturing process.

In addition, the proposed rule requires test reports on samples of any toy or toy product conducted by a Bureau of Indian Standards (BIS)-recognized laboratory in India or by an overseas laboratory that has a mutual recognition agreement with BIS, of which there are none. Test reports from ILAC-accredited laboratories are not accepted under this proposed rule. As noted in the *2012 TBT Report*, it appears India’s safety objectives are currently – and can continue to be – achieved by accepting test results from internationally recognized laboratories, such as ILAC-accredited laboratories.

Indonesia

Bilateral Engagement

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

Horticulture Products – Labeling Requirements

In September 2012, Indonesia issued Ministry of Agriculture’s (MOA) Regulation 60 and Ministry of Trade’s (MOT) Regulation 60 (amending MOT Regulation 30). These regulations impose a broad range of requirements on the importation of horticultural products into Indonesia and include provisions related to labeling. MOA’s Regulation 60 requires that MOA consider the “packaging requirement and labeling in Indonesian,” among other considerations prior to issuing a “recommendation for the import of horticultural products” or RIPH. MOT’s Regulation 60 contains labeling and packaging requirements. For instance, the regulation requires that Bahasa Indonesia labels be attached to the packaging prior to entering the Indonesian customs area. Indonesia did not notify these regulations to the TBT Committee.

The United States raised concerns about the labeling and packaging requirements contained in these measures at the November 2012 TBT Committee, as well as in numerous bilateral meetings. The United States requested that a WTO dispute settlement panel be established regarding MOT regulation 60 and MOA regulation 60, as well as other regulations in connection with their import licensing and quantitative restrictions in March 2013. The United States will continue to raise concerns in 2013 regarding the labeling aspects of the measures.

Processed Foods – Bahasa Labeling Requirement

In September 2010, Indonesia’s National Agency for Drug and Food Control (BPOM) announced that it would require all imported processed food products to be labeled exclusively in the Bahasa language and require the labels to be affixed to product containers prior to “entering Indonesian territory” effective March 1, 2011. Indonesia agreed to a U.S. request to delay enforcement until March 1, 2012. Also in response to U.S. concerns, Indonesia agreed to accept supplemental Bahasa language labels in lieu of original, exclusive Bahasa language labeling.

In June and July 2012, Indonesia notified two new BPOM regulations to the TBT Committee, G/TBT/N/IDN/60 and G/TBT/N/IDN/59, laying out new requirements for registration and labeling for processed foods. Together, the measures establish an extensive and complex registration system for processed food products and burdensome labeling requirements, including mandating the disclosure of confidential and proprietary information and requiring unnecessary warning statements for products containing colorants and artificial sweeteners. At the November 2012 TBT Committee, the United States raised concerns and asked that Indonesia delay enforcement until after comments from interested parties could be taken into account. The U.S. submitted written comments in August 2012.

Effective January 2013, Bahasa language labeling before entering Indonesia is required. However, enforcement is done via signed statements from importers stating that labeling requirements are met. BPOM conducts periodic checks at importers’ warehouses since they are not allowed to enter customs areas. In 2013, the United States will continue to raise concerns regarding these requirements.

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

In 2009, BPOM announced licensing requirements for companies that distribute food, health food supplements, drugs, and cosmetics in Indonesia, including imported products. Although the proposed licensing requirements vary by product type, they all could significantly disrupt trade. For example, imported food distributors would be required to provide reference letters from the overseas production facility, certifications for health or *halal* status, and a certificate stating that the production process was radiation free. The United States raised concerns about the proposed licensing requirements with Indonesia bilaterally and in TBT Committee meetings. BPOM issued a proposed replacement regulation in early 2011, which addresses some of the potentially burdensome requirements. For example, the revised proposal no longer requires *halal* certificates for products that do not claim to be *halal* consistent. The United States will continue to raise concerns with this regulation with Indonesia.

Toys – Standards and Testing Requirements

In 2012, Indonesia's Directorate General of Manufacturing Industries proposed to enforce a recently enacted toy safety standard, SNI 8124:2010. The U.S. toy industry is concerned that the safety standard will require redundant and burdensome in-country testing. The United States raised concerns regarding SNI 8124:2010 bilaterally and in TBT Committee meeting in 2012. At the request of the United States, Indonesia notified the draft decree to the WTO in July 2012, as G/TBT/N/IDN/64. The United States is encouraging Indonesia, in lieu of in-country testing, to allow foreign suppliers to provide laboratory test reports by ILAC- accredited laboratories. Recognition of test results from ILAC-accredited laboratories is common international practice in the toy sector, prevents market-access delays, and reduces the burden on local testing and certification facilities. The United States also raised concerns over the requirement that toys be affixed with a mark indicating compliance with SNI ISO 9001:2008. Indonesia has responded that it is in the process of developing technical guidance concerning the requirement. The United States will remain engaged on this subject as Indonesia develops its guidance and continue to press Indonesia to accept testing performed by ILAC-accredited laboratories.

Japan

Bilateral Engagement

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

Organic Product Requirements

During 2012, the United States actively engaged Japan through a series of bilateral meetings to address outstanding issues regarding trade in organic products, and initiate negotiations towards increasing bilateral trade in these products. These meetings have facilitated the technical exchange needed to bring U.S. concerns closer to resolution, and the United States and Japan are engaged in the negotiation of a possible mutual organic equivalence arrangement.

While the negotiations are underway, the United States continues to raise specific concerns with Japan. In contrast to U.S. organic standards, Japan will not certify as organic any agricultural products produced with alkali extracted humic acid or lignin sulfonate. Humic acids are used in farming to improve soil structure, increase water retention, promote seed germination, and improve yields. Lignin sulfonate is used as a flotation device for cleaning fresh fruits.

The United States also continues to express concern that Japan does not allow the use of the Japan Agriculture Standard (JAS) organic logo in conjunction with U.S. logos. In addition, Japan does not allow USDA certified products to affix the JAS logo in the United States, unless the certifier is JAS accredited. The product must instead be imported into Japan by a JAS accredited importer who then affixes the required JAS organic logo. The cost of doing this in Japan adds additional cost to the product. This topic is being discussed in the equivalency negotiations.

The United States will continue to work closely with Japan to address these concerns through the negotiation process and hopes to improve access to Japan's market for U.S. organic products.

Kenya

Bilateral Engagement

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

Alcoholic Beverages – Labeling Requirement

As noted in the *2012 TBT Report*, Kenya previously notified in 2011 labeling requirements, the “Alcoholic Drinks Control (Licensing) Regulations,” for alcoholic beverages. The requirements, which are presently suspended because of domestic litigation, could prove onerous to U.S. exporters if they go into effect. For example, one of the requirements is that a warning message comprise at least 30 percent of the package's surface area.

In December 2012, Kenya notified to the WTO proposed revisions to the measure. The revisions appear to make some positive changes, such as removing the restriction that foreign broadcasts and publications cannot promote alcoholic beverages, however, the revision still requires that a warning message appear on the package although there is uncertainty as to its required size. In January 2013, the United States requested clarification on the size of the warning label and stated that the requirement to change the warning statement every 100 bottles appears to be overly restrictive and burdensome.

The United States will continue to closely monitor this issue in 2013.

Korea

Bilateral Engagement

Korea and the United States regularly discuss TBT issues through bilateral consultations. The consultations serve as an important forum for discussing and resolving these issues and are augmented by a broad range of senior-level policy discussions. In June 2012, the United States and Korea held bilateral trade consultations leading to the resolution of a number of TBT issues, such as avoiding duplicative electrical safety testing and the adoption of the latest international standard for electronic devices and providing a one-year grace period for new cosmetic labeling regulations to allow industry time to adjust. In addition, the United States raises TBT issues with Korea during and on the margins of TBT Committee meetings. Opportunities for bilateral engagement on TBT issues will continue to increase through the work of the TBT Committee and an Automotive Working Group, established under the United States – Korea Free Trade Agreement, which entered into force on March 15, 2012.

Cosmetics – Labeling

In August 2012, the National Assembly proposed legislation that would require labeling for all packaging of all cosmetics products despite existing exemptions for small packages under 10 ml

or grams. U.S. companies will potentially encounter a considerable financial burden if the bill is enacted into law. Consequently, the United States will continue to monitor this issue in 2013.

Chemicals – Act on the Registration and Evaluation of Chemicals (REACH)

In February 2011, Korea’s Ministry of Environment (MOE) released a draft “Act on the Registration and Evaluation of Chemicals (REACH)” to the National Assembly. As announced, Korea REACH would create a complex registration system for chemical products, perhaps as early as 2014. U.S. industry submitted comments to MOE on Korea’s proposal, and the United States raised this issue with Korea bilaterally and in the TBT Committee in June and November 2011.

In 2012, Embassy Seoul monitored the draft Act and continued to discuss concerns about the burden and lack of clarity of Korea’s proposed Act, in particular the draft law’s proposed *de minimis* level of 0.5 tons (rather than the EU REACH one ton) and duplicative reporting requirements. Many of these concerns, including the *de minimis* level and reporting requirements, were addressed in the version of the Act that MOE submitted to the National Assembly in September 2012. The Act has not been approved by the National Assembly, and the legislature continues to work with the MOE to refine the legislation; it is unclear whether areas in which MOE reflected industry comments will all be maintained in the final law. The United States seeks to ensure that Korea’s final requirements are not unnecessarily trade-restrictive.

In 2013, the United States will continue to monitor developments related to the proposed registration system and urge Korea to take U.S. industry’s comments into account.

Organic Products – Requirements and Conformity Assessment Issues

Korea’s Act on Promotion of Eco-Friendly Agriculture and Management of Organic Products (the “Organic Products Act”) becomes effective on May 29, 2013. The Organic Products Act clarifies requirements previously adopted in 2008 for organic certification and labeling that mandate certification of processed organic products by a certifier accredited by the Ministry of Food, Agriculture, Fisheries, and Forestry (MIFAFF). Under the new requirements, U.S. organic products would need to be re-certified to maintain their organic labeling. Many U.S. producers and certifiers are reluctant to seek product re-certification due to the difficulty of ensuring that individual ingredients also meet certification requirements. However, the Organic Products Act permits the conclusion of equivalence agreements, which might alleviate burdens on U.S. products. Nevertheless, the Organic Products Act does not permit equivalence agreements to go into effect until January 2014. The United States, Canada, Australia, New Zealand, and the European Union requested Korea to suspend its new certification and labeling requirements until equivalence agreements can be concluded. On November 13, 2012, Korea agreed to this request and will permit foreign organic products to be labeled as organic in Korea without MIFAFF-accredited certification. The United States seek to initiate discussions negotiations with Korea on an equivalency agreement in 2013 with the view to concluding an arrangement that will facilitate exports of U.S. organic products.

Information Technology Equipment – Electrical Safety Regulations

U.S. industry has been working closely with KATS and the Radio Research Agency on the re-

organization of safety regulations for information technology equipment. The United States has advocated for streamlined procedures that reflect the realities of contemporary manufacturing and would provide an appropriate level of safety certification for low-risk information technology equipment, such as printers and computers. KATS amended its regulations in July 2012, addressing many of the U.S. concerns, such as expanding the scope of products subject to a supplier's declaration of conformity, and adopting the most current IEC standard. However, some concerns remain unaddressed. For example, the regulation does not allow for safety certifications to be made by a single multinational enterprise for all identical products; rather, the regulation requires separate certification with respect to each factory's products. Currently, there is also no certificate renewal process. Furthermore, despite being a member of the IECEE CB scheme, KATS is not currently accepting CB reports without additional testing.

We will continue to raise this issue with Korea in 2013.

Solar Panels – Testing Requirements

Korea requires solar panels to be certified by the Korea Management Energy Corporation (KEMCO) before they can be sold in Korea in projects receiving government support (which means in practice the vast majority of sales). KEMCO's certification standards prevent certain types of thin-film solar panels manufactured by U.S. industry from entering the Korean marketplace. For example, KEMCO has established a standard for thin film solar panels that can only be satisfied by panels manufactured from amorphous silicon. As a result, other leading types of thin film solar panels made by U.S. firms, including Cadmium Telluride (CdTe) and Copper Indium (di) Selenide (CIS), cannot be tested or certified under the Korean standard and thus remain shut out of most of Korea's market. The United States urged Korea at the 2012 bilateral trade consultations and at TBT Committee meetings to adopt the relevant international standard, IEC 61646, without limiting its application solely to the type of thin-film solar panel its industry produces. If Korea did so, it would both facilitate trade and afford Korean consumers access to the best available technologies.

In response to U.S. concerns, Korea conducted an environmental impact review on the use of cadmium in solar panels, and determined that a hazard existed for using CdTe, while the hazard of CIS was relatively small. Korea has said it will consider developing a new certification standard for CIS based on the results of that study. U.S. industry has raised methodological concerns with the studies Korea used to disqualify CdTe. The United States will continue to raise this issue with Korea in 2013.

Motor Vehicle Parts - Safety Standards and Certification

In August 2011, Korea published draft regulations for comment, which mandated that specified replacement motor vehicle parts comply with Korea Motor Vehicle Safety Standards (KMOVSS) and established a self-certification system for indicating compliance with the safety standards. The final regulation, promulgated in December 2011, reflected some of the comments submitted by the foreign automotive industry but did not reflect important requests related to the acceptance of parts certified to non-Korean standards. In April 2012, Korea published draft administrative guidelines, which contained implementation details for the new system and which raised additional concerns related to the allowable methods for marking the parts. The United States worked closely with Korea over several months on these proposed measures and U.S. concerns regarding use of non-KMOVSS standards for parts and allowable methods for

marking parts were resolved.

In 2013, we will continue to monitor the implementation of these measures.

Cellular Phones – Specific Absorption Rate (SAR) Labeling

In October 2012, Korea published and notified draft technical regulations that would establish two labeling categories for SAR levels (absorption of electromagnetic radiation) for mobile phones. Korea allows phones with a SAR level of 1.6 W/kg or less to be marketed in Korea. The proposed regulation, however, would establish two tiers within the allowable range: phones with a SAR of 0.8 W/kg or less would be labeled as “Level 1,” while phones with a SAR between 0.8 and 1.6 W/kg would be labeled “Level 2.” U.S. industry has submitted comments on the regulation raising concerns that there is no clear rationale or scientific basis for distinguishing between phones that meet the relevant safety regulation, and that the label could mislead, rather than inform, consumers by suggesting that there is a safety difference between the two categories. The United States has raised this concern with Korea in bilateral consultations and we will continue to do so 2013.

Malaysia

Bilateral Engagement

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

Meat and Poultry Products – Halal Standards

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

In January 2011, Malaysia implemented a food product standard – MS1500: 2009 – that sets out general guidelines on *halal* food production, preparation, handling, and storage. MS1500: 2009 creates standards that go well beyond the internationally recognized *halal* standards, which are contained in the Codex Alimentarius. Specifically, the guidelines require slaughter plants to maintain dedicated *halal* production facilities and ensure segregated storage and transportation facilities for *halal* and non-*halal* products. In contrast, the Codex allows for *halal* food to be prepared, processed, transported, or stored using facilities that have been previously used for non-*halal* foods, provided that Islamic cleaning procedures have been observed.

In April 2011, Malaysia notified to the WTO its “Draft Malaysian Protocol for the Halal Meat and Poultry Productions.” The protocol provides additional information and guidance on complying with MS 1500: 2009. In May 2011, the United States provided comments on the protocol and subsequently raised concerns regarding the protocol during the June and November 2011 TBT Committee meetings. Following that, Malaysia scheduled mandatory audits for establishments seeking to export to Malaysia. These audits took place in September 2012. The

United States recently received notice from Malaysian officials that only one U.S. establishment passed the audit. All the other establishments failed the audits and are accordingly prohibited from exporting to Malaysia.

Additionally, in early 2012, Malaysia changed its pet food requirements such that porcine ingredients are now banned from food for cats, which many Malaysians keep as pets. Malaysia did not notify this change to the WTO, nor has Malaysia produced satisfactory justification for this prohibition, other than to indicate it will help consumers avoid purchasing products with porcine (i.e. non-*halal*) ingredients. Malaysia has not begun to enforce these requirements yet. The United States has suggested that Malaysia's objectives could also be achieved through alternative measures such as labeling.

The United States will continue to pursue all *halal* related concerns with Malaysia in 2013.

Mexico

Bilateral Engagement

The United States discusses TBT matters with Mexico during TBT Committee meetings and on the margins of these meetings. The United States and Mexico also engage on standards and regulatory issues in the NAFTA Committee on Standards-Related Measures, which met in February and October of 2012, and as part of the United States – Mexico High-Level Regulatory Cooperation Council, which was established in 2010, and issued a Work Plan in February 2012.

Energy Efficiency Labeling

In September 2010, Mexico's Secretariat of Energy published the "Catalogue of equipment and appliances used by manufacturers, importers, distributors and marketers that require mandatory inclusion of energy consumption information." The Catalogue was notified to the TBT Committee in June 2011 and imposes labeling obligations for manufacturers, importers, distributors, and marketers of those products. The labels to be placed on the products must contain information regarding the product's energy efficiency and confirming that the product meets certain testing requirements. U.S. industry has raised concerns that the scope of the products subject to the catalog's labeling requirements remains unclear. Accordingly, U.S. industry has requested that Mexico delay implementing the catalog until those issues are resolved. The United States raised these concerns with Mexico both bilaterally and in the June and November 2011 TBT Committee meetings. Furthermore, in 2012, the U.S. and Mexican governments met on numerous occasions to discuss how to better align the two countries' energy consumption labeling regulations and energy efficiency policies.

Although the catalog entered into force in September 2011, it has not been enforced. Mexico did engage with U.S. industry to clarify the catalog's requirements. However, the United States will seek to identify product categories that can be removed from the catalog due to their *de minimis* energy consumption. The United States will continue to engage Mexico on this issue in 2013.

Sanitation Pipes – Standards

As noted in prior *TBT Reports*, the United States is concerned that Mexico's National Water

Commission (NWC) has not recertified U.S. producers of certain plastic pipe for waste water systems, drinking water systems, and domestic service connections, under the Mexican standard applicable at the time (NOM-001-CONAGUA-1995).⁴⁷ According to industry, NWC has instead sought to enforce an obsolete ISO standard on high density polyethylene (HDPE) plastic pipe, that is not incorporated into the Mexican standard and that relies on design and descriptive characteristics, rather than performance abilities. Furthermore, although both HDPE pipe and polyvinyl chloride (PVC) pipe – a competing product – cannot satisfy the design characteristics of the this ISO standard, NWC appears to only be enforcing this standard on HDPE pipe and not PVC pipe, the latter of which is manufactured predominantly by the domestic industry. Industry reports that HDPE pipe meets the standard contained in NOM-001-CONAGUA-199, as well as relevant performance characteristics as described in other, more up-to-date, state-of-the-art international standards.

The United States has raised this issue with Mexico both bilaterally and in the TBT Committee, and continues to request that Mexico ensure that the standards NWC adopts are applied on a non-discriminatory basis, are science-based, and are developed through transparent processes as required by the TBT Agreement. Additionally, the United States has encouraged Mexico to apply the Mexican standard as written. On February 17, 2012, CONAGUA released an amended mandatory standard, NOM-001-CONAGUA-2011, which authorizes acceptance and use of standards that are utilized in the markets of Mexico’s trading partners, including the United States. Under this standard, U.S. pipe manufacturers, therefore, appear entitled to recertification under standards utilized in the United States, including ASTM International standards F2764, F2736, and F2947. However, despite accepting U.S. HDPE manufacturers’ requests for recertification and the completion of relevant testing, in February 2013, NWC stated that it still cannot recertify HDPE plastic pipe because NWC has been unable to confirm that ASTM International is an internationally recognized standard setting body, notwithstanding that the amended mandatory standard does not appear to limit the standards for recertification to only those produced by internationally recognized standards setting bodies and that ASTM International is generally recognized as an internationally recognized standard setting body.

Medical Device – Equivalency

In October 2010, Mexico published an executive order related to article 194B of the General Health Law that would streamline conformity assessment procedures for shipments of medical devices and certain over-the-counter (OTC) drugs from the United States. Under these rules, any producer or importer of medical devices or equipment can obtain a sanitary registration within 35 days, provided that U.S. regulators have approved the product for sale. The Mexican regulator, Federal Commission for Protection Against Sanitary Risks (“COFEPRIS”) has had difficulties in implementing this process and has been working with industry to improve implementation. While some progress has been observed, numerous U.S. companies continue to complain about excessive wait times of one to two years for sanitary registration approval.

⁴⁷ Mexico has since amended NOM-001 several times. The most recent amendment, NOM-001-CONAGUA-2011, was notified to the WTO in February 2012.

In October 2012, COFEPRIS announced the implementation of an agreement that will expedite the registration in Mexico of new pharmaceutical products already reviewed and approved by regulatory agencies in the United States, Australia, Canada, Switzerland and the EU. According to COFEPRIS, the agreement will promote public health in Mexico by giving Mexican consumers access to innovative pharmaceutical products approved for sale in the United States and elsewhere. In addition, COFEPRIS asserts that agreement will reduce from 360 days to 60 days the approval time for certain drugs.

The United States will continue to monitor the implementation of the Agreement in 2013.

Vitamin Supplements – GMP Certification

In August 2008, Mexico issued an administrative decree amending articles 168 and 170 of the Regulation for Health Supplies, which required Good Manufacturing Practices (GMP) certification by Mexican certifiers for foreign companies that sought to sell pharmaceutical and nutritional supplements in Mexico. GMPs are production and testing practices meant to ensure the quality level of a product. In January 2010, U.S. officials requested that Mexico clarify its compliance requirements for vitamin supplements and other products marketed as nutritional supplements in the United States. Because the FDA does not issue export certificates to confirm compliance with GMPs for supplements, the United States has asked whether COFEPRIS would accept either a manufacturer's self-declaration of GMP compliance or a GMP certificate issued by a third-party certifier. COFEPRIS has indicated it allows third party certification by COFEPRIS authorized certifiers or local/state authorities.⁴⁸ The United States will continue to ask COFEPRIS to consider third-party certification by non-COFEPRIS authorized certifiers or perhaps conducting manufacturing facility inspections in the United States.

Russian Federation

The Russian Federation is a Party to the Russia-Kazakhstan-Belarus Customs Union (CU) as well as the Eurasian Economic Community (EurAsEC). Technical regulations, standards, and conformity assessments systems in Russia are governed by the CU's Eurasian Economic Commission, as well as at the national level. The CU Parties as well as the Members of EurAsEC have agreed to harmonize their policies and regulatory systems in the TBT arena.

On August 22, 2012, Russia became the 156th Member of the WTO. Russia's entry into the WTO brought the largest market outside of the WTO into the global trading regime's rules-based organization. Russia pledged to liberalize its trade regime to create an open and level playing field, thereby increasing its transparency and predictability.

In 2012, the United States commented on the Ministry of Economic Development's Decree on determining the criteria for notifying technical regulations and establishment of its WTO TBT Inquiry Point. In 2013, the United States will continue to emphasize the importance of timely notifications of draft technical regulations to the WTO, to ensure the availability of reasonable comment periods on draft regulations and reasonable implementation periods for final regulations, as well as a clear point of contact for each notification.

⁴⁸ State health departments in the United States do not issue GMP certificates for supplements.

Russia made its first two WTO TBT notifications on December 21, 2012. The first notification, by the Ministry of Industry and Trade, was “Amendments to the Technical Regulation of the Customs Union on Safety of Wheeled Vehicles,” and the second was the “EurAsEC Technical Regulation on Alcohol Product Safety”. The latter was notified only after a specific request by WTO Members, and did not provide a comment period. The United States will continue to urge Russia to be forthcoming in making its notifications to the WTO Secretariat for both technical regulations and amendments.

Bilateral Engagement

The United States will work with Russia in the TBT Committee and bilaterally through the Business Development and Economic Relations Working Group (BDERWG) established under the United States – Russia Bilateral Presidential Commission. The BDERWG provides a forum for the United States and Russia to discuss, *inter alia*, standards-related regulatory cooperation. In 2013, the United States and Russia will look to increased engagement, as a matter of priority, in the area of standards and conformity, launching programs to understand better each other’s standards and regulatory structures, find areas for increased cooperation, and eliminate unnecessary obstacles to trade.

Food – Labeling Requirements

In October 2012 the Eurasian Economic Commission (EEC) of the CU published a revision to the “Technical Regulations on Food Products Labeling.” The revision imposes numerous labeling requirements, including with respect to nutritional components, allergens, and GE foods. In addition, the revision requires that products containing sweeteners must carry a warning statement that overuse will cause digestive problems, and those products with food coloring must declare that it affects children’s ability to concentrate. This revision was not notified to the WTO. While implementation of these rules is scheduled for July 1, 2013, the EEC will allow products labeled under the previous regulations to circulate in the market until February 15, 2015. The United States sent comments to the EEC in December 2012. The comments expressed concern that the revised regulations require labeling for GE products and nutritional components beyond the recommended guidelines established in the Codex General Standard for Food Labeling. Additionally, the United States noted that the requirements for labeling of allergens in food are unclear. These claims are not based on the latest scientific research nor do they appear consistent with the Codex. The United States has not received a response to its December 2012 comments. In 2013, the United States will continue to engage the EEC in 2013 to resolve outstanding concerns.

Alcoholic Beverages – “Strip Stamps”

As noted in last year’s *TBT Report*, Russia levies excise taxes on alcohol and enforces these taxes through a system that requires alcohol beverage containers to bear an excise “strip stamp” label. Over the last year U.S. industry has reported some positive improvements with respect to Russia’s strip stamp requirements, including advanced notice and comment of requirements and a more effective transition from the use of old stamps to new stamps with an adequate grace period and functioning electronic registration.

Alcoholic Beverages – Conformity Assessment Procedures, Standards, and Labeling

The EEC revised its “Technical Regulation on Alcoholic Product Safety” in November 2012, and included some positive changes, including removing a requirement mandating the aging of rums and reducing the size of the warning statement to allow for other consumer and branding information on containers.

However, the United States still has significant concerns with the EEC draft “Technical Regulation on Alcoholic Product Safety” which is proposed to enter into force in July 2013. Most notably, the proposed measure would impose duplicative conformity assessment procedures, administered by at least three different government authorities, all of which appear to have the same objective of data registration. Specifically the proposed requirements call for a new alcohol beverage notification procedure to be administered in Russia by the Federal Service for the Regulation of the Alcohol Market. U.S. industry is concerned that the multiple conformity assessment procedures administered by different agencies add an unnecessary level of complexity leading to increased costs and time delay. Furthermore, the United States is aware that Russia, outside of the work of the EEC, has passed a law (Amendment SF171) which contains another similar notification procedure for alcoholic beverages. It is scheduled to go into effect on March 1, 2013. The United States has requested that Russia postpone implementation of SF171.

The EEC “Technical Regulation on Alcoholic Product Safety”, also introduces burdensome and unique requirements to label all alcoholic beverages, with an expiration date, or include a label indicating that “the expiry date is unlimited if the storage conditions are observed.” U.S. industry notes that the proposed requirement does not provide accurate or beneficial information for products containing more than 10 percent alcohol, because these products do not expire. Furthermore, the proposed expiration date requirement appears inconsistent with international guidelines – particularly with Article 4.71(vi) of the Codex General Standard for the Labeling of Prepackaged Foods, which exempts beverages containing 10 percent or more by volume of alcohol from such date-marking requirements. The United States will encourage Russia to eliminate this requirement for alcoholic beverages containing more than 10 percent alcohol by volume, and urge Russia to adopt international standards or guidelines.

The proposed technical regulation gives rise to other issues that could affect U.S. exports of alcoholic beverages, including unclear definitions for wine and wine beverages and a requirement that whiskey be aged no less than three years. In February 2013, the United States provided comments to the EEC and will continue to work with Russia on this matter.

Alcoholic Beverages - Warehousing Requirements

The United States has been engaged with Russia on its storage requirements for alcoholic beverages. Those storage requirements are set forth in Regulation Order #59n. As a result of bilateral discussions that took place in 2011, Russia issued a revised regulation in 2012, which offered some improvements, such as the removal of the requirement that pallets be 15 mm high from the floor. However, outstanding issues remain. For example, the United States seeks clarification regarding the specificity of warehouse construction requirements, the stringency of warehouse inspections, and temperature controls, which appear to exceed international standards. The United States provided comments to Russia in August 2012. As of February 2013, the United States has yet to receive a response. The United States also raised concerns in

the WTO about the revised requirements with Russia during the November 2012 TBT Committee, and urged Russia to provide timely and transparent inspections, because distilled spirits manufacturers continue to experience costly delays awaiting inspection approvals.

South Africa

Bilateral Engagement

The United States and South Africa discuss TBT matters during TBT Committee meetings, bilaterally on the margins of these meetings, and under the United States – South Africa Trade and Investment Framework Agreement. USDA and the South African Department of Agriculture, Forestry and Fisheries (DAFF) discuss TBT matters through their annual bilateral forum in Pretoria, South Africa.

Liqueurs – Alcohol Content Restrictions

In 2009, U.S. industry expressed concerns about South Africa’s classification of alcoholic beverages. Alcoholic products cannot be sold in South Africa unless they fall within a designated classification, which is determined in part by alcohol content. South Africa classifies “liqueurs” as beverages having a minimum alcohol content of 24 percent and classifies “spirit coolers” as beverages having 15 percent or less alcohol by volume (ABV). South Africa does not maintain any classification for spirit-based alcoholic beverages with an alcohol content of between 15-24 percent, with the exception of products that fall into the “Cream Liqueur” classification, namely spirit-based alcoholic beverages that contain a dairy product, or “Cocktail/Aperitif” classification, beverages based on herbs or other flavorings of vegetable origin that differ from wine with alcohol volume content between 15 and 23 percent by volume. As a result, any U.S. products that fall in the gap between the “liqueur” and “spirit cooler” classifications, and outside the Cream Liqueur or Cocktail/Aperitif classification, cannot be sold in South Africa.

Not only have these requirements kept certain U.S. products out of the market, but industry has reported that South Africa may not be applying its requirements equally to domestic and imported products. In particular, U.S. importers have reported that South Africa granted at least one exception to a domestic product containing 15-23 percent alcohol level by volume.

During 2013, the United States will continue to raise concerns regarding South Africa’s alcoholic beverage standards and, if appropriate, will urge South Africa to eliminate or modify its “liqueur” definition, or seek another solution that facilitates trade, such as an exemption, so that U.S. alcoholic beverage producers can sell their products in South Africa.

Taiwan

Bilateral Engagement

The United States discusses TBT matters with Taiwan during TBT Committee meetings and bilaterally on the margins of these meetings as well as under the auspices of the United States – Taiwan Trade and Investment Framework Agreement (TIFA).

Ceiling Panels – Requirements for Incombustibility Testing Methods

As discussed in the 2012 TBT Report, U.S. companies that manufacture finished interior building materials, such as ceiling panels and wood paneling, continue to raise concerns regarding the testing method that Taiwan mandates for determining whether those materials meet applicable incombustibility requirements. According to U.S. industry, Taiwan's present measure gives U.S. ceiling tiles a lower incombustibility rating than is otherwise warranted. In some instances, U.S. ceiling tiles unreasonably fail the test altogether. The reason the testing is problematic according to U.S. industry is that Taiwan's measure applies a variation of the ISO 5660 standard for Reaction to Fire Tests - Heat Release, Smoke Production and Mass Loss Rate, which at the time was not complete; however, U.S. industry notes that a recent revision of the ISO standard incorporated additional guidelines that will ensure better and more reliable incombustibility ratings and should therefore be adopted by the Taiwan authorities as soon as possible. In October 2012, USTR urged Taiwan to adopt the ISO committee's revised standard. USTR continues to monitor Taiwan's process in adopting a standard mirroring the revised ISO 5660 (released in January 2013 as ISO 5660-3).

Commodity Goods – Labeling Requirements

As discussed in the 2012 report, the United States raised concerns that Taiwan requires all "commodity goods" (consumer goods) to be labeled with the manufacturer's or producer's name, telephone number, and address. In addition to concerns over protecting proprietary information under the requirements of such labeling, industry notes that some commodity goods are produced by several different manufacturers and product labels may not be large enough to contain all of the required information. This measure imposes costs for firms, including the cost of developing unique labeling requirements for the Taiwan market.

U.S. officials have raised these concerns with Taiwan's representatives, including on the margins of the TBT Committee meetings as well in staff-level meetings under the TIFA. We will continue to monitor this issue in 2013.

Product Multipacks – Labeling Requirements

U.S. industry has raised concerns over a reinterpretation by Taiwan's Ministry of Economic Affairs (MOEA) of its "Commodity Inspection Act" and "Commodity Labeling Act" in 2006 to require all units included in a retail multipack to be labeled for individual sale, even if the retailer will not divide up the multipack for sale as single units. U.S. suppliers have asserted that this requirement imposes unnecessary additional costs as it forces them to add additional labels on their products to continue exporting to Taiwan.

U.S. officials raised this issue with their Taiwan counterparts during TBT Committee meetings and most recently in an October 2012 TIFA working-level meeting. Taiwanese officials responded that Taiwanese consumers typically purchase bulk items such as socks in individual units rather than multipacks and therefore that individual units included in multipacks must be labeled to avoid the risk of fraudulent country of origin labeling. U.S. officials requested that Taiwan notify the WTO of its revised labeling rules to provide an opportunity for WTO Members to submit comment. MOEA has yet to do so.

Turkey

Bilateral Engagement

The United States discusses TBT matters with Turkey during, and on the margins of, TBT Committee meetings, in meetings of the Council established under the United States – Turkey Trade and Investment Framework Agreement (TIFA), in United States – Turkey Economic Partnership Commission (EPC) talks, and in the bilateral cabinet-level Framework for Strategic Economic and Commercial Cooperation (FSECC). The FSECC is designed to reinforce the work of the EPC and TIFA and provide political-level guidance on particularly challenging commercial and economic issues.

Pharmaceuticals – GMP Decree

In late 2009, Turkey’s Ministry of Health issued a “Regulation to Amend the Regulation on the Pricing of Medicinal Products for Human Use,” which took effect on March 1, 2010. The regulation requires foreign pharmaceutical producers to secure a Good Manufacturing Practice (GMP) certificate based on a manufacturing plant inspection by Turkish Ministry of Health (MOH) officials, before their products can be authorized for sale in Turkey.

The United States, although it does not oppose MOH inspection requirements for pharmaceutical manufacturing facilities, has concerns with respect to this measure. Specifically, the United States is concerned that Turkey did not publish or notify this regulation to the WTO. In addition, the United States is concerned that Turkey no longer accepts U.S. FDA’s GMP certifications, and that pharmaceutical producers face significant delays in meeting the inspection requirements because of the MOH’s extensive backlog of GMP inspections. In the February 2013 bilateral Trade and Investment Framework Agreement meeting, Turkey stated that it would consider amending its regulatory practices in order to allow MOH’s review of the pharmaceutical product dossier to take place concurrently with the pharmaceutical producer’s process of obtaining GMP certification.

While we still need to monitor progress in 2013, this is potentially a significantly positive step, which the United States encouraged using various engagement opportunities in 2012.

Food and Feed Products – Mandatory Biotechnology Labeling

In 2009, Turkey’s Ministry of Agriculture published a regulation governing biotechnology in food and feed. The measure was not publicly announced or notified to the WTO in advance of entry into force, and contained no phase-in period. Turkey has since published several amendments to the regulation and later superseded this regulation with the enactment of the “Biosafety Law,” which was notified to the WTO. This Law became effective in September 2010 and mandates the labeling of ingredients derived from biotechnology in all food and feed if the biotechnology content exceeds a certain threshold, a requirement that impedes U.S. food and feed exports to Turkey. In addition, Turkey’s Biosafety Law goes beyond mandatory method-of-production labeling, which refers to the mandatory labeling that a product or ingredient in a product was produced using biotechnology. The labeling requires that “GMO” labels on food should contain health warnings if the biotechnology food differs from the non-biotechnology food.

This labeling requirement raises additional concerns because it appears to presume, incorrectly, that food containing biotechnology products is inherently more risky from a health perspective than its non-biotechnology food counterpart. Consequently, such health warnings could unnecessarily cause public alarm while providing no additional public health protection. For example, changes in edible 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 food safety.

In addition to the labeling requirement, the Biosafety Law mandates strict traceability for all movement of biotechnology feed and includes onerous requirements for each handler to maintain traceability records for 20 years. The United States has engaged bilaterally with Turkey in the margins of the TBT Committee meetings on issues related to Turkey's Biosafety Law. The United States will continue bilateral talks on these issues with Turkey in 2013.

Vietnam

Bilateral Engagement

The United States discusses standards-related issue with Vietnam during TBT Committee meetings and on the margins of TPP negotiations, as well as through the bilateral United States – Vietnam TIFA Council meetings. The United States also works with Vietnam in advancing standards and conformity assessment issues through ASEAN and APEC.

Food Safety Law – Registration Requirements for Processed Foods

The United States has concerns regarding Decree 38, the implementing regulation for Vietnam's Food Safety Law, which was signed into law in June 2012. The measure was notified to the SPS Committee in March 2011, and was notified to the TBT Committee in December 2012. Under the measure, exporting manufacturers of prepackaged processed foods, food additives and food packaging materials must complete numerous forms and certificates to obtain affirmations of the product's conformity to Vietnamese laws and regulations. Products without these conformity assessments may not be exported to Vietnam.

Although the implementation date for Decree 38 was June 11, 2012, implementation has been gradual as the various ministries involved sort out their responsibilities and enforcement activities. The United States, along with other WTO Members, has requested that enforcement of the Decree, as well as any subsequent implementing regulations, be delayed until the specific concerns of the United States and other trading partners can be fully addressed.

At the June 2012 TBT meeting, the United States raised concerns about Decree 38 with support from Australia, the EU, New Zealand, Canada, and Chile, and also submitted extensive written comments and technical questions to Vietnam at that time. The United States continued to raise concerns with Vietnam over Decree 38 throughout 2012, both at the November 2012 TBT meeting and in Hanoi.

The United States will continue to monitor the issue and raise concerns with Vietnam in 2013.

XII. Appendix A: List of Commenters

1. Almond Board of California
2. American Potato Trade Alliance
3. American Soy Bean Association
4. California Table Grape Commission
5. Distilled Spirits Council of the United States
6. Grocery Manufacturers of America
7. Herbalife
8. National Confectioners Association
9. National Potato Council
10. North American Export Grain Association
11. Royal Thai Government
12. Toy Industry Association
13. Underwriters Laboratories
14. U.S. Dairy Export Council & National Milk Producers Federation
15. U.S. Wheat Associates
16. Yum! Restaurants International

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

ANSI	American National Standards Institute
APA	Administrative Procedure Act of 1946
APEC	Asia Pacific Economic Cooperation
EU	European Union
FSCF	Food Safety Cooperation Forum
FSCF PTIN	Food Safety Cooperation Forum's Partnership Training Institute Network
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
MRA	Mutual Recognition Agreement
NAFTA	North American Free Trade Agreement
NAMA	Non-Agricultural Market Access
NEI	National Export Initiative
NIST	National Institute of Standards and Technology
NTTAA	National Technology Transfer and Advancement Act
NTB	Non-Tariff Barrier
NTE	National Trade Estimate Report on Foreign Trade Barriers
OECD	Organization for Economic Cooperation and Development
OMB	Office of Management and Budget
SCSC	Subcommittee on Standards and Conformance
SDO	Standards Developing Organization
SME	Small and Medium Size Enterprise
SPS	Sanitary and Phytosanitary Measures
TAA	Trade Agreements Act of 1979

TBT	Technical Barriers to Trade
TEC	United States – European Union Transatlantic Economic Council
TFTF	Trade Facilitation Task Force
TIFA	Trade and Investment Framework Agreement
TPP	Trans-Pacific Partnership
TPSC	Trade Policy Staff Committee
USDA	U.S. Department of Agriculture
USITC	U.S. International Trade Commission
USTR	Office of the United States Trade Representative
WTO	World Trade Organization

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

2013 Report on Technical Barriers to Trade

United States Trade Representative

Summary Notes

**Compiled by Lock Kiermaier, Staff
Citizen Trade Policy Commission
October 2013**

Foreward (page 1)

- This is the 4th year in which this report has been published by USTR in response to concerns from US companies, farmers, ranchers and manufacturers in response to non-tariff trade barriers such as product standards, testing requirements and other technical requirements;
- Non-tariff trade barriers are also known as Technical Barriers to Trade (TBTs);
- TBTs are problematic for small and medium enterprises (SMEs); and
- USTR is committed to removing unnecessary TBTs through the negotiations for the TPPA and TTIP;

Executive Summary (page 3)

- Standards based measures are important to facilitating international trade and are necessary to protecting public health, the environment and preventing deceptive practices;
- But when standard based measures are unreasonable, discriminatory or lacking in transparency, they are referred to as TBTs;

Introduction (page 5)

- The Obama administration has reaffirmed its support for a transparent, rules-based approach to international trade and in doing so, has focused on the growing prevalence of TBTs as a significant hindrance to international trade;
- In particular, the USTR has focused on two prominent TBTs:
 - Sanitary and phytosanitary (SPS) measures; and
 - Standards-related measures;
- The USTR TBT Report grew out of efforts by the USTR to promote understanding of non-tariff measures that function as TBTs;
- This TBT report is being supplemented by a simultaneous USTR report entitled, “2013 Report on Sanitary and Phytosanitary Measures”;
- Sources of information for this report include solicited stakeholder comments, reports from different US foreign embassies, comments from other federal agencies and consultations with stakeholders and trading partners;
- In 2012, the USTR succeeded in reducing the number of significant TBTs that were identified in the previous TBT Report;

- A basic overview on *Standards-Related Measures* included the following points:
 - Standards-related measures are defined as standards, technical regulations, and conformity assessments which play an important role in the flow of international trade;
 - The use of tariffs has significantly decreased in recent years, only to be replaced, in effect, by TBTs;
 - When carefully conceived, standards-related measures can:
 - Provide reliable standards that manufacturers can use to efficiently produce products for international trade;
 - Facilitate and encourage technological innovation;
 - Encourage the increased confidence of both buyers and sellers; and
 - Assist SMEs in gaining access to global supply chains;
 - On the other hand, poorly conceived standards-related measures can:
 - Reduce competition;
 - Stifle innovation; and
 - Create TBTs
 - A crucial question is how standards-related measures can be crafted that are effective but not so overly restrictive as to become TBTs.

Overview of Trade Obligations and Standards-Related Measures (page 9)

- The current WTO Agreement on Technical Barriers to Trade (TBT Agreement) includes rules to ensure that standards-related measures:
 - serve legitimate objectives;
 - are transparent; and
 - do not function as TBTs;
- Key principles of the TBT Agreement include the following:
 - Trade regulations and standards should be nondiscriminatory;
 - Unnecessary obstacles to trade are to be avoided;
 - Strive for better alignment of technical regulations, standards, and conformity assessment procedures;
 - Make use of performance-based requirements;
 - Develop and implement international systems of conformity assessment;
 - Acceptance of one nation's technical requirements as equivalent;
 - Strive for mutual recognition of conformity assessment;
 - Strive for increased transparency;
 - Provide mutual technical assistance to trading partners;
 - Make use of the WTO Dispute Settlement Body for dispute resolution and enforcement [*Staff Note: the WTO Dispute Settlement Body appears to resolve trade conflicts between nations and make use of a process somewhat similar to ISDRs*];
 - Make use of a "Code of Good Practice" which identifies and applies voluntary standards.
- The number of specific trade concerns raised under the terms of the TBT Agreement has steadily increased from 4 in 1995 to a total of 94 new and previous concerns in 2012;

- All FTAs developed after the TBT Agreement make reference to the TBT Agreement as the fundamental trade approach to handling TBTs; and
- Certain FTAs that the US has agreed to go beyond the requirements of the TBT Agreement; for example, the FTAs in question require that FTA partners will accord the same recognition to US certification bodies as they do to their own certification bodies;

U.S. Statutory and Administrative Framework for Implementing Standards-Related Trade Obligations (page 19)

- The primary legal tools used by the USTR and other federal agencies for implementation of the TBT Agreement and FTAs are:
 - Administrative Procedure Act of 1946 (APA) and
 - Trade Agreements Act of 1979 (TAA);
- The TAA establishes the USTR as the lead agency in the US federal government for coordinating and developing trade policy with regards to standards-related matters;
- The APA ensures transparency in the development of federal regulations pertaining standards-related issues and ensures that notification of such regulations is provided to the WTO;
- Centralized federal review of proposed federal regulations is accomplished by the Office of Management and Budget(OMB) which refers trade related regulations to the USTR for review to ensure conformity with the TBT Agreement and the various FTAs;
- Whenever possible, in the formulation of regulations pertaining to standards-related measures, Federal agencies are encouraged to make use of existing “voluntary consensus standards” as opposed to “government unique standards”;

Standards (page 23)

- The use of voluntary standards largely developed by the private sector is touted as advantageous by the USTR in the following ways;
 - The increased facilitation of buyer-seller transactions;
 - Spurring competition and innovation;
 - Increase the efficiency of production;
 - Unify markets; and
 - Promote societal goals;
- The TBT Agreement requires members to base standards and regulations on relevant international standards, guides and recommendations but does not recognize any specific standardizing entity as “international”;
- As defined by the TBT Agreement, the concept of “international standard” has the following principles:
 - Openness;
 - Transparency;
 - Impartiality and consensus;
 - Relevance and effectiveness;
 - Coherence; and
 - The prospect for further development;

- The USTR applies these principles of international standards to its implementation and enforcement of FTAs.

Conformity Assessment Procedures (page 27)

- TBT Agreement definition of "conformity assessment procedures": "*Any procedure used directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled*";
- Conformity assessment (CA) encourages confidence regarding specific product requirements;
- Costs associated with unnecessary CA are a concern to international trade; and
- Current federal law, the National Technology and Transfer Act (NTTAA), requires the coordination of CA activities between federal, state and local entities with private CA measures with the goal of removing unnecessary duplication;

US Processes for Identifying Standards-Related Trade Barriers and Determining How to Address Them (page 29)

- The USTR heavily scrutinizes any activities that foreign governments use to enact standards-related measures that may result in barriers to US trade and coordinates the various efforts of federal agencies to determine what barriers may have been created.

Engagement in Voluntary Standards Activities (page 31)

- In the U.S., standards development is led by private sector with the significant involvement of the federal government;
- The federal government has 5 fundamental strategic objectives for involvement in standards development:
 1. Produce timely and efficient CAs that are necessary;
 2. Achieve cost-efficient and effective solutions to satisfy policy objectives;
 3. Promote standards that encourage innovation and foster competition;
 4. Enhance US economic growth and ensure non-discrimination;
 5. Facilitate international trade and avoid unnecessary trade barriers.

Overview of US Engagement on Standards-Related Measures (page 33)

- Through the USTR, the U.S. maintains a constant overview of trying to prevent unnecessary barriers to trade and standards-related measures;
- The USTR accomplishes this overview through participation in the WTO TBT Committee and through administering the different provisions of the various FTAs;
- In 2012, the USTR raised an average of 25 TBT concerns at each meeting of the TBT Committee;
- The USTR makes consistent use of a triennial review of the TBT Committee to ensure that systematic issues relating to TBT issues are well understood and current;

- The US Department of Commerce makes use of a Total Economic Engagement program (TEE) to provide technical assistance and a collaborative approach to foster greater regulatory harmonization and convergence;
- The USTR also actively engages in the Asia Pacific Economic Cooperation (APEC) agreement with 21 member nations to reduce economic barriers to trade and to promote good regulatory practices in such areas as energy, green technology, green building practices, information and communication technologies, and food safety;
- The USTR has also used APEC meetings as an opportunity to eliminate TBTs pertaining to emerging green technologies such as smart grids, solar technologies and commercial green buildings. In addition, APEC has been utilized by member nations to address issues around food safety through the development of uniform standards and adherence to international science-based standards;
- The USTR has sought to use the TPPA negotiations to reduce the use of TBTs and unnecessary standards-related measures and plans to use the TTIP negotiations in the same manner;
- President Obama issued an Executive Order in 2012 entitled “Promoting International Regulatory Cooperation” to reduce and eliminate unnecessary TBTs and standards-related measures;
- In the context of the EU and the recently started TTIP negotiations, the EU’s application of standards based measures presents a challenge to the U.S.;
- In anticipation of the TTIP negotiations, the U.S. and the EU formed the U.S. - EU High Level Working Group on Jobs and Growth (HLWG) as a first step to discuss job creation, economic growth and international competitiveness. One of the goals of the HLWG was to investigate ways of reducing and preventing non-tariff barriers. The HLWG ended up issuing a report recommending that the TTIP pursue negotiations on regulatory issues and non-tariff barriers with a focus on:
 - SPS and TBT issues;
 - Regulatory coherence and transparency;
 - Sector-specific outcomes and regulatory cooperation; and
 - Development of a framework for ongoing consideration of regulatory issues.
- The USTR has also been engaging the leaders of Mexico and Canada in the furtherance of regulatory transparency and coordination with a formal agreement which focuses on:
 - Regulatory approach to nanomaterials;
 - Transportation railroad safety;
 - Transportation emissions; and
 - Globally harmonized standards for workplace chemicals.

2012-2013 Trends Regarding Standards-Related Measures (page 45)

- Several nations including Thailand and Chile have recently implemented significant labeling requirements for different food and nutritional products;
- The EU has recently pursued reaching a series of regional agreements regarding the conformity assessment and acceptance of industrial products which include:
 - Machinery;
 - Electrical products;
 - Pressure equipment;

- Medical appliances;
- Gas appliances; and
- Pharmaceuticals.

These regional agreements have caused concern for U.S. manufacturers;

- Several prominent nations, including China and Korea, have pursued the adoption of voluntary measures as trade barriers. The USTR maintains that implementation of these voluntary measures essentially renders them to be mandatory; and
- The issue of mandatory labeling requirements for foods derived from genetic engineering is an issue of serious contention between the U.S. and EU nations. The U.S. approach relies on a science based approach to food labeling and requires that foods that are produced through genetic engineering only be labeled as such when there is material information that would significantly differ from food that is conventionally produced. In contrast, the EU approach has been to require that food produced with genetically engineered ingredients must be labeled as such.

Country Reports (page 49)

This section provides information about specific countries that have made use of TBTs from the USTR's perspective. The countries reviewed include:

- **Argentina** requires that all inks, lacquers, and varnishes used in producing printed materials undergo testing for lead content and that the testing results conform to Argentinean requirements as to maximum allowable lead content. Argentina also has mandatory conformity assessment requirements for electrical and electronic products. In both cases, the USTR maintains that these requirements are excessive and constitute TBTs;
- **Brazil** has instituted a requirement that a Certificate of Good Manufacturing Practices must be obtained before certain medical devices can be sold and used in the country. The USTR maintains that the certification process is excessive and significantly slower than other similar standards used in other countries. Brazil also has a similar type of certification requirement for the sale and use of certain telecommunications equipment;
- **Chile** has in place a series of food labeling requirements that require reporting and labeling of foods that contain excessive amounts of fat, calories, sugar and salt. The USTR questions the effect that this requirement will have on foods imported into Chile as well as wondering how this requirement can be enforced in food that is served in restaurants;
- **China** has instituted a regulation that requires food manufacturers to disclose through labeling, the exact percentages of each food additive used for each particular food product. The USTR maintains that this requirement is excessive and that it unfairly requires the disclosure of competitive proprietary information. China also requires that all products be subject to testing to obtain a safety mark authorized by the Chinese government. The USTR maintains that this requirement is excessive, costly, time consuming and not uniformly applied to Chinese domestic products. The USTR also alleges numerous TBT allegations with respect to information system products, medical

devices, patent requirements, pollution control requirements, and cosmetic labeling requirements;

- **Columbia** currently requires that all distilled spirits products must meet certain standards pertaining to ingredient quality and identity. Columbia is also instituting a requirement that diesel emissions from commercial vehicles must meet certain EU emission standards which are significantly more stringent than US standards;
- According to the USTR, the **EU** has a rather long list of standards, rules and requirement which constitute TBTs. This list includes:
 - Biotechnology labeling requirements;
 - Accreditation rules;
 - Food safety certification and labeling requirements;
 - Chemical safety requirements as embodied in the so-called REACH regulations;
 - Definition and use of descriptive terms used in the production and sale of wine;
 - Aging requirements for distilled spirits products; and
 - Biofuel certification and use requirements;
- **India** has a number of alleged TBTs including cosmetic registration requirements, a ban on the importation of biotech crops, licensing and testing requirements for telecommunications equipment and registration and testing requirements for all toy products sold in India;
- **Indonesia** has also instituted a fair number of alleged TBTs which include labeling requirements for the importation of horticultural products, labeling requirements for all imported processed food products, required licensure for the distribution of foods, supplements, drugs and cosmetics and excessive safety standards and testing requirements for all toys sold in the country;
- **Japan's** standards for organic product requirements are at considerable variance with those of the U.S. In contrast with the U.S., Japan will not certify as organic any products treated with certain forms of alkali. Furthermore, Japan does not allow its organic certification logo to be used in conjunction with U.S. logos;
- **Kenya** has certain labeling requirements for alcoholic beverages which are at odds with the requirements set by the U.S.;
- The USTR maintains that **Korea** has instituted a number of significant TBTs which include:
 - Certain labeling requirements for cosmetics sold in Korea;
 - A detailed set of complex regulations regarding chemical safety;
 - A rigorous process of organic certification which significantly differs from U.S. certification requirements and requires U.S. certified organic products to be recertified under Korea's standards;
 - Some important variations in the process used to regulate and approve the use of information technology equipment;
 - A set of testing requirements for solar panels which require additional testing for products already approved for use in the U.S.;
 - Safety standards and certification of auto parts which requires additional standards for parts already certified elsewhere to non-Korean standards;
 - A two-tier regulation for the use of certain phones which establishes levels of certification that do not exist in countries other than Korea;

- **Malaysia** has recently imposed a couple of regulations which the USTR regards as TBTs. First, Malaysia has a food product standard which requires food products to be approved according to a set of Islamic practices. In addition, Malaysia has banned the importation of cat food that has porcine (pork) ingredients;
- **Mexico** has established a list of requirements or standards that the USTR regards as TBTs. This list includes:
 - The imposition of energy efficiency labeling requirements which exceed those used in the U.S.;
 - The use of a standard for the certification of sanitation pipes which is at variance with worldwide standards;
 - An allegedly lengthy certification process for the use of medical devices; and
 - Some variation in the certification process used to approve vitamin supplements;
- As a relatively new member of the WTO, **Russia** has instituted a number of trade practices which the USTR regards as TBTs:
 - A detailed set of food labeling requirements;
 - The imposition of an excise tax on the sale of alcoholic beverages;
 - An allegedly duplicative set of conformity assessment procedures, standards and labeling requirements for alcoholic beverages sold in Russia; and
 - A nonconforming set of regulations for the warehousing of alcoholic beverages;
- The USTR maintains that **South Africa** has an unfair classification system with regards to the permissible level of alcohol that can be contained in beverages;
- According to the USTR, **Taiwan** has enacted several significant TBTs:
 - The imposition of a combustibility standard for ceiling panels which is at odds with the current U.S. and international norms;
 - A set of labeling requirements for all commodity goods sold in Taiwan; and
 - A further set of commodity labeling requirements pertaining to the individual units contained in retail multipacks;
- **Turkey** has imposed a unique certification process on all pharmaceuticals offered for sale in the country. Turkey has also enacted a mandatory labeling requirement for all food and feed products that have ingredients derived from a biotechnology manufacturing process; and
- **Vietnam** has instituted an allegedly excessive registration process for all processed food products offered for sale in the country.



EUROPEAN COMMISSION

Directorate-General for Trade

Directorate E

Unit E1, Trade relations with the United States and Canada

Brussels, 20 June 2013

	
COUNCIL OF THE EUROPEAN UNION	
Trade Policy Committee	
m.d. :	238/13
source :	Commission
for :	Information
date :	21 - 06 - 2013

LIMITED

NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: Transatlantic Trade and Investment Partnership (TTIP)

ORIGIN: Commission, DG Trade, Unit E1

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OBJECTIVE: *For information*

REMARKS: *Please find attached the following papers that will be sent to the US side ahead of the first round. Additional papers could follow subsequently.*

Initial position papers on: Regulatory Issues - Cross-Cutting Disciplines and Institutional Provisions; Technical Barriers to Trade; Regulatory Cluster: automotive sector, chemicals, pharmaceuticals; Sanitary and Phytosanitary issues (SPS); Trade and Sustainable Development; Anti-Trust & Mergers, Government Influence and Subsidies; Trade and Investment in Raw Materials and Energy.

Non-paper on: Public Procurement

* * *

Initial position paper

Limited

Without prejudice, 20 June 2013

Subject: TTIP; regulatory cluster; initial position papers for discussion at the first round

Please find enclosed in the annex three distinct sectoral initial position papers on the automotive sector, on chemicals and on pharmaceuticals, which we suggest to discuss at the first negotiating round, in addition to the ones on cross-cutting disciplines and TBT. These sectoral papers contain the Commission's initial reflections on a number of joint submissions received from stakeholders on both sides of the Atlantic in response to the public consultations on TTIP.

The Commission is still in the process of analysing these submissions and preserves the right to present, ahead of the next negotiating round, additional initial position papers in other goods and services' sectors, including in areas where there are no (joint) submissions.

Please note that the regulatory component of TTIP is meant to cover both goods and services. Regulatory issues pertaining to the financial services sector will be discussed within the services' cluster but this is without prejudice as to where the provisions covering these issues will ultimately be placed in the agreement.

Annex I

Initial position paper Motor vehicles in TTIP

The purpose of this paper is to outline the main elements of a possible approach under the TTIP to promote regulatory compatibility/convergence and recognition in the motor vehicles sector, while achieving the levels of health, safety, and environmental protection that each side deems appropriate. These elements build on the ideas put forward jointly by the motor vehicles and parts and components industries from the EU and the US as well as the need and the duty of regulators to achieve the necessary health, environmental and safety protection levels.

1. Objectives

A high level of ambition in this sector is warranted not only by the expectations of the EU and US industries, but also by the very substantial efficiency gains and cost-savings that would arise from addressing regulatory divergences in addition to eliminating tariffs , without lowering safety, health or environmental protection levels. Furthermore, a joint EU-US approach would create a basis for genuine international leadership on motor vehicle standards and regulations.

Accordingly, the ultimate goal pursued in the TTIP negotiations would be twofold:

- firstly, the recognition of motor vehicles (and their parts and components, including tyres) manufactured in compliance with the technical requirements of one party as complying with the technical requirements of the other. Such an ultimate objective would be pursued in stages: it is expected that substantial results should already be reached at the time the negotiations are concluded (i.e. recognition of equivalence for regulations deemed to have similar test and in-use effects), and that a built-in agenda for further regulatory convergence would be defined with, insofar as possible, concrete timelines.

- secondly, a significant strengthening of EU-US cooperation also in the framework of UNECE 1998 Agreement, especially on new technologies. This process should lead in the near future to the adoption of Global Technical Regulations (with a limited number of options and modules) subsequently incorporated in the national legislations – see built-in agenda below.

2. Methodological approach

EU and US motor vehicle regulations, even though they contain diverging technical requirements, provide for a high level of safety and environmental protection. Overall, there is little doubt that the levels of safety required by both sides are broadly comparable. In fact, some motor vehicles manufactured according to the US specifications can already drive legally in the EU under the individual approval system.

Thus, in principle, the technical divergences between both regulations are not a sufficient reason to stand in the way of recognition of each other's regulations: equivalence of outcome is a more relevant consideration. Methods can be devised to make possible the assessment of equivalence, which would open the way to recognition. Assessing the equivalence of the environmental performance of certain motor vehicle categories may warrant adapted methods.

If the overall level of protection is comparable, the main concept and starting point in such a methodological approach – as proposed by ACEA and AAPC - could consist in a presumption that the regulations of one side should be considered as equivalent (i.e. having the same effect) to those of the other side, unless it can be established that the regulations of the other side do not offer a comparable/similar level of protection as that provided for by the domestic regulations. Such a presumption would not be a legal presumption – i.e. a legal requirement that equivalence exists unless proven otherwise -, but would form part of a methodological approach in order to facilitate the task of assessing equivalence of regulations, to be conducted by regulators.

Such an approach would require the contribution of industry and, as appropriate, of other relevant stakeholders. The EU and US industry would be requested to provide, as an input to the TTIP discussions, relevant information to help conduct such an assessment: this would include as much evidence and data as possible (including on the economic value of establishing the

equivalence) in support of the request for consideration of equivalence. Pending a more detailed data-driven analysis, the lists of matching regulations submitted by the industry in their joint contributions, already provide a valuable indication of industry's expectations for this negotiation. As a starting point, it would be appropriate to focus on a first batch of regulations on which work would begin immediately. This could concern regulations which have important economic value and indeed presumed similar effect, be it on safety or on the environment. This approach would allow the Commission and the US agencies to test and refine the methodology for the examination of equivalence in the remainder of the regulations. The data for these first cases should be provided in the shortest possible timeframe.

Importantly, as absence of recognition of any individual regulation could imply important additional costs, the examination of equivalence should be comprehensive and extend to all relevant technical regulations applicable to motor vehicles – going even beyond the list proposed by the industry so far. Other stakeholders would also be able to provide input.

Regulators would conduct such an equivalence assessment based on emission levels and data provided by the industry as well as on the data used in the legislative process (e.g. cost-benefit analysis and health data). If regulators establish that there is no equivalence, the reasons for this conclusion should be identified as well as the means that would enable recognition of equivalence for future standards.

It will be critical that such an evaluation focuses on the outcome of the regulations, i.e. their effects in terms of protection of safety and the environment. Therefore, differences in specific technical requirements or testing methods would not per se constitute a proof of absence of equivalence, unless it is determined that such differences have a significant material impact in terms of protection.

3. Possible deliverables during the negotiations

In the course of the negotiations, both sides would identify the areas where there could be recognition of equivalence between the EU/UNECE and FMVSS and other regulations relevant for safety and the protection of the environment. The objective would be to establish a list in the TTIP agreement

covering a high number of matching EU/UNECE-FMVSS and other regulations, both in the field of safety and the environment. For areas where there is recognition of equivalence, such recognition would mean in legal terms that compliance with the relevant regulations of the other TTIP partner would have the same legal effects as compliance with domestic regulations, and therefore be considered for all purposes (although with limitations with respect to conformity assessment, see below) as compliance with the relevant corresponding domestic regulations.

Such recognition would concern the technical requirements applicable to motor vehicles and their parts and components, and cover the technical specifications, how they are measured (i.e. tests carried out to assess compliance), and marking requirements. Such recognition could not be extended to conformity assessment, in view of the wide divergence between conformity assessment systems (prior type approval in the EU, in accordance with the UNECE system, and self-certification with market surveillance in the US). However, in order to facilitate trade and the recognition of the substantial technical requirements, EU type-approval authorities would be required to test US vehicles destined for the EU market against US regulations using US testing methods, while US bodies would, in their market surveillance activities, test EU vehicles against EU/UNECE regulations and their testing methods. The agreement would have to specify how to make the two systems work smoothly alongside each other, and reduce paperwork as much as possible, whilst respecting their integrity.

4. Built-in agenda

For cases where equivalence cannot be established during the negotiations because of important differences in the effects of technical requirements, the agreement should identify those areas where further convergence would be necessary. It should also define how and when to achieve it: the gaps should be specified and a clear process and timeline (in-built agenda) would be agreed. This should be complemented by a strengthening of EU-US cooperation in the framework of UNECE 1998 Agreement.

Reinforced cooperation in the context of the UNECE 1998 agreement would

also be the central element to cover new technologies and lead to the adoption of EU-US and ultimately of Global Technical Regulations, in areas such as hydrogen and electric vehicles, test-cycle on emissions, and advanced safety technologies. The objective would be for a quick incorporation of the resulting GTRs in national legislation, insofar as possible abstaining from options, exemptions and modules - or otherwise providing for recognition of the options that the other party may have chosen. Progress in this work would be regularly monitored under the relevant bodies of TTIP at the highest level.

Insofar as possible, some outcomes on these topics could be achieved during the timeframe of the negotiations and reflected in the resulting texts.

5. Future convergence

In addition to the areas identified for further work, there could also be a provision concerning other future regulations, according to which whenever either side considers that a new regulation is required they will consult the other and commit to work together in order to establish common rules, in principle in the framework of the 1998 Agreement.

6. Practical considerations – work organisation

The next step would be to agree on a work plan and concrete steps to be carried out during the negotiations, in particular during the course of 2013. Stakeholders would be invited to provide the necessary information to support the process. On the EU side, Member States (which are responsible for type-approval activities) will need to be consulted regularly.

Within the framework of the TTIP negotiations, regulators from both sides would develop the methodology and identify areas and questions requiring further work.

Annex II

Initial position paper

Chemicals in TTIP

The purpose of this paper is to outline the main elements of a possible approach under TTIP to promote regulatory convergence and recognition in the chemicals sector. These elements build on the ideas put forward jointly by Chemicals Industry Associations of the EU and US.

1. Overall objectives

Both industry associations and governments are aware that neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU: REACH (Regulation (EC) 1907/2006) and TSCA (Toxic Substances Control Act) are too different with regard to some fundamental principles. The recently completed REACH Review concluded that REACH should not be amended, while in the US a bipartisan proposal to amend TSCA has been introduced into Congress in May 2013. However, the draft legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation, while it would give the EPA new and easier possibilities to conduct chemical assessments and adopt risk management measures such as restrictions. The objective of the negotiations, therefore, must be to find and agree on all possibilities for regulatory co-operation/convergence within the limits of the existing basic frameworks – details are set out below. Some of these objectives could already be achieved at the time the negotiations are concluded, while for others only adherence to certain regulatory principles and mechanisms for further work might be feasible.

2. Detailed objectives

Four main areas have been identified in which a higher degree of convergence may be sought to increase efficiency and reduce costs for economic operators:

2.1. *Co-operation in prioritisation of chemicals for assessment and assessment methodologies:* prioritisation happens in the US in the framework of the so-

called Chemicals Management Plans of the EPA as well as through the selection of chemicals for the so-called 'Reports on Carcinogens' by the National Toxicology Programme (NTP), and in the EU through (a) the establishment of the Community Rolling Action Plan (CoRAP) for Evaluation under REACH drawn up by ECHA (**to note**, though: evaluations under REACH are expected to be much more targeted and limited in scope than the full assessments made by the EPA under its chemicals management plans), as well as (b) in a much less formalised and purely voluntary risk management option analysis followed by proposals for restrictions, substances of very high concern (SVHC) identification (candidate list), authorisation and proposals for harmonised classification and labelling under Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP). None of these processes in the EU and US, respectively, currently foresees the consultation or involvement of authorities of the other, but TTIP could be an opportunity to develop relevant mechanisms. Methods for assessment/evaluation are also an area where EPA and ECHA already co-operate and this can be intensified – in particular in the development/integration of new scientific developments. The already existing Statement of Intent¹ signed between EPA and ECHA could be a good basis for developing further co-operation activities. The US Agencies should also accept to monitor the activities of individual States in this regard and inform the EU about all draft measures envisaged at sub-Federal level.

2.2. Promoting alignment in classification and labelling of chemicals: this is an area with great potential, because an international standard exists, which is essentially a 'fusion' of the earlier EU and US systems. In the EU the CLP Regulation constitutes a comprehensive implementation of the UN GHS, whereas in the US, only OSHA has implemented the GHS for chemicals used at the workplace. EPA (and possibly also the Consumer Product Safety

¹ The European Chemicals Agency has already a cooperation agreement with the US EPA. This agreement on technical and scientific cooperation is underpinned by revolving work plans. The interaction with the peer organisation includes regular director level meetings and technical dialogue between experts when topics of mutual interest to share information and best practice on the regulatory science, IT tools and databases relevant for sound management of chemicals. The cooperation under the current agreement does not include the exchange of confidential business information.

Commission CSPC) would have to also implement the UN GHS for legislation under their responsibility if this objective were to be reached. The EU and US authorities could also commit to implement the regular updates of the GHS and, in areas, where a certain flexibility is allowed, to work towards convergence. ACC/CEFIC also called for a common list of chemicals with agreed classifications, which fits with an initiative in the UN GHS promoted by the US for a global list of agreed GHS classifications. The EU already maintains a list of binding harmonised classifications in Annex VI to the CLP Regulation, and an inventory of all existing industry self-classifications – which are not fully harmonised yet - has been established in the C&L Inventory maintained by ECHA. An enhanced EU-US co-operation on agreeing classifications for chemicals could become a good basis for a global list.

2.3. *Co-operation on new and emerging issues:* Co-operation on new and emerging issues in a forward looking manner has the greatest potential to avoid trade irritants in the future. Current topics of interest would be endocrine disruptors (where contacts between the Commission and EPA are already established), nanomaterials (contacts also already established) and mixture toxicity. Mutual consultation as of an early stage, whenever US agencies or the Commission start developing new criteria or new legislation, could relatively easily become part of the preparatory processes conducted by both.

2.4. *Enhanced information sharing and protection of confidential business information (CBI):* this has been proposed by ACC/CEFIC, including also a call to identify ‘existing barriers for exchanging information’. The US EPA and OSHA (mainly to obtain full test study reports from the EU) as well as ECHA (mainly to receive full information about substance identities from the US authorities, e.g. in the Chemical Data Reporting scheme) have also expressed interest. In addition, several animal welfare organisations have called on the authorities to increase data exchange to avoid duplication of tests involving animals. While it is undoubtedly important that the EU and US authorities exchange information, both sides also make vast and increasing amounts of data publicly available. Therefore, several elements would require additional

consideration before deciding what further steps could be taken or what benefits an agreement on sharing CBI would bring. For example, the US EPA is content with working with robust summaries (and does not require full study reports) in the context of the OECD HPV Programme. Also, neither ECHA nor the Member States authorities do normally receive full study reports as part of REACH Registration or even evaluation – these are owned by the industry and shared between the registrants via Substance Information Exchange Fora (SIEFs) which could be approached directly by the EPA. It also has to be ascertained that information exchange would be mutual, which raises the question of the limits on the US authorities to give any confidential information to other authorities under Section 8 of TSCA. This analysis should also include to what extent the definitions of CBI is equivalent in the EU and in the US.

3. Possible deliverables during the negotiations

Realistically achievable deliverables during the course of the negotiations will differ for the specific objectives set out in section 2, as detailed in the following. It should also be noted that both for the negotiation and later implementation the relevant US agencies need to cooperate internally to avoid diverging developments on the US side, which would make convergence with developments in the EU impossible.

For objective 2.1: agreement on a mechanism for mutual consultation on prioritisation of chemicals for assessment/risk management and for co-operation in the development of assessment methodologies, which could be described in an article in the relevant sector annex for chemicals. commitment by both sides to inform about activities at sub-Federal level in the US and Member State activities in the EU, respectively.

For objective 2.2: commitment to implement the UN GHS for a broad range of chemicals by a certain date and to implement the regular updates of the GHS. There could also be agreement on a mechanism for mutual consultation and involvement in processes for classification and labelling of substances (i.e. harmonised classification in the EU under CLP – NTP reports on cancer in the US), or on other ways of establishing a common list of classifications for substances (e.g. reviewing existing lists and identifying commonalities, working through the OECD or others). These elements could be described in an article in

the relevant sector annex for chemicals

For objective 2.3: agreement on a mechanism to regularly consult with each other on all new and emerging issues – in particular those of regulatory relevance, which could be described in an article in the relevant sector annex for chemicals. Commitment to consult and respond to comments/questions from the other side and undertake efforts to work towards common criteria/principles/measures on such new and emerging issues, where feasible.

For objective 2.4: completion of a full analysis on the expectations of each side, possible obstacles to exchange of (confidential) data, possible benefits of such exchange and perspectives for reciprocity. If considered worthwhile, commitment to undertake negotiations on a relevant mechanism with an objective to conclude them within X years.

4. Built-in agenda

The sector annex could contain a provision to periodically review the functioning of the mechanisms developed for each of the above objectives and their revision as appropriate. Furthermore, both sides could commit to periodically examine whether additional and new objectives could be covered and the sector annex be amended accordingly.

5. Future convergence

The horizontal chapter of TTIP would have provisions concerning an effective bilateral cooperation/consultation mechanism and an improved feed-back mechanism, for both parties to get sufficient time to comment before a proposed regulation is adopted and to receive explanations as to how the comments have been taken into account. For the chemical sector, this would include in particular risk management proposals for prioritised substances at Federal/EU level and US State/Member State level.

6. Practical considerations – work organisation

The next step would be to establish a work plan and concrete steps to be carried out during the negotiations and in particular during the course of 2013. This would include in particular the identification of all relevant actors (i.e. agencies on the US Side, COM and ECHA on the EU side). Stakeholders would be invited to provide proposals to support the process.

Annex III

INITIAL POSITION PAPER

PHARMACEUTICALS IN TIIP

INTRODUCTION

The final report of the US - EU High Level Working Group on Jobs and Growth (February, 2013) highlights that as regards regulatory aspects TTIP should contain in addition to cross-cutting disciplines and TBT plus elements provisions concerning individual sectors.

The purpose of this paper is to present some possible elements for a TTIP annex on pharmaceutical products. It is based on ideas put forward by EU and US industry and builds on existing cooperation between EU and US regulators in this area. It is anticipated that stakeholders will continue to support the process and could play an active role towards the implementation of some of the identified objectives.

Regulatory cooperation between EU and US in the pharmaceutical area supported by existing confidentiality arrangements is very well established both at bilateral level as well as at multilateral level via ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use).

TTIP could reinforce existing collaborative processes on pharmaceuticals by:

- establishing bilateral commitments that would facilitate pharmaceutical products authorization processes and optimise agencies resources (notably with respect to reliance on each other's GMP inspections results and exchange of confidential information),
- fostering additional harmonization of technical requirements in new areas or in areas where the need to improve harmonization at bilateral or international level has been identified (e.g. biosimilars, paediatrics, generics, terminology),
- reinforcing joint approaches on scientific advice and evaluation of quality by design applications).

POSSIBLE ELEMENTS FOR A PHARMACEUTICALS ANNEX IN TTIP

GMP inspections

Both Parties could explore possibilities for the improvement of the recognition of each other's GMP inspections carried out in third countries and inspections carried out in EU and US territory.

An advantage of this approach would be that FDA and EU Member States would be able to focus their resources on inspecting high risk areas (which are located outside EU and US) instead of spending resources on inspecting third countries facilities and EU and US facilities which have been already inspected by one of the Parties. In addition, this approach would entail significant cost savings for the industry.

Although the EU has functional MRAs or equivalent in place with Canada, Japan, Switzerland, Australia, New Zealand and Israel, between the EU and US a more flexible approach could be taken.

Therefore, in TTIP, a system based on mutual reliance on each other's GMP inspections (instead of legally binding mutual recognition) could be envisaged. Such approach should include progressive targets that would contribute to confidence building.

Provisions on the exchange of confidential/trade secret information should be in place for such approach to function.

Exchange of confidential information and trade secret information

Both Parties should explore possibilities for allowing the exchange of confidential information and trade secret information between EU Member States/EU institutions and FDA. This approach would apply not only to GMP and other inspection reports but also to data and information on marketing authorizations applications.

TTIP could entail legal provisions allowing the exchange of confidential information in the horizontal chapter as well specific confidentiality provisions in the pharmaceuticals annex.

Innovative approaches from industry could greatly contribute to the realisation of this objective.

Establishing functioning systems for the authorisation of biosimilars

Both Parties could commit on establishing functioning systems for the authorisation of biosimilars. The FDA could benefit from the experience of EMA that has already completed opinions on 16 biosimilars. FDA and EMA are expected to pursue their scientific exchanges which contribute to the development or review of their respective guidelines. In particular, a formal acceptance of comparative clinical trials based on reference medicines sourced in the EU or US or in third countries should be envisaged.

An advantage of this approach would be the potential increase of approved biosimilars in both markets. In addition, US and EU could shape the international approach for the review/authorization of biosimilars.

Revising requirements for Paediatrics authorization

Both Parties could work towards the revision of ICH guidelines on paediatrics in particular by agreeing on clinical studies design (paediatric investigation plans) and by mutually accepting clinical studies. In addition, both Parties should agree on the timing for data submission.

Terminology for pharmaceutical products

Both Parties could work towards the implementation of a harmonized terminology for pharmaceutical products (unique identification of medicinal products and substances, pharmaceutical forms, routes of administration, etc.).

This approach would improve the information flow between enterprises and regulators and between regulators of both Parties.

Bilateral cooperation on joint assessment approaches

Both Parties could commit to continue existing cooperation on 'parallel scientific advice' (joint discussion between EMA, FDA and applicant/sponsor of scientific issues during the development phase of a new product) and existing cooperation on 'parallel evaluation on quality by design applications' (joint list of questions to the applicant and harmonized evaluation of the applicant's responses).

This approach would have the advantage of optimizing product development and avoiding unnecessary clinical trials/testing replication, optimising agencies

resources (sharing assessment reports/authorisation decisions) as well as important costs savings for industry.

Provisions on the exchange of confidential/trade secret information or industry readiness to allow such exchange should be in place to allow such approach to function.

NEXT STEPS

Taking into account that the objective of the current paper is to present a first analysis of possible elements for a TTIP annex on pharmaceutical products, the first negotiation meetings could aim at:

- discussing how to combine health regulators' agendas (focus on protecting human health) with more general competitiveness objectives (increased trade, growth and jobs);
- calling on stakeholders to see how they can best support these objectives;
- identifying common goals and possible scope of commitments;
- deciding on whether the identified goals should be achieved at bilateral level or at multilateral level (e.g. ICH) and within which time frame;
- discussing the best tools to achieve in a pragmatic way the goals (e.g. GMP recognition vs. reliance on GMP results);
- determining what type of deliverables can be expected within TTIP in the short and medium term;
- discussing implementing measures and what type of resources (financial, human, legal) will be necessary to put in practice TTIP commitments.

**EU initial position paper on SPS matters for the TTIP negotiations –
Without prejudice, 20.6.2013**

In its Final Report, the High Level Working Group on Jobs and Growth (HLWG) recommended that the United States of America and the European Union (hereinafter "the Parties") should seek to negotiate an ambitious "SPS-plus" chapter. To this end a mechanism to maintain an improved dialogue and cooperation should be established to address bilateral sanitary and phytosanitary (SPS) issues. The chapter will seek to build upon the key principles of the World Trade Organization (WTO) SPS Agreement .

This chapter – as part of the FTA discussions within the TTIP - will seek to build upon the key principles of the World Trade Organization (WTO) SPS Agreement, including the requirements that each side's SPS measures be based on science and on international standards where these exist, while recognising the right of each Party to appraise and manage risk in accordance with the level of protection it deems appropriate and with the objective of minimising negative trade effects. Measures taken, in particular, when relevant scientific evidence is insufficient, must be applied only to the extent necessary to protect human, animal, or plant life or health, must be developed in a transparent manner and must be reviewed within a reasonable period of time.

This chapter should seek to address market access issues and to facilitate the resolution of differences. It should be without prejudice to the right of the EU and Member States to adopt and enforce, within their respective competences, measures necessary to pursue legitimate public policy goals such as public health and safety in accordance with the WTO SPS Agreement.

The SPS chapter will form part of a broader move to also address regulatory issues and non-tariff barriers. In this context, the two sides should also seek to strengthen upstream cooperation by regulators and to increase their cooperation on standards setting at an international level. Regulatory convergence shall be without prejudice to the right to regulate in accordance with the level of health, safety, consumer and environmental protection that either Party deems appropriate, or to otherwise meet legitimate regulatory objectives.

At present, the 1999 *Agreement between the United States of America and the European Community on sanitary measures to protect public health and animal health in trade in live animals and animal products* (the so-called Veterinary

Equivalence Agreement or VEA) aims to facilitate trade in animals and animal products by offering a framework for establishing the equivalence of EU sanitary measures relative to the US level of protection and vice-versa, for US sanitary measures relative to the EU level of protection. The VEA also provides for recognition of the animal health status of the exporting Party, the recognition of the regionalisation, guidelines for border checks, procedures for the conduct of verification visits, improved information exchange and transparency, amongst other things.

The new SPS chapter should build upon the existing VEA and make it part of the overall architecture of any future comprehensive Free Trade Agreement. In particular it should take into account the experienced gained thus far, maintaining those elements of the VEA that have worked well and improving on those that have done less well.

Other existing forms of cooperation like the EU-US technical working groups on animal and plant health, or existing ad-hoc cooperation for example in multilateral fora or standard setting bodies, should be examined and updated in the same way, to reflect the overall experience gained to date.

Overall, the new SPS chapter should in particular seek to:

1. minimise the negative effects of SPS measures on trade through close regulatory, confidence building and technical cooperation,
2. respect legitimate objectives to safeguard human, animal and plant health measures applicable to trade in order to prevent and eliminate unnecessary barriers,
3. improve transparency by bringing certainty and consistency to the adoption and application of SPS measures.

To this end existing sanitary and phytosanitary measures should be revisited in a collaborative manner and with the aim to remove unnecessary barriers

Special focus should also be given to trade facilitation measures where a number of areas can be potentially benefit (e.g. approval and/or authorisation procedures where the administrative burden, redundancies, etc could be reduced).

In summary, the SPS component of the overall agreement should seek to achieve full transparency as regards sanitary and phytosanitary measures applicable to trade,

establish provisions for the recognition of equivalence, implement a 'pre-listing' approach for establishments, prevent implementation of pre-clearance, provide for the recognition of disease-free and pest-free health status for the Parties and recognise the principle of regionalisation for both animal diseases and plant pests.

In order to achieve these objectives, the EU proposes, *inter alia*, to cover the following elements:

- Scope and definition: the future chapter should apply to all SPS measures that directly or indirectly affect trade. It should complement and build upon the WTO SPS Agreement. To this end, the rights and obligations under the WTO SPS Agreement should be re-affirmed. The definitions established in the WTO SPS Agreements and by relevant international standard setting bodies should be used.
- Competent authorities: The chapter should be legally binding for both Parties and applicable to the Parties' territories at all administrative levels in order to ensure its maximum efficiency and effectiveness. It is paramount in this regard, that the Parties recognise each other as single entities for SPS purposes.
- Reducing administrative burdens, excessive bureaucracy or adherence to needless rules and formalities and replacing them by transparent, slim and predictable processes in order to allow real trade in due time: It is, in particular, essential to include predictability and transparency into the approval and/or authorisation procedures applicable to imported products, including risk assessments, timelines and technical consultations where necessary.
- Privileged Relationship - It should provide for the elements to set up a privileged relationship between the Parties, including e.g. a pragmatic and open approach for a more efficient recognition of equivalence. Consultations along the adoption of SPS measures or the import authorization process together with an early warning of upcoming legislative changes would also allow convergence among the two systems.
- Trade facilitation provisions: an ambitious set of trade facilitation measures should include, among other things, a clear and streamlined procedure for the listing of establishments based on an audit approach, whose frequency is risk- and performance-based. There should also be a procedure for the determination of equivalence. The EU is keen to discuss provisions on equivalence (comparability) assessments for systems or a certain category of goods, or alternative specific measures.

Initial position paper

Limited

- Trade conditions: SPS related import requirements and certification conditions for all commodities should be available upfront, grounded in scientific evidence or the relevant international standards and apply to the entire territory of the exporting Party. Among other issues, it is paramount to set up a clear procedure which will include timelines for the recognition of animal health status, pest status and regional conditions, in line with international standards. Provisions on safeguard measures or emergency measures should ensure that trade is not unnecessarily or unjustifiably restricted. Pragmatic and open procedures should be established to recognise alternative measures.
- Fees and Charges: Among the trade facilitations measures, reciprocal treatment as regards fees and charges imposed for the procedures on imported products is of key importance. Both Parties commit to bear their own costs related to imports from the other Party namely with regard to the procedures of registration, approval authorisation, inspections or audits.
- Transparency and information exchange on key areas such on the verifications/audit activities, non-conformities at the border inspections post, new scientific developments, early consultation procedure of upcoming legislative changes and changes on the import conditions, etc.
- Enforcement: The establishment of a Committee with sufficient tools to monitor and ensure the implementation of the chapter.
- Cooperation: The SPS chapter should also include provisions to develop the cooperation on animal welfare aspects and to facilitate the exchange of information, expertise and experiences in this field. Cooperation in other areas of common interest, including in the WTO SPS Committee and in relevant international standards setting bodies should be also explored.

Initial position paper

Limited

A possible skeleton of the Agreement related to the SPS+ issues should at least address the following points

The part of the agreement:

1. Objective;
2. Competent Authorities
3. EU and US as single entities for SPS purposes
4. Reaffirmation of multilateral obligations
5. Scope
6. Definitions
7. Trade facilitation
8. Animal Health
9. Plant health
10. Animal welfare
11. Equivalence
12. Verification (audit)

13. Export certification

14. Import checks/fees

15. Transparency/Information exchange

16. Notification/Consultation

17. Safeguard and emergency measures

18. Collaboration in international fora (multilateral and bilateral)

EU INITIAL POSITION PAPER ON TRADE AND SUSTAINABLE DEVELOPMENT

I. Introduction

1. Sustainable development is an overarching policy objective of the international community. It stands for meeting the needs of present generations without jeopardising the needs of future generations. It offers a model of progress that reconciles immediate and longer-term needs. Social development, economic growth and environmental protection are inter-related and mutually reinforcing components of sustainable development. Sustainable development aims at bringing about economic prosperity through and with a high level of environmental protection and social equity and cohesion.
2. The EU is committed to furthering these objectives, both by an active engagement with its partners in the international arena and through the design, adoption, and implementation of its internal policies. The Treaty of Lisbon, establishing the core EU rules, enshrines sustainable development as a fundamental principle of the EU action, both domestically and in its relations with the wider world – be it political partnerships, trade relations, international cooperation, or external representation. Sustainable development therefore informs and guides the EU policy-making process and is high on the agenda of the EU institutions and key constituencies, including the European Parliament.
3. As part of this overall framework, maximising the important contribution that trade can make to sustainable development is a key objective that the EU consistently pursues both multilaterally and in all its bilateral and regional trade negotiations. In this context, the launch of the Transatlantic Trade and Investment Partnership (TTIP) negotiations presents opportunities and challenges in respect of sustainable development
4. The EU sets out on the path towards the TTIP with the US in the firm belief that our aspirations and objectives are based on a common overarching objective of sustainable development. Notably, the EU believes that, by building on the EU and the US commitment to high levels of protection for the environment and workers, including in their trade agreements, as also reflected in the HLWG's report, the TTIP negotiations will pave the way for a comprehensive and ambitious approach to trade and sustainable development issues – thereby responding to expectations on a true “21st century deal” in this area.
5. In addition to the recognition of sustainable development as a principle that should underlie the TTIP in all areas, we envisage an integrated chapter specifically devoted to aspects of sustainable development of importance in a trade context - more specifically, on labour and environmental, including climate change aspects, as well as their inter-linkages.

II. Trade and Sustainable Development (TSD) Chapter

6. The EU has developed a consistent practice of including chapters on Trade and Sustainable Development in its FTAs, aiming at ensuring that increased trade is mutually supporting environmental protection and social development, and does not come at the expense of the environment or of labour rights. Building on this experience, the EU would consider the following areas as building blocks for the TTIP negotiations.

a. Internationally agreed sustainable development objectives and commitments

7. The EU believes that the TTIP should reflect the Parties' commitments regarding a set of internationally agreed principles and rules, as a basic framework underlying our economic and trade relations. In the labour domain, the starting point for discussions should be the Parties' existing commitments in relevant areas, including the ILO 1998 Declaration on Fundamental Rights and Principles at Work, as well as its follow-up, and the 2008 ILO Declaration on Social Justice for a Fair Globalization, which applies to all ILO members. In respect of environmental issues, the starting point should be the recognition of the importance of global environmental governance to tackle environmental challenges of common concern, whereby Multilateral Environmental Agreements (MEAs) are of critical importance to deliver global benefits.
8. On that basis, the TTIP negotiations should reflect the Parties' commitments in the labour area with respect to ILO principles and rules. In this regard, the EU considers that ILO core labour standards, enshrined in the core ILO Conventions and internationally recognised as the fundamental labour rights, are an essential element to be integrated in the context of a trade agreement, and could be further complemented by other ILO standards/conventions of interest, as well as by a resolve to promote the ILO Decent Work agenda. A similar approach should be followed regarding adherence to core MEAs and other environment-related bodies as internationally recognised instruments to deal with global and transboundary environmental challenges, including the fight against climate change. Due to their subject matter and cross linkages with trade aspects the EU considers the following MEAs to be of particular importance in trade negotiations: the Convention on International Trade in Endangered Species of Wild Fauna and Flora and its amendments, the Montreal Protocol on Substances that Deplete the Ozone Layer, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, the Convention on Biological Diversity and its Protocols, the United Nations Framework Convention on Climate Change, the Stockholm Convention on Persistent Organic Pollutants, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

9. Our common commitment to the effective domestic implementation of these labour and environmental standards and agreements should also be an important element to emphasise.

b. Levels of labour and environmental protection

10. The integration of environmental and labour considerations in the TTIP is without prejudice to each Party's right to regulate in order to reflect its own sustainable development priorities. This means recognising in the TSD chapter each Party's right to define and regulate its own domestic levels of environmental and labour protection at the level deemed necessary, consistently with internationally agreed standards and agreements, as well as to modify its relevant laws and policies accordingly, while pursuing high levels of protection.
11. Furthermore, the overarching aim of the TSD chapter should be to ensure that trade and economic activity can expand without undermining the pursuit of social, and environmental policies. On the other hand, domestic labour and environmental standards should not be used as a form of disguised protectionism, nor lowered as a means of competing for trade or investment. Accordingly, the TSD chapter should expressly reflect the fact that the respective domestic authorities will not fail to enforce, and will not relax, domestic labour or environmental domestic laws as an encouragement of trade and investment.

c. Trade and investment as a means to support and pursue sustainable development objectives

12. In order to promote a greater contribution of trade and investment to sustainable development, it is important to discuss initiatives in areas of specific relevance. In this regard, the TSD chapter should promote, for instance:
 - trade and investment in environmental goods and services and climate-friendly products and technologies. Moreover, further reflection could also be undertaken on other related trade actions which could be pursued under other chapters of the TTIP (e.g. frontloading liberalisation of such products, addressing NTBs in the renewable energy sector, consider environmental services);
 - the use of sustainability assurance schemes, i.e. voluntary tools on environmental sustainability or fair and ethical trade initiatives;
 - corporate social responsibility practices, further supporting relevant principles endorsed by both the EU and the US (e.g. international guidelines, bilateral joint statement of shared principles for international investment within the framework of the Transatlantic Economic Council).

13. Similarly, the TSD chapter should emphasize the Parties' commitment towards the conservation and sustainable management of biodiversity and ecosystems, the sustainable use and management of natural resources, and the role that trade could play in this regard. These considerations would apply to areas such as forests, fisheries, wildlife, and biological resources. The promotion of trade in legally obtained and sustainable products should thus be a key area to be covered, against the background of internationally recognised instruments, as well as the common determination of the EU and the US to address in their FTAs issues related to trade in such resources obtained or produced illegally.

d. Good administrative practices

i) Scientific information

14. The TSD chapter should recognise the importance of taking into account international guidelines and principles on the use of scientific and technical information as well as on risk management, when preparing and implementing measures aimed at protecting the environment or labour conditions which may have an impact on trade and investment.

ii) Transparency

15. Transparency is of particular relevance in the context of trade and sustainable development, in order to ensure that stakeholders, particularly non-state actors, can be informed about, and provide views and inputs on, the development, introduction, and application of measures related to labour or the environment. This also applies to measures concerning the implementation of the TSD chapter. Therefore, the TSD chapter should foresee appropriate channels for engaging with the public.

iii) Review and assessment

16. Appropriate recognition should also be given to the fact that, once the TTIP is in force, it will be important for the Parties to have an active policy of review and assessment of the effects of the agreement on sustainable development objectives.

e. Working together

17. The TTIP could also establish priority areas for share of information, dialogue, and joint initiatives on the trade-related aspects of sustainable development, such as:
- Cooperation in international fora responsible for social or environmental aspects of trade, including in particular the WTO, ILO, MEAs and UNEP;

- Strategies and policies to promote trade contribution to green economy, including eco-innovation;
- Trade-related aspects of the ILO Decent Work agenda and, in particular, on the impact and inter-linkages of trade and full and productive employment, labour market adjustment, core labour standards, labour statistics, human resources development and lifelong learning, social protection floors and social inclusion, social dialogue and gender equality;
- Trade impacts of labour or environmental protection and, *vice versa*, the impacts of trade on labour or environmental protection;
- Trade-related aspects of natural resources and the protection and use of biological diversity, including ecosystems and their services, such as measures to enhance trade in legal and sustainable timber, fish, or wildlife products as well as other issues related to biodiversity and ecosystems;
- Trade-related aspects of the climate change strategy, including consideration of how trade liberalisation or trade-related regulatory cooperation can contribute to achieving climate change objectives and more generally to ensure increased production of renewable energy, implemented in a sustainable manner and increased energy efficiency.

f. Implementation, monitoring, and enforcement

18. In order to ensure an appropriate implementation of the TSD chapter, in the EU's view it is crucial to incorporate a strong monitoring and follow-up mechanism. The EU is convinced that an effective mechanism should be based on transparency, regular dialogue, and close cooperation between the Parties, and provide for effective channel of communications and means for reaching mutually agreed positions on any matter related to the TSD Chapter.
19. In this context, the EU sees an essential role for civil society, both domestically and on a bilateral basis, in ensuring that sustainable development considerations are brought to the attention of the Parties to the TTIP, as well as in providing advice and follow-up on the implementation of the TSD chapter and related matters.
20. Finally, it is important to ensure that there are channels for the Parties to deal effectively with disagreements on any matters which might arise under the TSD chapter, such as government consultations and independent and impartial third-party assessments to facilitate the search for and implementation of solutions.

Initial position paper

Technical Barriers to Trade

1. Introduction

The final report of the HLWG refers to five basic components of TTIP provisions on regulatory issues, as follows: cross-cutting disciplines on regulatory coherence and transparency; provisions concerning technical barriers to trade (TBT) and sanitary and phytosanitary measures (SPS); provisions aimed at promoting (greater) regulatory compatibility in individual sectors; and a framework providing an institutional basis for future cooperation.

With respect to the horizontal TBT Chapter, the HLWG specifically recommends the following:

“An ambitious “TBT-plus” chapter, building on horizontal disciplines in the WTO Agreement on Technical Barriers to Trade (TBT), including establishing an ongoing mechanism for improved dialogue and cooperation for addressing bilateral TBT issues. The objectives of the chapter would be to yield greater openness, transparency, and convergence in regulatory approaches and requirements and related standards development processes, as well as, inter alia, to reduce redundant and burdensome testing and certification requirements, promote confidence in our respective conformity assessment bodies, and enhance cooperation on conformity assessment and standardization issues globally.”

This draft presents some elements that could be contained in the horizontal TBT Chapter of the future TTIP.

In particular, this paper addresses general issues concerning technical regulations, standardization, conformity assessment and transparency. It is limited to aspects covered by the WTO TBT Agreement. It therefore does not cover issues related to services, public procurement, and aspects covered by the WTO SPS Agreement.

As indicated above, it is envisaged that separate provisions will be made for specific product sectors. Many technical sectors have regulatory peculiarities arising either from their nature, or for historical reasons, and where such peculiarities exist, or where the economic importance of a sector is such as to justify it, specific measures will be considered in a separate sectoral annex, limited to that set of products. It is the purpose of this discussion to address the general case, i.e., where sectoral measures are not, or not yet, envisaged for the TTIP as a whole, or where sectoral measures are intended to complement measures of general application.

2. Principles

The EU considers that transparency and predictability of the regulatory and standard-setting process is key to trade and growth in general. It has therefore been a strong advocate, both in the SPS and TBT Committees, for improving regulatory and standardization practices of WTO Members, in particular through the application of principles of transparency and good

regulatory practice at all stages of the regulatory and standard-setting process as well as convergence to international standards.

The EU views for the TBT component of the TTIP are based on a number of guiding principles.

First, as far as possible, measures should *aim at removal of unnecessary barriers to trade* arising from differences in the content and application of technical regulations, standards and conformity assessment procedures.

Second, although compatibility is important, it must be recognised that the systems of the two regions are different, both to meet the specific needs of their economies and for historical reasons, and *it is not possible for one side to impose its system on the other; nor can either side be expected to treat its partner more favourably than its own side.*

Third, while the need for a high level of protection remains, measures should aim for *methods* of regulation, standardisation and conformity assessment that are *not more trade-restrictive than necessary* to achieve the relevant public interest objective, while taking into account the need to give preference to internationally harmonized methods.

Fourth, closer co-operation between the EU and the US *should not result in new hindrances to their trade with the rest of the world.*

Finally, it should be recognised that there are existing voluntary instruments of transatlantic co-operation in or related to TBT matters, arising from earlier sectoral or general trans-Atlantic initiatives, *and that the results of such initiatives should not be compromised in any new Agreement.*

3. *Understanding the functioning of the EU and US internal markets – Improving framework conditions for market access*

As a scene-setter, it is proposed to gain a better understanding of the principles governing inter-State commerce in the US and free movement of products in the EU internal market, i.e. the conditions under which products lawfully placed on the market of any US State or EU Member State can benefit from free circulation within the respective internal markets.

A shared objective should be to look into ways to improve framework conditions for market access on both sides (for the benefit of products and suppliers of both Parties), regardless of the actual level of compatibility of the substantive regulatory requirements and standards.

This involves consideration of basic issues concerning the functioning of the EU and US internal markets and pertaining, *inter alia*, to:

- (i) the overall predictability and transparency of the EU and US regulatory systems and whether the rulebook is easily accessible and understandable, having regard in particular to the needs of Small and Medium-Sized Enterprises (SMEs);
- (ii) scope of sub-regional (in the EU) and sub-federal (in the US) TBT-related measures, and their relevance in connection with market access requirements;
- (iii) available mechanisms in either system to prevent the erection of / eliminate barriers to trade as a result of sub-regional (EU) or sub-federal measures (US);

Any agreement must take account of any divergences with regard to the above aspects, with the aim of maintaining an overall balance of commitments in the TBT area. From an EU perspective, it would be important for such an overall balance that the commitments to be agreed in the TTIP apply also to both the sub-regional (in the EU) and the sub-federal level of regulation (in the US).

4. *Transparency*

The WTO Agreement on Technical Barriers to Trade (TBT) already provides for a system of notifications of new draft technical regulations and conformity assessment procedures, and the EU and the US both participate actively in this. The EU and US sides have in the past been working on a draft understanding aimed at improving transparency in the TBT (and SPS) notification procedures. The parties could not agree on a common approach as their notification practices differ significantly.

Although it is not proposed to duplicate notifications already made in the context of the WTO, there is an interest in providing for improved transparency through a dialogue of regulators with regard to notification of draft legislation and replies to written comments received from the other party. In this context, notification of all draft technical regulations and conformity assessment procedures (including proposed new legislation), regardless of the initiator of the proposal in compliance with Articles 2.9 and 5.6 of the TBT Agreement, as well as the possibility to receive feedback and discuss the written comments made to the notifying party in compliance with Articles 2.9.4 and 5.6.4 of the TBT Agreement shall be ensured. Of particular importance will be the possibility to receive written replies to comments and the ability of regulators to communicate with each other during the comments procedures.

The possibility to provide for an advanced information exchange between regulators, before the TBT notifications are carried out, may also be examined in this chapter or the context of cross-cutting disciplines. The Agreement might make it possible to identify sectors that would be of interest for such an exchange to take place at a preliminary stage.

5. *Technical regulations*

Divergent technical regulations act as barriers to transatlantic trade. Clearly, there is a gain from removing unnecessary duplicative compliance costs in the

transatlantic market. There is also a potential gain to be had through measures such as improvements in information transfer and regulatory co-operation, and where possible through measures towards convergence – or at least, compatibility - of the parties' regulations themselves. This Section outlines some mechanisms and tools that could contribute to achieving this goal

5.1 Harmonisation or acceptance of technical regulations

Addressing potential differences at the source is more effective than removing barriers that have found their way into our respective regulatory systems. Where neither side has regulations in place, the making of common – or at any rate coherent – technical regulations may be considered by the Parties. Wherever appropriate, consistent with Article 2.8 of the TBT Agreement, consideration should be given to basing such common / coherent regulations on product requirements in terms of performance rather than detailed design prescriptions. The EU's positive experience of the "New Approach" as a method of regulating based on setting "essential requirements" for health and safety without prescribing specific technical solutions, which themselves are laid down in supporting voluntary standards, shows that this is, for large industrial product sectors, a very efficient, flexible and innovation-friendly regulatory technique.

Wherever possible, global harmonization of technical requirements should be pursued in the framework of international agreements / organisations in which both the EU and the US participate. This would then allow both sides to recognise each other's technical regulations as equivalent, as was done for instance with the 2004 Mutual Recognition Agreement on marine safety equipment, where equivalence rests on the parties' legislations being aligned with certain International Maritime Organisation Conventions).

Another practical example is the area of electric vehicles (EVs) where EU and US collaborate closely in UNECE on global technical regulations (GTRs) relating to safety and environmental aspects. Such an approach is perhaps difficult to achieve in the general case; but there may be sectors – particularly related to the regulation of innovative technologies, or where international regulatory activity exists or is planned – where it might be found profitable. Provision for such a process might be included.

5.2 The reference to standards in technical regulation

Standards are often referenced in legislation, as a means of determining compliance with technical regulations. Such standards ought in principle to be left voluntary, in order to allow sufficient flexibility for industry to choose the technical solution that best fits its needs, thus also stimulating innovation. In general, consistent with Article 2.8 of the TBT Agreement, which favours the use of performance-based technical requirements, mandatory legislation should neither copy nor reference standards (thereby making them mandatory themselves); ideally, mandatory legislation should only set general requirements (e.g. health, safety, and the protection of the environment) and then leave flexibility to the market as to how compliance should be assured.

5.3 Sub-regional and sub-federal technical legislation

Both the EU and the US have decentralised structures in which the States or Member States have some freedom to regulate.

As regards placing of products on the market, the EU is a single entity: on the one hand, compliance with harmonised technical requirements at EU level gives full access the whole EU market while, on the other hand, for those products / risks where national requirements apply in the absence of EU legislation, effective circulation throughout the EU is ensured by the application of the principle of mutual recognition of national requirements derived from the case-law of the European Court of Justice interpreting the EU Treaty provisions on free movement of goods. Strict procedures safeguarding the rights of economic operators apply when EU Member States intend to restrict the free movement of products. In addition, Member States are not permitted to erect new national barriers to trade and a specific notification procedure for draft national technical regulations has been in place for almost 30 years, effectively preventing new intra-EU obstacles to trade as a result of national regulations.

It is understood that the scope of the federal US Government is analogously limited, insofar as some States are permitted to make autonomous technical regulations for application on their own territory. Several submissions received in response to the various public consultations on the TTIP report on EU exporters' difficulties with accessing and understanding the rules they have to comply with to gain access to the US market, in particular where multiple layers of regulation (federal/ state / municipality) coexist.

As stated under Section 3 above, while taking into account any divergences with regard to the above aspects, the EU considers that the aim of maintaining an overall balance of commitments in the TBT area can only be achieved if both the sub-regional (in the EU) and the sub-federal (in the US) regulations are covered.

5.4 The TBT Agreement

All of what is proposed here is considered to be consistent with, and supplementary to, the WTO TBT Agreement, to which both EU and US are signatories. Consideration should be given to incorporating the TBT Agreement into this agreement, in order to make its terms part of the agreement, and to allow disputes arising out of its terms to be dealt with bilaterally.

6. Standardisation

6.1 The EU and US approaches to standard setting and international standards

The convergence of standards and technical regulations on the basis of the use of international standards is one of the most significant tools to facilitate trade. This is acknowledged by the WTO, which puts significant emphasis on international standards (e.g. in the TBT or SPS Agreements). The EU is therefore a major supporter of the international standard-setting system. Agreeing on common standards at international level is the best way to avoid costs related to differences in product development and proliferation of different (often conflicting) technical requirements.

Although in some areas (such as electronics), the use of international standards is widespread in both Parties, there are a number of sectors where differences resulting from their different standard setting practices may create unnecessary barriers to trade. Efforts to reconcile these diverging views and systems have been high on the bilateral agenda for years. Further consideration should be given to improving links between the systems, while allowing each to maintain its distinctive character. This may offer an opportunity for progress in specific areas such as innovative products and technologies (e.g. electric vehicles, IT, green chemistry, bio-based products, cloud computing).

6.2 Implementing the "bridge-building" document

In a joint document adopted in November 2011, entitled "Building bridges between the US and EU standards systems", the EU and the US agreed on specific actions to improve each side's processes for the use of voluntary standards in regulation. Mechanisms should be created to promote cooperation and coherence in this area, in view of minimizing unnecessary regulatory divergences and better aligning the respective regulatory approaches.

The EU side has given a political commitment that in its standardisation requests to the three European Standardisation Organisations (ESOs) (European Committee for Standardization - CEN, European Committee for Electrotechnical Standardization - CENELEC and European Telecommunications Standards Institute - ETSI) the European Commission will instruct them to consider, as a basis for EU regional standards, "consensus standards developed through an open and transparent process and that are in use in the global marketplace".

The US side has given a political commitment to instruct federal agencies to consider international standards when developing regulatory measures, consistent with law and policy.

Furthermore, both sides gave a political commitment to encourage the ESOs and the American National Standardisation Institute (ANSI) to strengthen transparency and facilitate comments by stakeholders on draft standards.

6.3 Improving cooperation on common standards to further the development of international standards

Improved cooperation between US and EU standardisation bodies should be sought, including the development of joint programmes of work, and the use – or potential use – of the resulting common standards in connection with legislation. The results of bilateral cooperation should be also used to further global harmonization through the development of international standards.

There may be areas in which the development of common or technically equivalent standards could be considered. A mechanism by which the EU and

US standards systems could – by common agreement – work on common standards, for transposition in both economies, might be developed (maybe in the form of a common web-based standardisation platform).

Clearly the preference would be for such common standards to be developed by international standardisation organisations and such a bilateral approach could not apply in the general case, but the possibility should be considered in some areas of mutual interest. At any rate, exchange of technical information between expert committees in the development of standards, while leaving the possibility for each side to provide standards to the market later on, should be considered and encouraged.

6.4 Co-operation in international standards bodies

The Parties are both members of several international standardisation organisations, and as developed economies, share an interest in the development of coherent and advanced standards that are acceptable world-wide to their trade partners. Consideration could be given to systematic co-operation in the context of such bodies, possibly with exchange of technical data, common actions within such bodies, and commitment to transposing the results.

6.5 Specific technical areas

The above is intended to address the general case. There are a number of distinct technical areas in which the Parties already co-operate more closely, such as in motor vehicles, pharmaceuticals and medical devices. The Agreement should encourage the development of similar sectoral mechanisms, and be flexible enough to take into account the specific nature of the products, and the existing and planned standardizing and regulatory structures.

7. Conformity assessment

7.1 Similarities and divergences in the systems of the Parties

Although the desired level of consumer and other users' protection might be considered broadly similar in the parties, regulators on either side of the Atlantic have developed different approaches to the conformity assessment of specific products and risks. For example, the US requires third party testing or

certification for a number of products for which the EU requires only a suppliers' declaration of conformity (SDoC), e.g., safety of electrical products, and machinery. In other sectors, different conformity assessment requirements apply owing to the differences in the classification of the product; for example, in the EU there is a specific regulation for cosmetic products, while the US either does not specifically regulate them or classifies them as Over the Counter Drugs (OTCs), which sometimes implies a stricter regulatory regime.

While differences of this kind should of necessity be respected, some attempts to reduce the obstacles to trade arising from such differences between the respective systems should be considered.

7.2 The level of conformity assessment applied to products

The EU largely does not require mandatory third party certification for many products considered of low risk, and instead relies on more trade-facilitative solutions, such as manufacturers' self-declaration of conformity, with a freedom to perform any necessary testing in a laboratory of the manufacturer's choice.

Deeply rooted regulatory traditions may be difficult to change. While we should not abandon hopes to achieve greater compatibility of our conformity assessment regimes in those areas over time, we should pragmatically acknowledge that prospects for substantial convergence will generally be less promising than in new areas linked to innovative technologies or emerging risks.

However, as both the US and EU regularly re-evaluate the regulations applicable to different industrial sectors over time, some re-evaluation might be possible on a common basis when it is prompted by the same reasons (such as significant but similar market changes in both the EU and the US, changes in technology or supply chain management, or major safety issues such as the parallel substantial revision of both EU and US toy safety legislation triggered by similar concerns regarding gaps in legislation and supply chain control). These opportunities should not be missed to explore potential convergence not only as regards the technical product requirements but also in the level of certification required. Where there is demand in the market for such regulatory revision, it might be made a priority.

A future commitment might be explored by which regulators on both sides, when introducing new rules, agree in principle (as set out in the TBT agreement) to apply common criteria with a view to identifying the least trade restrictive means of conformity assessment, commensurate with the relevant risks..

In areas where registration / authorisation procedures and similar requirements apply in both Parties, approaches could be devised to make such procedures as compatible as possible and identify opportunities for administrative simplification that would alleviate burdens for manufacturers and facilitate their business under both systems.

7.3 Mutual recognition of conformity assessment

In situations where there is a valid case for mutual recognition (e.g., where the Parties both require third party conformity assessment), experience has shown that the application of mutual recognition is much more successful when based on similar requirements, usually based themselves on an international standard and/or an international agreement / scheme; furthermore, it is preferable from a trade-facilitation perspective if the agreement / scheme is not closed or applied bilaterally only, but open to several partners who apply the international standard and wish to be part of the agreement / scheme (e.g. the UN 1958 Agreement on harmonization of technical requirements for motor vehicles, the OECD Mutual Acceptance of Data system for chemicals, the IECEE CB scheme for electronics, etc.).

Usually, the concept of 'mutual recognition' is applicable to conformity assessment procedures (e.g. testing, certification). Mutual recognition of conformity assessment, in the absence of convergence of the substantive requirements underlying conformity assessment (i.e. similar technical requirements or standards) delivers limited market access benefits – such agreements are cumbersome and onerous to apply, and do not offer any incentive for the partners in question to bring their systems closer together. Furthermore, in cases where there may be differences between the level of development or regulatory rigour of the partners, there is also a basic issue of confidence in each other, undermining the commitment to mutual recognition.

The 1998 Mutual Recognition Agreement has been successful only in two areas: telecommunications, and electromagnetic compatibility (though in the

latter the EU no longer applies third party certification). It is therefore not proposed to consider extending the 1998 MRA in its present form to new areas. In the other areas that it nominally covers as well in any additional specific, mutually agreed sectors, other approaches to facilitate conformity assessment may be considered at a sectoral level.

7.4 Accreditation

Both the EU and the US rely to some extent on accreditation as a means of determining the competence of conformity assessment bodies, though their systems are different. Arrangements for mutual recognition between accreditation bodies exist through organisations such as the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF); there may be some merit in encouraging greater use of these agreements to facilitate the mutual recognition of accreditation certificates.

7.5 Marking and labelling

Marking and labelling are mentioned briefly in the TBT Agreement, but it is suggested that some disciplines be added for trade between the Parties, so that compulsory marking requirements are limited as far as possible to what is essential and the least trade restrictive. This may include origin marking where obligatory requirements are made for such marking, in which case it would be appropriate to enable EU manufacturers to mark their products as originating in the EU. Furthermore, consideration should be given to measures to inhibit the use of markings that may mislead consumers.

8. *Irritants*

A mechanism to cover trade irritants arising from the application of technical regulations, standards and conformity assessment procedures should be included as part of a common system under the Agreement as a whole.

9. *Sectoral measures*

*Initial position paper
Limited*

As indicated above, this outline is intended to cover only the general case. A number of sector specific initiatives are already in place, with the participation both of the EU and the US. These should not be affected, nor – as indicated above - should any new sectoral initiatives for enhanced co-operation be inhibited.

Anti-Trust & Mergers, Government Influence and Subsidies

I. Anti-trust & mergers

Objectives

The report of the EU-US High Level Working Group on Jobs & Growth concludes that a "comprehensive and ambitious agreement that addresses a broad range of bilateral trade and investment policies, including regulatory issues" could generate substantial economic benefits on both sides of the Atlantic.

Trade liberalisation has led to the globalisation of the markets. In some instances, however, traditional tariff barriers have been replaced by behind-the-border barriers such as anti-competitive practices by private and public enterprises. Such practices may have serious adverse impacts on international trade and can often be addressed in an effective manner through a proactive enforcement of competition laws.

The EU considers competition policy an essential element to ensure well-functioning markets, both domestically and abroad, and an important part of its trade relations. Although the EU and US competition systems have developed at different times and under different conditions, both partners share a belief in the need for impartial and proactive competition enforcement, subject to the rule of law and the control of the courts. The shared objective of promoting open, fair and competitive international markets have allowed effective cooperation in practice, bilaterally and in the framework of multilateral forums such as the International Competition Network (ICN) and the OECD Competition Committee (OECD CC). The relationship between the EU and the US in competition matters is the bedrock on which global competition enforcement is based.

The TTIP therefore provides the parties with a unique opportunity to jointly articulate the shared values and affirm the existing practices and procedures which they adhere to. Both the EU and the US have consistently sought to include ambitious competition related provisions in their respective bilateral negotiations with other important trading partners. Drawing from the two partners' special relationship in the field of competition enforcement, the TTIP's competition provisions would set a benchmark and send a strong message to trading partners around the world for future negotiations.

Proposed content

In light of the global context and the objectives set out above, the TTIP should include provisions with anti-trust & merger disciplines. These provisions should reflect the shared global interests and concerns and thereby constitute a platform for further development of competition disciplines and cooperation of interest also for other economies and markets. In this context, the EU and the US may wish to address anti-competitive behaviour that should be disciplined, the legislative and institutional framework for the enforcement of these disciplines that contain provisions on cooperation and exchange of information. The TTIP could also address rules and principles aiming at ensuring competitive neutrality by envisaging enforcement of competition laws on all enterprises. More specifically, the provisions on antitrust and mergers could address the following issues:

- Recognition of the benefits of free and undistorted competition in the trade and investment relations;
- Consideration of best practices and of the possibility to consolidate some of them;
- A commitment to maintain an active enforcement of antitrust and merger laws, with a generally worded description of the types of anti-competitive behaviour it should cover;
- A commitment to ensure that competition policy is implemented in a transparent and non-discriminatory manner, in the respect of the principle of procedural fairness, irrespective of the ownership status or nationality of the companies concerned;
- Provisions regarding the application of antitrust and merger rules to state owned enterprises (SOEs) and enterprises granted special or exclusive rights or privileges (SERs), save for narrowly defined legitimate exceptions (e.g. “Services of General Economic Interest” in the EU);
- Moreover, to address specifically the bilateral cooperation aspects between the EU and the US, the TTIP could include provisions on cooperation between the competition agencies of the parties, reflecting and building on the current practice under the existing EU-US cooperation agreements. In addition, it could be explored whether the parties could address the possibility for a further deepening of the cooperation arrangements in case related work in the future, such as creating a framework allowing for the exchange of confidential information in the absence of confidentiality waivers between competition authorities when they are investigating the same or related cases (while barring the use of this information for criminal sanctions). The TTIP could include a basis for developing such arrangements in a separate arrangement.

- A commitment to cooperate in multilateral forums with the aim of promoting convergence of antitrust and merger rules at a global level.
- Provisions on antitrust/mergers shall not be subject to the general dispute settlement mechanism of the agreement.

II. Government influence and subsidies

II.1. State-owned enterprises (SOEs) and enterprises granted special or exclusive rights or privileges (SERs)

Objectives

The EU is increasingly concerned about the discriminatory behaviour and the subsidization of state owned, controlled and influenced companies around the world. Overall, state presence in the global economy remains significant and has even increased in recent years. State involvement and influence can extend to all levels of government and to different sectors of the economy.

Various types of advantages and privileges that governments grant to companies can in some cases unjustifiably disadvantage EU and US companies. The EU and the US could therefore identify and discuss the concerns they have in this respect and identify issues that should be tackled in a global context.

The EU concerns regarding state ownership or influence extend to enterprises granted special and exclusive rights or privileges (SERs). State ownership, control and influence can take various forms, ranging from designating monopolies to SOEs but also include companies that have been granted special rights or privileges, regardless of ownership. The EU considers that it is important to cover those companies that can otherwise escape competitive pressures of the market as a result of government action, save for narrowly defined legitimate exceptions (e.g. “Services of General Economic Interest” in the EU).

The EU Treaties are neutral as to the ownership of companies and competitive neutrality between public and private actors is ensured in the EU legislation. Therefore, the EU is not against public ownership in itself, provided that publicly owned or controlled enterprises are not granted a competitive advantage in law or in fact. In certain circumstances, however, advantages that SOEs/SERs enjoy may hinder market access, distort market conditions and affect export competition. Governments may interfere with the competitive process by

inducing or ordering SOEs/SERs to engage in anti-competitive behaviour, by taking regulatory measures favouring these companies, or by granting subsidies (or measures which have similar effects) to them. The same could apply to some formally private sector companies.

SOEs/SERs may therefore enjoy privileges and immunities that are not available to their competitors, thereby giving them a competitive advantage over their rivals. In the absence of a framework to ensure that such instances occur only under strict conditions, such state intervention can distort the level playing field between SOEs/SERs and companies which do not benefit from the same privileges and immunities. This may even have negative effects on global markets. For these reasons, the EU considers that rules should be developed to ensure a level playing field between state-owned or influenced companies and their competitors at all levels of government.

The TTIP should therefore serve as a platform to address issues where government interference is distorting markets, both at home and in third countries at all levels of government. The objective of the EU is to create an ambitious and comprehensive global standard to discipline state involvement and influence in private and public enterprises, building and expanding on the existing WTO rules. This could pave the way for other bilateral agreements to follow a similar approach and eventually contribute to a future multilateral engagement.

Proposed content

The parties should jointly seek to identify the types of companies and behaviour that need to be addressed with a view to creating fair market conditions between private and public companies.

This could cover monopolies and state enterprises but also address enterprises granted special rights or privileges (SERs). Definitions should be sufficiently broad to catch all the relevant market players and to ensure that rules are comprehensive and not easily circumvented. In the case of state enterprises, the parties could consider a definition which rests both on ownership but, alternatively, also on effective control, aiming at capturing the possibility of the state to exercise decisive influence over the strategic decision making of the enterprise.

The distinction should effectively be made between those companies (public or private), which have been afforded a special or exclusive right or privilege, and those where the government has a controlling interest but which compete on the market. Provisions would cover all levels of government in order to catch the important SOEs/SERs that might exist at sub-central levels. Both existing and designated enterprises should be covered.

In view of the above, the following provisions on SOEs/SERs could be considered:

- Rules that address discriminatory practices of SOEs/SERs when selling and purchasing (while leaving government procurement issues to be addressed in the relevant chapter of the TTIP). SOEs/SERs which provide a distribution/transmission network to competitors should also follow these rules.
- An obligation for SOEs/SERs to act according to commercial considerations. However, enterprises would not necessarily need to meet the obligation to act according to commercial considerations when fulfilling the specific purpose (e.g. universal service obligation) for which they have been granted a special or exclusive right or privilege.
- A prohibition to cross-subsidise a non-monopolised market, similar to that contained in GATS Article VIII, should be considered also for goods.
- Transparency is the starting point for levelling the playing field between private and public enterprises. This calls for rules based on the relevant international best practices. These rules could aim at fostering transparency related to e.g. ownership and decision making structures, links with other companies, financial assistance received from the state, and regulatory advantages such as exemptions, immunities and non-conforming measures.

II.2 Subsidies

Subsidies may distort competition and may contribute to disruption in global markets and the terms of trade. Subsidization can artificially shift competitive advantage to the subsidizing countries. Subsidies to SOEs/SERs may further distort the level playing field between these enterprises and companies that do not benefit from such subsidies. The EU is concerned about the subsidization not only of SOEs/SERs but also of the private sector in some situations, e.g. by direct grants, below-market interest rates on loans or unlimited guarantees.

The WTO Agreement on Subsidies and Countervailing Measures (ASCM) disciplines the use of subsidies, and regulates the actions countries can take to counter the effects of subsidies. Also GATS stipulates that negotiations will be held with a view to developing necessary disciplines to avoid the trade-distortive effects of subsidies that may arise in certain circumstances and to address the appropriateness of countervailing procedures. It also requires members to exchange information concerning all subsidies related to trade in services that they provide to their domestic service suppliers.

Subsidy disciplines in a bilateral context are aimed at preventing trade distortions and nullification of the commitments negotiated in the agreement. The TTIP would provide an important opportunity to explore the shared concerns in this area, taking the already binding WTO disciplines, in particular those foreseen in the ASCM, as a starting point to improve the global approach.

Improved transparency and cooperation, in line with but not necessarily limited to the existing requirements of the WTO regarding subsidies, could be a first step. Such combined efforts could have a demonstration effect on other WTO members subject to the same WTO transparency requirements. The TTIP also provides an opportunity to develop consultation mechanisms related to subsidies affecting trade between the EU and the US.

In view of the fact that services form an important part of trade between the EU and the US, the parties could analyse the impact of related subsidies and consider if there could be a shared interest in addressing them. In general, disciplining the most important and distortive types of subsidies could contribute to meeting the objective of the TTIP to reach a more ambitious level of trade and economic integration between the EU and the US.

Proposed content

In the context of the TTIP, which aims at creating a more integrated EU-US market, the EU considers it appropriate to include provisions on subsidies, including subsidies to SOEs/SERs and financing to and from SOEs/SERs, and subsidies to services.

More specifically, the following provisions on subsidies could be considered:

- Mechanisms to provide improved transparency (subsidies to goods and services).
- Consultation mechanisms to allow for an exchange of information on subsidies to goods and services that may harm the other party's trade interests, with the view of finding a mutually acceptable solution.
- Addressing the most distortive forms of subsidies.

Without prejudice, 20 June 2013

TTIP: Cross-cutting disciplines and institutional provisions

INITIAL POSITION PAPER

I. Introduction

A. The five regulatory components of TTIP and purpose of this paper

The final report of the High Level Working Group on Jobs and Growth of 11 February 2013¹ refers to **five basic components of TTIP provisions on regulatory issues**: the SPS plus component would build upon the key principles of the WTO SPS Agreement, and provide for improved dialogue and cooperation on addressing bilateral SPS issues; the TBT plus component would build on provisions contained in the WTO TBT Agreement as regards technical regulations, conformity assessment and standards; sectoral annexes would contain commitments for specific goods and services sectors.

The other two components, which are the focus of this paper, consist in:

- i. “Cross-cutting disciplines on regulatory coherence and transparency for the development and implementation of efficient, cost-effective, and more compatible regulations for goods and services, including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices.”
- ii. “A framework for identifying opportunities for and guiding future regulatory cooperation, including provisions that provide an institutional basis for future progress.”

This paper is meant to provide elements for a reflection on component i) which would be part of a horizontal chapter, as well as on component ii). In line with the usual practice for trade agreements, the main provisions pertaining to component ii), e. g. the substantial tasks and competences of the regulatory cooperation body or committee, would be outlined in the horizontal chapter, while the procedural rules (e.g. how this body operates, and its composition, terms of reference, etc.) would be placed in the institutional chapter of TTIP (see further section II C point 4). Although the horizontal chapter would apply to all goods and services sectors, specific adaptations for certain sectors (e.g. financial services) could be envisaged.

¹ http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf

B. Rationale for an ambitious approach

Elimination, reduction and prevention of unnecessary regulatory barriers are expected to provide the biggest benefit of the TTIP². But far beyond the positive effects on bilateral trade the TTIP offers a unique chance to give new momentum to the development and implementation of international regulations and standards (multilateral or otherwise plurilateral). This should reduce the risk of countries resorting to unilateral and purely national solutions, leading to regulatory segmentation that could have an adverse effect on international trade and investment. Joint EU and US leadership can contribute to such an objective.

New and innovative approaches will be needed in order to make progress in removing unnecessary regulatory complexity and reducing costs caused by unnecessary regulatory differences, while at the same time ensuring that public policy objectives are reached.

C. Scope of the horizontal chapter

The ultimate scope of the TTIP regulatory provisions – i.e. the precise definition of the regulations/regulators to which TTIP will apply - will need to be determined in the course of the negotiations in the light of the interests and priorities of both parties. In principle, the TTIP regulatory provisions would apply to regulation defined in a broad sense, i.e. covering all measures of general application, including both legislation and implementing acts, regardless of the level at which they are adopted and of the body which adopts them. A primary concern when defining the scope will be to secure a ***balance in the commitments made by both parties***.

Disciplines envisaged

The horizontal chapter would contain principles and procedures including on consultation, transparency, impact assessment and a framework for future cooperation. It would be a “gateway” for handling sectoral regulatory issues between the EU and the US but could in principle also be applied to tackle more cross-cutting issues, e.g. when non-sector specific regulation is found to have a significant impact on transatlantic trade and investment flows. Further commitments pertaining specifically to TBT, SPS or various product or services sectors (e.g. automotive, chemicals, pharmaceuticals, ICT, financial services etc.) would be included respectively in the TBT and SPS chapters and sectoral annexes/provisions. Disciplines envisaged should not duplicate any already existing procedures under the TBT and SPS Agreements.

² According to the study “Reducing Transatlantic Barriers to Trade and Investment” (http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf, Table 17), reduction of non-tariff measures under an ambitious scenario would provide for ***two thirds of the total GDP gains of TTIP*** (56 % coming from addressing NTBs in trade in goods and 10 % in trade in services).

Coverage of products/services

The rules and disciplines of the horizontal chapter would in principle apply to regulations and regulatory initiatives pertaining to areas covered by the TTIP and which concern product or service requirements. The objective should be to go beyond the regulations and aspects covered by the WTO TBT and SPS Agreements. The precise elements determining coverage will need to be discussed, but it is understood that there will be a criterion related to the significant impact of covered regulations on transatlantic trade and investment flows. To the extent necessary, some specific aspects may be addressed in other chapters (e.g. trade facilitation, competition).

II. Possible outline and structure of a horizontal chapter

A. Underlying principles

Certain basic principles underlying the regulatory provisions of TTIP need to be highlighted, including the following:

- a) The ***importance of regulatory action to achieve public policy objectives***, including the protection of safety, public health, the environment, consumers and investors, at a level that each party considers appropriate. TTIP provisions should contribute to such protection through more effective and efficient regulation by the application of best regulatory practices and improved cooperation among EU and US regulators. Insofar as possible, priority should be given to approaches and solutions relying on international (multilateral or plurilateral) disciplines whose adoption and application by the EU and the US would encourage other countries to join in.
- b) TTIP provisions shall ***not affect the ultimate sovereign right of either party to regulate*** in pursuit of its public policy objectives and shall not be used as a means of lowering the levels of protection provided by either party.
- c) ***The tools used to achieve the regulatory objectives of TTIP will depend*** on the issues and the specificities of each sector. The general instruments available include consultations and impact assessment. Other instruments may be developed in the context of sector specific regulatory cooperation.

B. Overall objectives

The overall objective of the regulatory provisions of the TTIP will be to **eliminate, reduce or prevent unnecessary “behind the border” obstacles to trade and investment**. In general terms (although this may not be applicable in all cases), the ultimate goal would be a more integrated transatlantic market where goods produced and services originating in one party in accordance with its regulatory requirements could be marketed in the other without adaptations or requirements. Achieving this long-term goal will entail:

- **Promoting cooperation between regulators** from both sides at an early stage when

preparing regulatory initiatives, including regular dialogue and exchange of information and supporting analysis as appropriate.

- **Promoting the adoption of compatible regulations** through prior examination of the impact on international trade and investment flows of proposed regulations, and consideration of common/convergent or compatible regulatory approaches where appropriate and feasible.
- **Achieving increased compatibility/convergence in specific sectors, including through recognition of equivalence, mutual recognition or other means as appropriate.**
- **Affirming the particular importance and role of international disciplines** (regulations, standards, guidelines and recommendations) as a means to achieve increased compatibility/convergence of regulations.

C. Substantial elements

Cross-cutting regulatory disciplines would concentrate on three main areas: first, regulatory principles, best practices and transparency; second, assessment of the impact of draft regulations or regulatory initiatives on international trade and investment flows; and third, cooperation towards increased compatibility/convergence of regulations. Some institutional mechanisms will also be necessary to provide a framework for delivery of results and enable for necessary adjustments to ensure the effectiveness of the agreement in practice (see section II C point 4).

1. Regulatory principles, best practices and transparency

The TTIP could take as a starting point the 2011 Common Understanding on Regulatory Principles and Best Practices endorsed by the US government and the European Commission at the June 2011 meeting of the HLRCF³. The TTIP would incorporate the basic principles and main elements. The outcome should be a comparable level of transparency applicable on both sides along the process of regulation.

The main provisions would include:

- An effective bilateral cooperation/consultation mechanism. A commitment of both sides to keep each other informed in a timely manner on the main elements of any forthcoming regulatory initiatives covered by this chapter. This could be complemented with a strengthening of contacts, in any format, between both sides' regulators, so that each side can have a good understanding of the regulations or regulatory initiatives being considered or prepared by the other, in a way that they can share with the other side any relevant considerations (see next point). Note that early consultations may not be feasible where urgent problems of health protection arise or threaten to arise.
- An improved feedback mechanism:
 - Both parties should have the opportunity to provide comments before a

³ http://trade.ec.europa.eu/doclib/cfm/doclib_section.cfm?order=abstract&sec=146&lev=2&sta=41&en=60&page=3

proposed regulation is adopted in accordance with the respective decision-making processes and should be given sufficient time for doing so. They should also receive explanations within a reasonable timeline as to how these comments have been taken into account.

- This should be done without duplicating the activities under the WTO TBT and SPS Agreements in a manner consistent with the parties' respective decision-making processes.
 - For example, the TBT Agreement already introduces a system of notification of new draft technical regulations and conformity assessment procedures, in which the EU and the US actively participate. An improved bilateral mechanism for comments and replies in the context of the WTO TBT Agreement would provide for enhanced transparency and would allow for a dialogue between regulators with regard to the notified draft measure. Consistent with Article 2.9.4 and 5.6.4 of the TBT Agreement, this should enable both parties to provide feedback to each other, regardless of the initiator of the proposal. Of particular importance will be the possibility to receive replies to comments and to have a bilateral exchange on notified draft measures with the ability for regulators to communicate with each other during the comments procedures. As for the SPS Agreement, there is a mirroring notification system in place consistent with article 7 on Transparency and Annex B of the WTO SPS Agreement.
- Cooperation in collecting evidence and data. Regulatory compatibility and convergence of regulations could be enhanced through the collection and use by the parties, to the extent possible, of the same or similar data and of similar assumptions and methodology for analysing the data and determining the magnitude and causes of specific problems potentially warranting regulatory action. Such exchange would be of particular interest regarding best available techniques and could lead to convergence of requirements and provide inspiration to third countries.
 - Exchange of data/information: Effective cooperation requires regulators to exchange information, which may be protected and subject to different and sometimes conflicting legal requirements. While multiple approaches will continue to exist in areas such as data protection and privacy, a process could be put in place to facilitate data exchange, without prejudice to any sector-specific provisions.

2. Assessment of the impact of draft regulations or regulatory initiatives on international trade and investment

Both the Commission and the US Administration have different systems in place to assess the impacts of regulations and regulatory initiatives. As part of the TTIP both sides should agree to strengthen the assessment of impacts of regulations and regulatory initiatives on international trade and investment flows on the basis of common or similar criteria and methods and by way of closer collaboration. In their assessment of options, regulators from each side would for example be invited to examine impacts on international trade and

investment flows, including on EU-US trade as well as on increased compatibility/convergence.

TTIP could also include provisions furthering transatlantic cooperation on ex-post analysis of existing regulations that come up for review with a view to examining whether there is scope for moving toward more compatibility and coherence including towards international standards/regulations and removing unnecessary regulatory complexity.

3. Regulatory cooperation towards increased compatibility/convergence in specific sectors

Preparatory work on sectors has started with strong support from stakeholders on both sides of the Atlantic. Many organisations contributed to the Joint EU-US Solicitation on regulatory issues of September 2012 and explained their suggestions to EU and US regulators at the stakeholder meeting of the April 2013 EU-US High Level Regulatory Cooperation Forum. These suggestions form an important input into TTIP regulatory work on sectors.

By the time the TTIP is concluded, it is expected that a number of specific provisions will have been agreed as part of various sector annexes, the TBT or the SPS chapters and other parts of the agreement. Some of these provisions will be implemented either upon entry into force or, as necessary, at a later fixed date. Other issues will have been identified on which the parties will continue to work with the aim of achieving increased compatibility/convergence, including by way of recognition of equivalence, , mutual recognition, or other means as appropriate, and with fixed objectives and timetables where possible. Other provisions will strengthen EU-US cooperation and coordination in multilateral and plurilateral fora in order to further international harmonisation. As regards future regulations, there should also be provisions and mechanisms to promote increased compatibility/convergence and avoid unnecessary costs and complexities wherever possible.

However, there will remain a number of areas warranting further work, which will be either identified when the TTIP negotiations are finalized or subsequently (“inbuilt agenda”). For those areas the TTIP should provide regulators with the means and support they need to progressively move towards greater regulatory compatibility/convergence and make TTIP a dynamic, ‘living’ agreement sufficiently flexible to incorporate new areas over time. Regulators need to have clear authorization and motivation to make use of international cooperation in order to increase efficiency and effectiveness when fulfilling their domestic mandate and TTIP objectives.

From this perspective the TTIP could include:

- Provision of a general mandate (understood as a legal authorization and commitment) for regulators to engage in international regulatory cooperation, bilaterally or as appropriate in other fora, as a means to achieve their domestic policy objectives and the objectives of TTIP.
- Provision to launch, upon the request of either party, discussions on regulatory differences with a view to moving toward greater compatibility which would enable the

parties to consider recognition of equivalence in certain sectors, where appropriate. The request could be based on substantiated proposals from EU and US stakeholders.

Flexible guidance could be provided for the examination of these proposals, including on the criteria for the assessment for functional equivalence or other concepts and scheduling of progress towards regulatory greater compatibility/convergence.

4. Framework and institutional mechanisms for future cooperation

An institutional framework will be needed to facilitate the application of the principles of the five regulatory components as described under I. A, including the provisions of the horizontal chapter laid out in section II C 1, 2 and 3.

Essential components of such a framework include:

- A **consultation procedure** to discuss and address issues arising with respect to EU or US regulations or regulatory initiatives, at the request of either party.
- A **streamlined procedure to amend the sectoral annexes** of TTIP or to add new ones, through a simplified mechanism not entailing domestic ratification procedures.
- A **body with regulatory competences** (a regulatory cooperation council or committee), assisted by sectoral working groups, as appropriate, which could be charged with overseeing the implementation of the regulatory provisions of the TTIP and make recommendations to the body with decision-making power under TTIP. This regulatory cooperation body would for example examine concrete proposals on how to enhance greater compatibility/convergence, including through recognition of equivalence of regulations, mutual recognition, etc. It would also consider amendments to sectoral annexes and the addition of new ones and encourage new regulatory cooperation initiatives. Sectoral regulatory cooperation working groups chaired by the competent regulatory authorities would be established to report to the regulatory cooperation council or committee. The competences of the regulatory cooperation council or committee will be without prejudice to the role of committees with specific responsibility on issue areas such as SPS.

EU-US FTA negotiations
Non paper on Public Procurement

1 Preliminary remarks

The EU suggests devoting the discussions in the first meeting/round to operational issues related to the negotiations on Public Procurement (PP). This implies that the discussion would focus on seeking a common view both on the overall substantive approach and the concrete organisation and sequencing of the negotiations.

In this initial process, the EU would like to emphasize the particular weight to be given to the understanding reached in the context of the High Level Working Group on Jobs and Growth with a view to achieving the goal of enhancing business opportunities through substantially improved access to government procurement opportunities at all levels of government on the basis of national treatment.

It is of utmost importance to make sure that both rules and market access issues are thoroughly dealt with in the course of the negotiations, with a view to reach as substantial result bilaterally as possible.

This approach does not preclude that the Parties would discuss issues in the course of the negotiations that prove relevant for the overall objective of further global liberalisation of trade in procurement.

First section: Substantive approach proposed by the EU

2 Overall architecture and scope of application of the PP chapter

2.1 Text structure

This negotiation would present an important opportunity for the EU and the U.S. to develop together some useful "GPA plus" elements to complement the revised GPA disciplines, with a view to improve bilaterally the regulatory disciplines. A model text agreed between the EU and the U.S., being the two largest trading partners in the world, could thus possibly set a

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higher standard that could inspire a future GPA revision and where appropriate serve as a basis for the works conducted under the work program outlined in the WTO GP committee's decisions adopted on the 31st of March 2012. Beside this aspect the main focus of these negotiations will be to ensure better market access terms for EU and U.S. companies.

Two drafting options could be considered for the text of the PP Chapter:

- A PP Chapter comprising only "GPA plus" rules but which will incorporate the revised GPA text by reference, or
- A PP Chapter directly taking over the revised GPA text, including the amendments required to achieve the "GPA plus" outcome targeted.

The extent to which improved rules compared to the revised GPA text are required, should be an important factor in deciding whether the second option (improved revised GPA text as a whole) would be necessary to bring sufficient clarity and legal certainty to the agreed provisions of the PP Chapter.

It would be useful if the PP Chapter would also include rules allowing the Parties to take into account possible changes in the GPA disciplines, including, if appropriate, the outcome of the works conducted under the Work Program outlined in the WTO GP committee's decisions adopted on the 31st of March 2012.

2.2 Scope of application

The EU proposes that, to the extent possible, the improved rules negotiated bilaterally would apply to the entire scope of the GPA commitments undertaken by both Parties, as well as to additional market access commitments undertaken under the bilateral FTA, at federal as well as at state level.

3 Improved rules to be developed in the PP Chapter

3.1 Remedies to address existing trade barriers linked to the existing domestic regulations or domestic practices at central as well as at sub-central levels

The EU would suggest to include the following topics for negotiations – without prejudice to others that may be deemed relevant to address at a later stage:

- Definitions
- Removal of barriers to cross-border procurement and to procurement via established companies

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- Consolidate and further improve the level of access to procurement-related information (transparency)
- Alleviate administrative constraints
- Make sure that the practical application of the e-procurement rules in the EU and the U.S. are not creating additional barriers to trade
- Make sure that the size of procurement contract is not used with a view to circumvent the market access commitments under the Chapter
- Ensure that technical specifications do not constitute an artificial barrier to trade.
- Provisions relating to qualitative award criteria
- The domestic challenge mechanisms

In addition, in certain other areas such as green procurement, rules could be examined and if need be improved.

3.2 Coverage-related disciplines

Besides the removal of the notes describing carve-outs in the Parties' schedules, we would propose to also make adequate provisions on coverage in the text. The EU would suggest to include the following topics for the negotiations for coverage-related disciplines - without prejudice to other topics that may be deemed relevant to address at a later stage:

- Ensure that rules on off-sets/set asides or domestic preferences such as, but not limited to, Buy America(n) and SME policies, do not restrict procurement opportunities between the EU and the U.S.
- Ensure committed coverage at federal level extends to cover also federal funding spent at the State level.
- Ensure the removal of possible discriminatory elements for example related to procurement by public authorities and public benefit corporations with multi-state mandates, interagency acquisitions, task and delivery order and in the field of taxation.

Moreover, discussions on additional elements of coverage, such as state-owned enterprises, public undertakings and private companies with exclusive rights may require the introduction of additional definitions and related rules.

Provisions should also be made for a mechanism for adjustments related to modifications and rectifications to coverage.

3.3 *Horizontal disciplines*

In the EU's views, the PP Chapter should as noted above under 2.2. also include rules allowing the Parties to take into account possible changes in the GPA disciplines.

4 Market Access discussions

4.1 *Scope of market access discussions*

4.1.1 *Improvement of GPA market access schedules*

Both Parties have accepted to enter into discussions affecting all the elements of their schedules at central as well as sub-central levels.

This implies that the negotiations should look for an expansion of coverage, to the extent possible, for all these schedules, by the removal of existing carve-out and by the offer of additional commitments.

In concrete terms, Parties should seek to improve access to and/or expand the coverage of:

- Central Government entities
- Sub-central entities
- Other entities with a view to specific sectors*
- Services
- Construction services
- Information society services, in particular cloud-based services

**including market access negotiations on transit/railways, urban railways and urban transport.*

The EU suggests - without prejudice - that the discussions on coverage would include:

For Annex 1, all central government entities and any other central public entities, including subordinated entities of central government.

For Annex 2, all sub-central government entities, including those operating at the local, regional or municipal level as well as any other entities whose procurement policies are substantially controlled by, dependent on, or influenced by sub-central, regional or local government and which are engaged in non-commercial or non-industrial activities.

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For Annex 3, all entities governed by public law, state owned companies and similar operating in particular in the field of utilities.

The elements required are here presented in the form of positive lists, but for the actual commitment the EU expects this to be done in the form of negative lists. It would also include procurement currently subject to restrictions related to domestic preferences programmes for example linked to federal funding or procurement pursuant to multi-jurisdictional agreement.

For the US system this would imply:

Annex 1 For example entities not yet covered such as the Federal Aviation Administration. It would also cover procurement currently subject to restrictions or domestic preferences related to federal funding as well as procurement regulated by specific policies and rules, such as those related to Buy America(n) provisions as well as those related to SMEs. The coverage would follow the projects funded by FAA even if they were channelled to a sub-federal level for actual spending.

Annex 2 It would concern all those States that are neither covered by the GPA nor by our bilateral agreement, such as Alabama, Alaska, Georgia, Indiana, Nevada, New Jersey, New Mexico, North Carolina, Ohio, South Carolina, and Virginia. It would also imply an upgrading to GPA standard of the access to North Dakota and West Virginia. Furthermore, it would imply a substantial upgrading of the coverage in the States currently covered in general by way of addressing current derogations as well as to include for example also larger cities and metropolitan areas such as New York, Los Angeles, Houston, Philadelphia, Phoenix, San Diego, San Jose, Jacksonville, Austin, San Francisco, Columbus, Fort Worth, Charlotte, El Paso, Memphis, Seattle, Denver, Baltimore, Washington, Louisville, Milwaukee, Portland and Oklahoma City.

Annex 3 For example entities not yet covered by neither the GPA nor by our bilateral agreement, such as procurement currently subject to restrictions or domestic preferences related to federal funding or procurement currently restricted by requirements for example decided by the Board of Directors of the Ports of New York and New Jersey.

Annex 4 All related **goods** not yet covered by the GPA or our bilateral agreement.

Annex 5 All **services** procured by entities listed in Annexes 1 through 3 in the coming

EU/US agreement.

Annex 6 All **construction services** not yet covered by the GPA or our bilateral agreement, including for example transportation services that are incidental to a procurement contract.

The above given examples are indicative – the EU reserves the right to revise the list and any listing would be for illustrative purposes only.

To ensure a uniform and extensive coverage:

- all entities falling under the “catch-all-clauses” as defined in Annex 1 to 3 would be covered by the Agreement.
- a system based on definition: an entity will be captured by the criteria laid down in the definitions.

4.2 Coverage related approach

For the purpose of these negotiations on improved schedules, the Parties will discuss the potential inclusion of new entities and sectors plus revised thresholds.

The EU suggests enlarging this approach to the expansion of coverage via discussions on **public private partnerships** (PPP). It is worth exploring what can be achieved in this domain to obtain a more comprehensive coverage of PPPs/and or a better clarification on the rules to be applied to such contracts, including contracts related to BOTs and similar set ups.

4.2.1 Systemic linkages with other FTA chapters

As made clear by several GPA parties under their respective schedules for services, market access commitments on services under the GPA do not concern the modes of supply of the services offered. Therefore, in the FTA context, it is important to establish a proper linkage between the schedules in the Services Chapter or the Investment Chapter and the schedules of the PP Chapter, to ensure, that economic operators can actually benefit in practice from concessions made in another Chapter.

Both parties should also explore how to bridge the PP Chapter with the Competition Chapter when dealing with the categories of SOEs, public undertakings and private companies with

exclusive rights. Issues relevant to investment in goods may also require similar considerations.

Second section: Organisation and sequencing of the negotiations
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5 Organisation of the negotiations

5.1 Text proposals for the PP chapter as a whole

Subject to the decision at the Chief Negotiator level, the EU is willing to submit text proposals on the PP Chapter, in parallel or not to a submission by the U.S. Texts could for example be exchanged at the second round.

5.2 Market access discussions

As for other Chapters, market access discussions should at points in time to be determined result in formal exchanges of requests and offers.

5.4 Organisation of intersessional discussions

The EU is open to the possibility of intersessional discussions.

INITIAL POSITION PAPER ON TRADE AND INVESTMENT IN RAW MATERIALS AND ENERGY FOR THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP) NEGOTIATIONS BETWEEN THE EU AND THE US

Introduction

This paper aims to identify common ground between the EU and the US regarding the treatment of raw materials and energy in the context of the EU–US Transatlantic Trade and Investment Partnership (TTIP) negotiations.

Non-discriminatory access to raw materials and energy and their subsequent trade across borders has remained at the margins of international trade and investment rules over the last decades. Yet forecasts suggest demand will continue to grow across sectors and countries as the world population grows and living standards improve. In parallel, efficient distribution has also become more pressing in particular for EU and US companies as production processes rely on a wider variety of critical inputs, some of which can be found only in a limited number of locations.

Although the US's energy landscape is changing, US and EU companies will remain dependent on open markets to source significant parts of their raw material and energy needs far into the future. Our companies operate complex raw material and energy supply chains, with varying dependences as processors, suppliers, importers and exporters, and as consumers too. Downstream companies depend on inputs of energy and raw materials from third countries, while upstream companies compete for access to resources abroad.

World Trade Organisation (WTO) rules have largely remained at the margins of international production and trade in raw materials and energy, as reflected in the WTO's 2010 annual report which was devoted to this issue. The WTO rulebook contains tough rules to tackle import barriers, and weaker concomitant rules to address export barriers. This has affected energy and raw materials disproportionately, insofar trade restrictions in this area are more pertinent on the export side. Other examples are the lack of definition of energy services in GATS, an absence of effective rules on international transit of energy goods transported by pipeline, prevalent trade and distribution monopolies in countries where domestic production is not monopolised, widespread use of local content requirements imposed on the equipment of foreign companies when they operate large scale projects in third countries, and insufficient transparency in regulatory processes pertaining to the granting of licenses for exploitation or trade in energy products.

The EU and the US have worked closely together over the past years and sent a strong signal in support of open trade and non-discriminatory access for raw materials and energy. Some of the above shortcomings have been partially addressed in the WTO accession protocols of countries like China or Russia, and in FTAs negotiated by the EU and the US. Some progress has also been achieved through the dispute settlement process. The multilateral trade system would however benefit from a stronger set of rules in the area of energy and raw materials. Indeed, international trade agreements have made only a modest contribution to promoting the application of market principles in this area regarding access, distribution, trade and sale.

The TTIP could therefore make an important contribution to the development of that process, within limits agreed by both sides. It could provide a basis to take the issues forward in a more comprehensive manner by providing an open, stable, predictable, sustainable, transparent and non-discriminatory framework for traders and investors in raw materials and energy, in a way that also serves our wider shared geo-strategic and political objectives for the longer term.

Disciplines agreed in the transatlantic context could serve as a model for subsequent negotiations involving third countries. It also sends a powerful signal to other countries that trade in raw materials and energy can be and will be subject to global governance, including the fundamental principles of transparency, market access and non-discrimination. In addition, agreed rules on trade and investment in raw materials and energy would also contribute to developing and promoting sustainability.

Approach

It is understood that general disciplines and commitments concerning trade in goods and services, and investment, negotiated in the TTIP will apply to raw materials and energy, including e.g. non-discrimination, the elimination of import and export duties and other restrictions relating to import or exports.

It is also understood that where the general rules do not address certain energy and raw materials related issues, these should be covered by energy and raw materials specific rules. Such rules would go beyond existing WTO provisions and in particular beyond the provisions in GATT and GATS. There are precedents as both the EU and the US have negotiated such specific rules with third countries.

Disciplines for the template

Scope

In principle, the scope of the specific rules could include measures related to trade and investment in raw materials i.e. raw materials used in the manufacture of industrial products and excluding e.g. (processed) fishery products or agricultural products, and energy products, i.e. crude oil, natural gas electrical energy and renewable energy.

The following areas have been identified around which specific raw material and energy provisions could be developed.

Transparency

Increasing transparency and predictability is the first and most important step towards a better (global) governance of trade in raw materials and energy. Transparency improves investment opportunities, facilitates continued production, and improves the functioning and expansion of infrastructure, including for transportation. The agreement should encourage **transparency** in the process of licensing and allocation conditions of licences that could be required for trade and investment activities in this area.

Market access and non-discrimination

In line with this objective, the elimination of export restrictions, including duties or any measure that have a similar effect should be ensured.

As regards exploration and production of raw materials and energy, it is important to confirm that the parties should remain fully sovereign regarding decisions on whether or not to allow the exploitation of their natural resources. Once exploitation is permitted **non-discriminatory** access for exploitation, including for corresponding trade and investment related opportunities, should be guaranteed by regulatory commitments. In terms of regulatory commitments related to exploration and production of energy, the US and EU should also have an interest in developing further common standards as regards off shore safety, on the basis of their respective domestic legislation. Additionally, it should be assessed how to incorporate elements related to the Extractive Industry Transparency Initiative (EITI), which reflects both the EU and US domestic legislation.

The EU and the US should consider rules on transport of energy goods by natural gas pipelines or electricity grids, which would be particularly relevant in countries with monopolized pipelines. In this context, there should be regulation of transport and transit. The agreement could provide that if private construction of infrastructure is not allowed or not economically viable, Third Party Access (TPA) should be mandatory, subject to regulatory control by an independent regulator vested with the legal powers and capacity to fulfil this function. Transit rules should be compatible with - and at least as favourable as - the transit rules defined in the Energy Charter Treaty. They should be established in a manner to avoid or mitigate an interruption of energy flows.

Competitiveness

There are at least two different areas where **competitiveness** in the raw materials and energy markets can be improved.

Government intervention in the price setting of energy goods on both the domestic market and of energy goods destined for export purposes should be limited. A prohibition on dual pricing should further limit the possibility for resource rich countries to distort the market and subsidize sales to industrial users thus penalising foreign buyers and exports. Whereas further reflection is needed, precedents like WTO Accession commitments (by Russia and Saudi Arabia) or relevant provisions from the NAFTA Agreement (Article 605(b)) could possibly be used to explore possible avenues in this respect.

As regards State Owned Enterprise (SOE) and enterprises granted Special or Exclusive Rights (SER) specific rules for raw materials and energy could be discussed. Although these rules should in principle be of a general nature, it could appear necessary during the negotiation process to agree on rules specifically for companies active in the raw materials and energy sector, especially in so far as they benefit from special or exclusive rights, in coordination with the horizontal rules.

Trade in sustainable energy

The EU and the US have a shared interest in improving global governance in the area of renewable energy. Liberalisation of trade in green goods and services would bring considerable environmental, social, economic and commercial benefits to the US and the EU. A rules-based, open international market would promote more cost-efficient and more widely available green goods and services (including green technologies). It would also foster innovation as well as create jobs and bring an important contribution to the achievement of environmental objectives and the fight against climate change.

The TTIP could build on the APEC agreement on environmental goods. The parties could agree on commitments to address non-tariff barriers which cause specifically in this area many trade irritants. In terms of concrete provisions, a confirmation of prohibition of local content requirements for goods, services and investments could be introduced. Commitments related to subsidies contingent on local content requirements and prohibitions on forced transfer of technology or set offs could also be included.

Energy efficiency and the promotion of renewable energies are a fundamental aspect of the energy policy of the EU and the US. They are being promoted through various policy measures, for instance regulatory measures, standards and incentive programmes. The TTIP should promote the objective of renewable energy and energy efficiency and should guarantee the right for each party to maintain or establish standards and regulation concerning e.g. energy performance of products, appliances and processes, while working, as far as possible, towards a convergence of domestic EU and US standards or the use of international standards where these exist.

Security of energy supply

The secure and reliable supply of energy is of crucial importance for any country. Consideration could be given to developing provisions on the security of energy supply designed, inter alia, to identify existing and upcoming supply and infrastructure bottlenecks that may affect energy trade, as well as mechanisms to handle supply crises and disruptions, taking into account and promoting multilateral obligations in this field (notably in the context of the International Energy Agency).

**Summary of EU TTIP position papers
Citizen Trade Policy Commission
September 19, 2013**

Introduction: In July of 2013, the Institute for Agriculture and Trade Policy, located in Washington D.C. and Minneapolis, Minnesota, posted on their website (<http://www.iatp.org/documents/european-commissions-initial-position-papers-on-ttip>) a series of leaked position papers on the TTIP from the European Union. Since these leaked papers are now publicly available on the internet and have a direct bearing on topics to be negotiated in the TTIP, the CTPC Chairs, Senator Troy Jackson and Representative Sharon Anglin Treat have asked that this summary of the various EU position papers be developed for review by the CTPC. The original downloaded document is 65 pages in length and will be available on the CTPC website soon after today's meeting. A single copy of the entire downloaded document is available for review during today's meeting.

Initial Position Paper: Motor vehicles in TTIP

- EU position should be one of promoting regulatory compatibility/convergence in the motor vehicles (MV) sector while at the same time achieving desired levels of public health and safety;
- Avoiding regulatory divergences would result in substantial efficiency gains and cost savings;
- EU goal is two-fold:
 - i. Recognition that the manufacture of MV parts in one country will meet the technical regulatory requirements of another country; and
 - ii. The need to adopt Global Technical Regulations that will be adopted into national legislation for each member nation.
- The current level of MV regulations in both the US and EU are comparable in ultimate outcome and purpose; technical divergence in regulations should not be the focus but rather the equivalence of outcome;
- The assessment of the desired level of overall level of protection to public health and safety should be based on relevant information provided by EU and US MV industry and should be based on a data-driven analysis;
- If regulatory equivalence cannot be achieved on a particular MV topic then the focus should be on identification of those areas that need further regulatory convergence.

Initial position paper: Chemicals in TTIP

- Ultimate goal is to promote regulatory convergence and recognition in the chemical industry;
- Full regulatory harmonization is probably not possible due to significant differences between the EU approach as represented by REACH and the US approach as represented by TSCA;

- Realistic goal is to focus on those areas of each regulatory approach that offer the opportunity for regulatory conformance;
- Four areas of commonality provide the best opportunity for regulatory conformance:
 - Cooperation in prioritizing the assessment of chemicals;
 - Promoting alignment in the classification and labeling of chemicals;
 - The importance of mutual cooperation in identifying new and emerging issues will reduce “trade irritants”; and
 - The enhancement of information sharing and protection of confidential business information.

Initial position paper: Pharmaceuticals in TTIP

- The current level of existing cooperation between US and EU regulators with respect to pharmaceuticals should be maintained;
- The current collaborative process could be reinforced by the following steps;
 - The establishment of a bilateral authorization process;
 - The furthering of bilateral harmonization of technical requirements;
 - Continuing the efforts to establish joint scientific approaches concerning advice and evaluation.
- Improving the mutual recognition of Good Management Practices (GMP) processes used by TTIP members in US, EU and other non-TTIP nations;
- Provide for the exchange of confidential and trade secret information;
- Achieving regulatory convergence on the topic of biosimilars; biosimilars are pharmaceutical products that are similar to previously patented products but are not identical to the original biologic products and thus significant differences in terms of unanticipated side effects and medical consequences may occur;
- Develop common requirements for pediatric clinical design studies and the mutual acceptance of the same;
- Implement a harmonized terminology for pharmaceutical products;
- Work towards the harmonization of assessment approaches.

EU Initial position paper on SPS matters for the TTIP negotiations

- To build upon WTO SPS (Sanitary & Phytosanitary) agreement, the High Level Working Group on Jobs and Growth (HLWG) recommended the inclusion of an ambitious SPS-plus chapter in the TTIP;
- Whenever possible, SPS chapter should be built upon the use of science and international standards but also recognize the rights of individual nation states to enforce and adopt measures deemed necessary to protect the public health and welfare;
- SPS chapter will be part of a broader move to promote regulatory convergence and non-tariff barriers;
- Goals of SPS chapter should include:
 - Minimize negative effects of SPS measures on trade;

- Respect legitimate objectives to safeguard human, animal or plant health measures in order to prevent and eliminate unnecessary trade barriers; and
- Improve transparency of SPS measures through the use of certainty and consistency;
- SPS chapter should be legally binding at all administrative levels; and
- Member states should strive for early warning of proposed legislative changes to help ensure regulatory convergence.

EU Initial position paper on Trade and Sustainable Development

- EU is committed to the concept of sustainable development (SD); i.e. meeting the needs of the current generation without jeopardizing the needs of future generations;
- TTIP should reflect EU goals for SD;
- Envisions a need for a separate chapter on SD which addresses labor, environment and climate change within a trade context;
- SD chapter should reflect internationally agreed upon rules and principles;
- SD chapter should not infringe upon member's rights to develop regulations to reflect its own SD priorities;
- SD chapter should promote the following:
 - Trade and investment in environmental goods and services; addressing non-technical trade barriers;
 - Use of voluntary tools on environmental sustainability and fair trade initiatives;
 - Use of corporate social responsibility practices;
 - Emphasize commitment towards conservation and sustainable management of biodiversity and ecosystems
- SD chapter should reflect importance of using international guidelines and principles on the use of scientific and technical information; and
- SD chapter should feature a strong monitoring and follow-up mechanism;

Initial position paper on Technical Barriers to Trade

- Technical Barrier to Trade (TBT) chapter should reflect the following:
 - Greater openness, transparency and convergence in regulatory and standards development approaches;
 - Reduce redundant testing and certification requirements;
 - Promote confidence in respective conformity assessment bodies; and
 - Enhance cooperation on conformity assessment and standardization issues.
- TBT chapter should remove unnecessary TBTs;
- Regardless of the need for compatibility, it is necessary to recognize that standards of one nation cannot be imposed upon another;
- Measures of regulation should not be any stricter than necessary to achieve the public interest objectives;
- Products that are lawful in one country should be able to be traded in other countries; the mutual importance of reasonable market access for all parties;

- TTIP commitments should apply to both sub-regional (EU) and sub-federal (US) levels of regulation;
- TTIP should remove all TBT barriers to transatlantic trade; removal of all duplicative compliance requirements is important;
- TTIP should reflect the harmonization of all technical requirements;
- TTIP should include voluntary standards of regulation which will be established by industry;
- TTIP should include a mutual recognition of conformity assessment mechanisms; however, mutual recognition of conformity measures is not a substitute for a convergence of substantive requirements;
- TTIP should limit the use of compulsory labeling requirements; and
- TTIP should include a mechanism that deals with trade irritants arising from TBTs

Initial position paper on Anti-Trust & Mergers, Government Influences and Subsidies

- In some nations, trade tariffs have been replaced by behind the border barriers such as anti-competitive practices;
- TTIP should include provisions with anti-trust and merger disciplines:
 - Recognition of benefits of free and unfettered trade and investment relations;
 - Consideration and use of generally accepted best practices;
 - Commitment to active enforcement of antitrust and merger laws;
 - Commitment to implementation of transparent and nondiscriminatory competition policy;
 - Clearly stated provisions dealing with the application of antitrust laws to state owned enterprises (SOEs) and enterprises that are granted exclusive rights or privileges (SERs).
- TTIP should reflect the need for a convergence of antitrust and merger regulations;
- The EU perspective reflects a need for a level playing field with respect to SOEs/SERs and the private sector;
- TTIP should reflect a distinction between entities that have been granted SERs and those entities controlled by the government but fairly compete with the private sector;
- The use of subsidies by SOEs and SERs also distort a level playing field with the private sector;
- The use of subsidies should be addressed by the TTIP by the following provisions:
 - Mechanisms to improve transparency;
 - Consultation mechanisms that provide for the mutual exchange of information about the threat that one nation's use of subsidies might pose to another nation; and
 - A recognition of the most abusive and damaging forms of subsidies.

Initial position paper on TTIP: Cross-cutting disciplines and Institutional provisions

- HLWG also recommended that the TTIP include a ‘horizontal’ chapter (cross cutting chapter that applies to all chapters) dealing with cross cutting disciplines and institutional issues such as the need for procedural rules;
- The elimination, reduction and prevention of unnecessary regulatory barriers should be the biggest benefit of the TTIP;
- New and innovative approaches will be necessary in the TTIP to help ensure that unnecessary regulatory trade barriers are removed;
- TTIP regulatory provisions in the horizontal chapter will need to be applied broadly to all measures including legislative and implementing acts irrespective of the governing body which adopts them;
- The horizontal TTIP chapter must contain principles and procedures which apply to the entire treaty;
- The objective of the TTIP horizontal chapter is to go beyond the regulations and provisions of the WTO agreements on SPS and TBT;
- Ultimate goal of TTIP is an integrated market where goods/services could be marketed without changes in regulatory environment;
- Cross cutting regulatory disciplines should focus on 3 areas:
 - Regulatory principles which reflect best practices such as bilateral consultation mechanism, improved feedback mechanism, cooperation in collecting evidence and data and exchange of data and information;
 - Strengthening the assessment of potential regulations and their effect on international trade;
 - Improving regulatory cooperation regarding convergence in specific topic areas; and
 - Developing an institutional framework for future cooperation.

EU-US FTA negotiations: Non paper on Public Procurement

- TTIP chapter on Public Procurement (PP) should supersede and improve upon the PP provisions of GPA (Government Procurement Agreement) adopted by the WTO in 1996;
- PP chapter should seek to remove barriers to cross-border procurement and to procurement with established companies;
- PP chapter should remove existing “carve-outs”
- PP chapter should supersede all Buy America and other SER policies;
- PP chapter should cover and be applied to all levels of government including central and sub-central; and
- PP chapter should be extended to apply to all Public Private Partnerships (PPP).

Initial Position Paper on Trade and Investment in Raw Materials and Energy for the TTIP Negotiations Between the EU and the US

- Current WTO rules are tough on import barriers but weak on export barriers resulting in a disproportionate effect on energy and raw materials;
- Coverage of raw materials should extend to those materials used in the manufacturing of industrial products and should exclude processed fishery products and energy products;
- Raw materials and energy provisions of TTIP should reflect increasing transparency and predictability;
- These provisions should seek to eliminate export restrictions;
- Nations should retain the right to determine whether exploitation of raw materials and energy should be permitted and, if so, such rules should be nondiscriminatory and access should be ensured;
- Competitiveness in the trade of raw materials and energy should be improved by:
 - Limiting government intervention in the form of price setting; and
 - Develop specific rules for SOEs and SERs
- A rules-based, open international market is needed for trade in sustainable energy;
- Non-tariff barriers need to be eliminated;
- There is a need for a convergence of international standards on energy performance products, appliances and processes; and
- With respect to the security of energy supplies, there is a need to anticipate supply bottlenecks and how to handle supply crisis and disruptions.

**Article notes: November 15, 2013
Citizen Trade Policy Commission**

Investor-State Dispute Resolution: The Monster Lurking Inside Free Trade Agreements; Glyn Moody, Techdirt.com, 4/16/13)

- Recent FTA's have included provisions authorizing the use of the Investor-State Dispute Resolution (ISDR) process as a means of resolving trade disputes between international corporations and sovereign nations;
- However, the current WTO agreement does not provide for the same type of ISDR mechanism as do more recent FTAs. Instead of empowering corporations to unilaterally bring trade disputes to a ISDS arbitration panel, the current WTO agreement stipulates that a corporation must first convince a sovereign nation that it has a legitimate trade grievance before it can be brought to the WTO for resolution;
- Originally, the use of current day ISDRs was justified by the perceived need to protect corporations from weak government structures in developing nations. But in recent years, ISDS has been used to challenge laws and regulations in highly developed countries when an alleged trade violation has occurred;
- The article quotes Lori Wallach of Public Citizen's Global Trade Watch as saying, "*The dirty little secret about [the negotiation] is that it is not mainly about trade, but rather would target for elimination the strongest consumer, health, safety, privacy, environmental and other public interest policies on either side of the Atlantic. The starkest evidence ... is the plan for it to include the infamous investor-state system that empowers individual corporations and investors to skirt domestic courts and laws and drag signatory governments to foreign tribunals.*"
- A recent report from the UN Conference for Trade and Development stated that 62 ISDR cases were initiated in 2012 which is the most ever. In total, by the end of 2012, 244 ISDR cases had been concluded and of those 42% were decided in favor of the State, 31% were resolved in favor of the investor and 27 % were settled;
- Although these statistics suggest that nations are winning more of the ISDR cases, the article points out that the legal costs to the nations can be significant and when a nation loses, the potential fines can be enormous; in 2012, an investor was awarded \$1.77 billion in a dispute with Ecuador.

A Transatlantic Corporate Bill of Rights: Investor privileges in EU-US trade deal threaten public interest and democracy (Seattle to Brunswick Network, Corporate Europe Observatory and Transnational Institute; October 2013)

- Written from a European perspective, this 12 page report warns against the dangers of negotiating the TTIP to authorize ISDRs which could be used by US corporations to overturn and undermine EU laws and regulations. The report also points out that this same process can be used by European corporations to subvert US laws;
- Recently, the threat of cases being brought up through ISDRs has often resulted in the back tracking or repeal of important legislation in the fields of environmental protection and public health and safety;

- Recent ISDR cases have involved investor challenges regarding:
 - Green energy policy;
 - Pharmaceutical policy;
 - Anti-smoking legislation;
 - Toxic chemical bans;
 - Environmental restrictions on mining;
 - Health insurance policies; and
 - Economic policy.
- Corporate lobbying groups have worked hard to push for inclusion of ISDR provisions in the TTIP; the US Chamber of Commerce has suggested that inclusion of ISDR in the TTIP should be considered as the “gold standard” for future “investment agreements”;
- Many nations are steering away from the use of ISDRs because they are perceived as contrary to the public interest;
- Inclusion of ISDRs in the TTIP will encourage international energy corporations like Chevron to challenge EU restrictions on the practice of fracking as a means of shale gas development;
- ISDRs are strongly supported by many prominent law firms which have a vested interest in the high legal fees that they receive from corporations in the ISDR process;
- Many public interest and citizen groups are mobilizing to oppose inclusion of ISDR in the TTIP; and
- A number of EU member states are beginning to question why ISDR is needed in the TTIP when both the US and the EU have highly developed and functioning judicial systems.

Letter to President Obama about treatment of pharmaceutical and medical device pricing in the TPP (numerous public interest organizations; 11/8/13)

- Fifteen national organizations, including the AARP, Consumers Union and AFSCME, wrote a letter to President Obama on 11/8/13 expressing their grave reservations about USTR proposals for the TPP which will limit the ability of federal and state governments to use programs like Medicare, Medicaid and the Affordable Care Act to effectively moderate increasing costs for prescription drugs and medical devices;
- The letter also expresses concerns about TPP provisions which would bind the US 12 year exclusivity period for brand name biologic drugs; an
- In addition the letter strongly urges that the TPP negotiating process be made much more transparent and points out that the current process excludes health care advocates while allowing access to pharmaceutical corporations.

This transatlantic trade deal is a full-frontal assault on democracy (George Monbiot, The Guardian, 11/4/13)

This EU-US trade deal is no “assault on democracy” (Ken Clarke, The Guardian, 11/11/13)

These two columns, which appeared in recent issues of The Guardian, provide contrasting perspectives on the desirability of the TTIP.

- In his column arguing against the need for the TTIP, George Monibut makes the following points:
 - The avowed purpose of the TTIP is to remove regulatory trade barriers between Europe and the US;
 - The TTIP will accomplish the removal of regulatory trade barriers through the use of ISDRs which undermine a nation state's sovereignty;
 - Recently ISDRs have been used to sue:
 - Australia for certain tobacco regulations ;
 - Argentina for restrictions on utility bills;
 - El Salvador for certain mining regulations; and
 - Canada for enforcement of certain pharmaceutical patent restrictions;
 - ISDRs can't be used by citizens for protection against corporate excesses;
 - ISDRs have a powerful chilling effect on potential legislation in both the US and the EU; and
 - The TTIP proposes to usurp functional and effective US and EU judicial systems with the imposition of a new "extrajudicial" system in the form of ISDRs.
- In his column responding to the previous piece, Ken Clarke advocates for the TTIP by making the following points:
 - The TTIP is an trade deal of unprecedented scope between the US and the EU which will create a free market for 800 million people living in the US and in the EU with a potential to increase the combined GNP by £180 billion (British pounds);
 - Adoption of the TTIP could reduce or eliminate expensive export tariffs and protect current liberal trading rules used by the British government;
 - The threat of ISDRs is completely overblown and their use can be appropriately regulated and adjusted in the TTIP negotiating process; and
 - The TTIP cannot be accurately described as a boon for large corporations and in fact will tend to favor smaller businesses through the harmonization of industrial and manufacturing standards.

Letter to USTR and NSA on surveillance in the realm of international trade policy (38 national organizations; 11/12/13)

- 38 diverse national organizations, including Food & Water Watch, Friends of the Earth U.S., Greenpeace, Public Citizen and U.S. PIRG, sent a letter dated 11/12/13 to the USTR and the National Security Agency (NSA) asking for a full disclosure as to whether the NSA has spied on domestic trade advocacy groups on behalf of the USTR.

KEI analysis of Wikileaks leak of TPP IPR text, from August 30, 2013 (James Love, <http://keionline.org/node/1825>; 11/13/13)

- Knowledge Ecology International (KEI) has published the complete copy of the negotiated text regarding the Intellectual Properties (IP) Chapter for the TPP. This document, dated 8/30/13, was leaked to Wikileaks who then passed it on to KEI for publication on their website;
- The IP Chapter is 95 pages in length, contains 296 footnotes and 941 instances of bracketed text with considerable detail on the negotiating positions of the TPP countries;
- In general, the negotiated text has the potential to expand the reach of intellectual property rights by;
 - increasing the duration of patents,
 - making patents easier to obtain;
 - creating the concept of intellectual property rights for data;
 - expanding right holder privileges; and
 - increasing penalties for copyright and patent infringement.
- KEI suggests that the IP chapter is detrimental to efforts to access knowledge, creating access to medicine and for efforts to innovate;
- KEI also maintains that the US appears to have the most anti-consumer and anti-freedom negotiating positions and that other TPP countries are willing to follow the hard-line US position in negotiating the IP chapter of the TPP;
- The KEI blog piece also points out that the TPP is being negotiated in near total secrecy but that nearly 700 corporate advisors have been cleared to review the text and provide advice to the USTR;
- From the KEI perspective, the leaked IP chapter demonstrates that the USTR position will result in *“new global legal norms that would allow foreign governments and private investors to bring legal actions and win huge damages, if TPP member countries does not embrace anti-consumer practices.”*

WikiLeaks publishes secret draft chapter of Trans-Pacific Partnership (Alex Hern and Dominic Rushe, The Guardian; 11/13/13)

- The Guardian’s story on the Wikileaks publication of the leaked IP Chapter of the TPP focuses on the extreme secrecy and lack of transparency used so far to negotiate the TPP;
- Wikileaks founder Julian Assange claims that the leaked IP chapter proves that the US is trying impose a highly restrictive view of intellectual property on the world and stated that *“If you read, write, publish, think, listen, dance, sing or invent; if you farm or consume food; if you're ill now or might one day be ill, the TPP has you in its crosshairs.”*;
- The Guardian article also mentions that a US foreign policy lobbying organization, Just Foreign Policy, has offered Wikileaks a \$70,000 reward for publication of the entire TPP text. The publication of the single leaked IP chapter does not yet meet the criteria for the reward.

House Stalls Trade Pact Momentum (Annie Lowrey, New York Times, 11/12/13)

- The Obama administration’s efforts to rush through the congressional approval of the TPP is hitting some significant roadblocks;

- 151 House Democrats (including Maine Representatives Chellie Pingree and Mike Michaud) have signed a letter opposing the administration's Fast Track Authority proposal regarding approval of the TPP;
- In addition, 22 House Republicans have also signed a separate letter to the President indicating similar opposition to the Fast Track proposal, thereby raising the total of House members who oppose Fast Track Authority to 173;
- Lori Wallach of Public Citizen commented, "*This could be the end of T.P.P. All these other countries are like, 'Wait, you have no trade authority and nothing you've promised us means anything? Why would we give you our best deal?' Why would you be making concessions to the emperor who has no clothes?'*";
- USTR Michael Froman continues to defend and promote the effort to have Fast Track approved by Congress before the end of the year. Ambassador Froman maintains that Fast Track represents an opportunity for Congress to codify an approach for negotiation of trade agreements like the TPP and that the TPP is important as a "*longstanding tool for shaping U.S. trade policy on behalf of the American people.*"; and
- Many members of Congress are concerned about issues surrounding food safety, intellectual property, privacy and the continued health of the US automobile industry. In addition, there is great concern among members of Congress regarding the level of secrecy that has been used by the administration to negotiate the TPP.

Investor-State Dispute Resolution: The Monster Lurking Inside Free Trade Agreements

Politics

by Glyn Moody

Tue, Apr 16th 2013 1:09am

<http://www.techdirt.com/articles/20130411/09574122678/investor-state-dispute-resolution-sleeping-monster-inside-free-trade-agreements-begins-to-stir.shtml>

from the *be-very-afraid* dept

We wrote recently about how multilateral trade agreements have become a convenient way to circumvent democratic decision making. One of the important features of such treaties is the inclusion of an investor-state dispute resolution mechanism, which Techdirt discussed last year. The Huffington Post has a great article about how this measure is almost certain to be part of the imminent TAFTA negotiations, as it already is for TPP, and why that is deeply problematic:

Investor-state resolution has been a common component of U.S.-negotiated pacts with individual nations since the North American Free Trade Agreement in 1994. But such resolution is not currently permitted in disputes with the U.S. and EU, which are governed by the WTO. All trade deals feature some kind of international resolution for disputes, but the direct empowerment of corporations to unilaterally bring trade cases against sovereign countries is not part of WTO treaties. Under WTO rules, a company must persuade a sovereign nation that it has been wronged, leaving the decision to bring a trade case before the WTO in the hands of elected governments.

Traditionally, this proposed political empowerment for corporations has been defended as a way to protect companies from arbitrary governments or weakened court systems in developing countries. But the expansion of the practice to first-world relations exposes that rationale as disingenuous. Rule of law in the U.S. and EU is considered strong; the court systems are among the most sophisticated and expert in the world. Most cases brought against the United States under NAFTA have been dismissed or abandoned before an international court issued a ruling.

As this rightly points out, investor-state dispute resolution mechanisms were brought in for agreements with countries where the rule of law could not be depended upon. That makes no sense in the case of the US and EU, both of whose legal systems are highly developed (some might say overly so.) The Huffington Post article quotes Lori Wallach, director of Public Citizen's Global Trade Watch, who explains what she thinks is really going on here: *"The dirty little secret about [the negotiation] is that it is not mainly about trade, but rather would target for elimination the strongest consumer, health, safety, privacy, environmental and*

other public interest policies on either side of the Atlantic," said Lori Wallach, director of Public Citizen's Global Trade Watch. "The starkest evidence ... is the plan for it to include the infamous investor-state system that empowers individual corporations and investors to skirt domestic courts and laws and drag signatory governments to foreign tribunals."

One recent example of the kind of thing that might become increasingly common if investor-state dispute resolution is included in TAFTA and TPP is provided by Eli Lilly and Company. As Techdirt reported earlier this year, the pharma giant is demanding \$100 million as compensation for what it calls "expropriation" by Canada, simply because the latter's courts refused to grant Eli Lilly a drug patent on the grounds that it didn't satisfy the conditions set down in law for doing so.

A new report (pdf) from the UN Conference for Trade and Development (UNCTAD), pointed out to us by IP Watch, reveals just how widespread the use of investor-state dispute resolution mechanisms has already become:

The Issues Note reveals that 62 new cases were initiated in 2012, which constitutes the highest number of known ISDS [investor-state dispute settlement] claims ever filed in one year and confirms that foreign investors are increasingly resorting to investor-State arbitration.

...

By the end of 2012, the total number of known cases reached 518, and the total number of countries that have responded to one or more ISDS claims increased to 95. The overall number of concluded cases reached 244. Out of these, approximately 42 per cent were decided in favour of the State and 31 per cent in favour of the investor. Approximately 27 per cent of the cases were settled.

Although that suggests that states are winning more often than investors, the cost of doing so is a drain on public finances, and ignores cases that never come to arbitration because governments simply give in. And when states lose, the fines can be enormous: the report notes that 2012 saw the highest monetary award in the history of investor-state dispute resolution: \$1.77 billion to Occidental, in a dispute with Ecuador.

As an accompanying press release from UNCTAD points out, this growing recourse to international arbitration

amplifies] the need for public debate about the efficacy of the investor-State dispute settlement (ISDS) mechanism and ways to reform it

Unfortunately, against a background of almost total lack of awareness by the public that supra-national structures are being put in place that allow their governments to be overruled, and their laws to be ignored, it is highly unlikely we will get that debate.

Follow me @glynmoody on Twitter or identi.ca, and on Google+

KEI analysis of Wikileaks leak of TPP IPR text, from August 30, 2013

<http://keionline.org/node/1825>

Submitted by James Love on 13. November 2013 - 4:32

KEI Comments on the August 30, 2013 version of the TPP IP Chapter

For more information, contact James Love, <mailto:james.love@keionline.org>, mobile +1.202.361.3040.

Knowledge Ecology International (KEI) has obtained from Wikileaks a complete copy of the consolidated negotiating text for the IP Chapter of the Trans-Pacific Partnership (TPP). (Copy [here](#), and on the Wikileaks site here: <https://wikileaks.org/tpp/>) The leaked text was distributed among the Chief Negotiators by the USTR after the 19th Round of Negotiations at Bandar Seri Begawan, Brunei, in August 27th, 2013.

There have been two rounds since Brunei, and the latest version of the text, from October, will be discussed in Salt Lake City next week.

The text released by Wikileaks is 95 pages long, with 296 footnotes and 941 brackets in the text, and includes details on the positions taken by individual countries.

The document confirms fears that the negotiating parties are prepared to expand the reach of intellectual property rights, and shrink consumer rights and safeguards.

Compared to existing multilateral agreements, the TPP IPR chapter proposes the granting of more patents, the creation of intellectual property rights on data, the extension of the terms of protection for patents and copyrights, expansions of right holder privileges, and increases in the penalties for infringement. The TPP text shrinks the space for exceptions in all types of intellectual property rights. Negotiated in secret, the proposed text is bad for access to knowledge, bad for access to medicine, and profoundly bad for innovation.

The text reveals that the most anti-consumer and anti-freedom country in the negotiations is the United States, taking the most extreme and hard-line positions on most issues. But the text also reveals that several other countries in the negotiation are willing to compromise the public's rights, in a quest for a new trade deal with the United States.

The United States and other countries have defended the secrecy of the negotiations in part on the grounds that the government negotiators receive all the advice they need from 700 corporate advisors cleared to see the text. The U.S. negotiators claim that the proposals need not be subject to public scrutiny because they are merely promoting U.S. legal traditions. Other governments claim that they will resist corporate right holder lobbying pressures. But the version released by Wikileaks reminds us why government officials supervised only by well-connected corporate advisors can't be trusted.

An enduring mystery is the appalling acceptance of the secrecy by the working news media.

With an agreement this complex, the decision to negotiate in secret has all sorts of risks. There is the risk that the negotiations will become hijacked by corporate insiders, but also the risk that negotiators will make unwitting mistakes. There is also the risk that opportunities to do something useful for the public will

be overlooked or abandoned, because the parties are not hearing from the less well-connected members of the public.

The U.S. proposals are sometimes more restrictive than U.S. laws, and when consistent, are designed to lock-in the most anti-consumer features. On top of everything else, the U.S. proposals would create new global legal norms that would allow foreign governments and private investors to bring legal actions and win huge damages, if TPP member countries does not embrace anti-consumer practices.

General provisions, and dispute resolution

The existing multilateral copyright and trade treaties, negotiated in the light of day, generally provide better balance between right holders and users. The WTO TRIPS Agreement is the only multilateral agreement with impressive enforcement mechanisms. The TRIPS agreement is defined not only by the specific provisions setting out rights and exceptions, but general provisions, such as Articles 1, 6, 7,8, 40 and 44, that provide a variety of safeguards and protections for users and the public interest. The US is proposing that the new TPP IPR provisions be implemented with few if any of the safeguards found in the TRIPS, or weaker versions of them.

The dispute resolution provisions in the TPP permit both governments and private investors to bring actions and obtain monetary damages if arbitrators find that the implementation of the agreement is not favorable enough to right holders. This effectively gives right holders three bites at the apple -- one at the WTO and two at the TPP. They can lobby governments to advance their positions before a WTO panel, and/or, the separate dispute mechanisms available to governments and investors in the TPP. There are no opportunities for consumers to bring such disputes.

The addition of the investor state dispute resolution provisions in the TPP greatly increases the risks that certain issues will be tested in the TPP, particularly when the TPP provisions are modified to be more favorable to right holders, or lack the moderating influence of the TRIPS type safeguards which the US is blocking in the TPP.

Access to Medicines

The trade agreement includes proposals for more than a dozen measures that would limit competition and raise prices in markets for drugs. These include (but are not limited to) provisions that would lower global standards for obtaining patents, make it easier to file patents in developing countries, extend the term of patents beyond 20 years, and create exclusive rights to rely upon test data as evidence that drugs are safe and effective. Most of these issues have brackets in the text, and one of the most contentious has yet to be tabled -- the term of the monopoly in the test data used to register biologic drugs. The United States is consistently backing the measures that will make drugs more expensive, and less accessible.

Some of the issues are fairly obvious, such as those requiring the granting of more patents with longer effective terms, or monopolies in test data. Others are more technical or subtle in nature, such as the unbracketed wording of Article QQ.A.5, which is designed to narrow the application of a 2001 WTO Doha Agreement TRIPS and Public Health, and its obligations to provide for "access to medicine for all." By changing the language, the TPP makes it seem as if the provision is primarily about "HIV/AIDS,

tuberculosis, malaria, [US oppose: chagas] and other epidemics as well as circumstances of extreme urgency or national emergency," instead of all medicines and all diseases, including cancer.

Patents on Surgical Methods

An interesting example of how the US seeks to change national and global norms are the provisions in the TPP over patents on surgical methods. The WTO permits countries to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." The US wants to flip this provision, so that "may also exclude from patentability" becomes "shall make patents available." However, when a version of the IP Chapter was leaked in 2011, the US trade negotiators were criticized for ignoring the provisions in 28 USC 287 that eliminated remedies for infringement involving the "medical activity" of a "medical practitioner." The exception in US law covered "the performance of a medical or surgical procedure on a body." The US trade negotiators then proposed adding language that would permit an exception for surgery, but only "if they cover a method of using a machine, manufacture, or composition of matter." The US proposal, crafted in consultation with the medical devices lobby, but secret from the general public, was similar, but different from the U.S. statute, which narrowed the exception in cases involving "the use of a patented machine, manufacture, or composition of matter in violation of such patent." How different? As Public Citizen's Burcu Kilic puts it, under the US proposal in the TPP, the exception would only apply to "surgical methods you can perform with your bare hands."

Why is the United States putting so much effort into narrowing if not eliminating the flexibility in the WTO agreement to provide exceptions for patents on "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals"? It did not hurt that AdvaMed, the trade association for the medical device manufacturers, hired Ralph F. Ives as Executive Vice President for Global Strategy & Analysis. Before becoming a lobbyist for the medical device industry, Ives was the head of pharmaceutical policy for USTR. And Ives is just one of an army of lobbyists (including former Senator Evan Bayh) representing the medical devices industry. ITAC3, the USTR advisory board for Chemicals, Pharmaceuticals, Health/Science Products And Services, includes not only Ralph Ives, but also representatives from Medtronic, Abbott, Johnson and Johnson, DemeTech, North Coast Medical and Airmed Biotech -- all companies involved in the medical device business. All are considered "cleared advisors" to USTR and have access to the TPP text.

Uncertainty over compulsory licenses on patents

At present, exceptions to exclusive rights of patents may be implemented under a general exceptions clause (Article 30 of the TRIPS), a rules based system (Article 31), or under other provisions, including limitations to remedies, the first sale doctrine, or the control of anticompetitive practices. The option to use the TRIPS Article 31 mechanisms has been proposed by New Zealand, Canada, Singapore, Chile and Malaysia, but is not currently supported by the US, Japan or other countries. This presents significant uncertainty over the freedom to use compulsory licenses. If QQ.E5quater is not accepted, the rules based WTO approach will not be possible, and governments will have to satisfy a restrictive three step test, and run the risk of litigation under investor state dispute resolution provisions of the TPP.

Article QQ.E.5quater: {Other Use Without Authorisation of the Right Holder}

[NZ/CA/SG/CL/MY propose: Nothing in this Chapter shall limit a Party's rights and obligations under Article 31 of the TRIPS Agreement or any amendment thereto.]

Copyright

There is little reason for any language on copyright in the TPP. All of the TPP member countries are already members of the WTO, which has its own extensive obligations as regards copyright, including obligations to implement Articles 1 through 21 of the Berne Convention. The TRIPS has already expanded copyright coverage to software, and provides extensive protections to performers, producers of phonograms (sound recordings) and broadcasting organizations. Moreover, the United States and Australia have proposed that all TPP member countries “ratify or accede” to two 1996 treaties (the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty), as well as the 1974 Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite. Despite this, the TPP provides its own nuanced and often detailed lists of obligations. Collectively, the copyright provisions are designed to extend copyright terms beyond the life plus 50 years found in the Berne Convention, create new exclusive rights, and provide fairly specific instructions as to how copyright is to be managed in the digital environment.

Copyright terms

There are significant differences in the positions of the parties on the term of protection. Some countries are opposing any expansion of the term found in the Berne Convention, the TRIPS or the WCT, which is generally life plus 50 years, or 50 years for corporate owned works.

For the TPP copyright terms, the basics are as follows. The US, Australia, Peru, Singapore and Chile propose a term of life plus 70 years for natural persons. For corporate owned works, the US proposes 95 years exclusive rights, while Australia, Peru, Singapore and Chile propose 70 years for corporate owned works. Mexico wants life plus 100 years for natural persons and 75 years for corporate owned works. For unpublished works, the US wants a term of 120 years.

While the US negotiators are indeed promoting US legal norms, they are promoting norms that most experts and consumers see as a mistake, that should be corrected. There is no justification for 95 year copyright terms for corporations, or 70 years of protection after an author is dead, or 120 years for unpublished works.

3-Step Test

One set of technically complex but profoundly important provisions are those that define the overall space that governments have to create exceptions to exclusive rights. The Berne Convention established a system combining “particular” exceptions for the most common and important topics such as quotations, news of the day, public affairs, speeches, uses of musical compensations, and education, and a general purpose exception to the reproduction right that could be implemented in any other case not covered by the particular exception. Any exception not spelled out as a particular exception was subject to a very restrictive three step test. When the WTO incorporated the bulk of the Berne Convention articles, it retained this system, and added additional areas of flexibility, including very broad freedom to apply the first sale doctrine (Article 6 of the TRIPS), to control anti-competitive practices (Articles 8 and 40), and to implement a liability rule approach through Article 44.2 of the TRIPS.

In recent years, the publisher lobby has sought to elevate the 3-step test to a high level filter to limit all copyright exceptions, including the so called "particular" Berne exceptions, as well as anything else that limits exclusive rights. In the TPP, the copyright lobby has succeeded in obtaining a formulation based in part upon the 1996 WIPO WCT treaty, which can be read to provide some recognition of the Berne particular exceptions, but (unlike the 2012 Beijing treaty) does not specifically reference the important agreed upon statements in the 1996 WCT, which support more robust exceptions.

In its current form, the TPP space for exceptions is less robust than the space provided in the 2012 WIPO Beijing treaty or the 2013 WIPO Marrakesh treaty, and far worse than the TRIPS Agreement. While this involves complex legal issues, the policy ramifications are fairly straightforward. Should governments have a restrictive standard to judge the space available to fashion exceptions for education, quotations, public affairs, news of the day and the several other "particular" exceptions in the Berne Convention, and more generally, why would any government want to give up its general authority to consider fashioning new exceptions, or to control abuses by right holders?

Formalities

The TPP goes beyond the TRIPS agreement in terms of prohibiting the use of formalities for copyright. While the issue of formalities may seem like a settled issue, there is a fair amount of flexibility that will be eliminated by the TPP. At present, it is possible to have requirements for formalities for domestically owned works, and to impose formalities on many types of related rights, including those protected under the Rome Convention. In recent years, copyright policy makers and scholars have begun to reconsider the benefits of the registration of works and other formalities, particularly in light of the extended terms of copyright and the massive orphan works problems.

In April 2013 a major workshop on this topic took place in Berkeley, titled: "Reform(aliz)ing Copyright for the Internet Age?" (<http://www.law.berkeley.edu/formalities.htm>), where the benefits and challenges of reintroducing formalities was discussed.

On the issue of formalities, the TPP language is an unnecessary and unwelcome barrier to introducing reforms.

TPM/DRM

The copyright section also includes extensive language on technical protection measures, and in particular, the creation of a separate cause of action for breaking technical protection measures. The US wants this separate cause of action to extend even to cases where there is no copyrighted works, such as in cases of public domain materials, or data not protected by copyright. It is worth noting that the restrictions on breaking technical protection measures include several exceptions, including, for example:

"lawfully authorized activities carried out by government employees, agents, or contractors for the purpose of law enforcement, intelligence, essential security, or similar governmental purposes"

In the United States the problem of TPMs and the complicated rulemaking process for exceptions and limitations to anticircumvention measures was part of a recent controversy when the Librarian of Congress refused to renew an exemption to allow the unlocking of cell-phones. After a petition by over 100,000 to the White House, the Obama Administration responded, agreeing that an exemption should exist to permit unlocking of cell-phones. Rep. Zoe Lofgren (D-CA) introduced a bill, co-sponsored with

bipartisan support, called the "Unlocking Technology Act" which would make clear that there is no liability for circumvention of a TPM where circumvention is done to engage in a use that is not an infringement of copyright. Such a bill is potentially threatened by the aggressive proposals on TPMs in the TPP.

The TPP provisions on technological protection measures and copyright and related rights management information are highly contentious and complex, and as a practical matter, impossible to evaluate without access to the negotiating text. Given the enormous public interest in this issue and other issues, it is very unfortunate that governments have insisted on secret negotiations.

Damages

One of the largest disappointments in the ACTA negotiations was the failure to sufficiently moderate the aggressive new norms for damages associated with infringements. The TPP negotiation has been far more secretive than the ACTA negotiation, and what is now clear is that as far as the issue damages is concerned, the TPP text is now much worse than the ACTA text. Particularly objectionable is the unbracketed Article QQ.H.4: 2ter, which reads as follows:

2ter. In determining the amount of damages under paragraph 2, its judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

Aside from the obvious overreaching of requiring consideration of "the suggested retail price," the US is ignoring all sorts of national laws for copyright, patents and trademarks, and TRIPS rules as regards layout-designs (topographies) of integrated circuits, that set different standards for damages in cases of infringements. The following are just a few examples:

Under the Article 36 of TRIPS, damages for certain infringement are limited, by the WTO, to "a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design."

Under the Affordable Care Act, a company infringing on undisclosed patents for biologic drugs is only liable for a reasonable royalty, or no royalty, depending upon the nature of the disclosure.

The US DOJ and the USPTO recently took the position that certain patents infringements related to standards setting activities, should be limited to a reasonable royalty.

The US proposal in the TPP will also prevent the United States from using limitations on remedies for infringement as part of a larger effort to expand access to orphaned copyright works -- an approach that has been endorsed by the US Copyright Office, and by Senator Patrick Leahy.

For several other examples, see: "Two areas where ACTA is inconsistent with US law, injunctions and damages, [KEI Policy Brief, 2011:2](#), as well as: Access to Orphan Works, and ACTA provisions on damages [KEI Policy Brief 2010: 1](#).

Concluding comments

Although there are some areas of agreed to text, the leaked text from August 30, 2013 also highlights the numerous areas where parties have yet to finalize the agreement. That there are over 900 brackets means that there is still plenty of opportunity for countries to take positions that will promote the public interest and preserve consumer rights. These areas include substantive sections of the most

controversial provisions on patents, medicines, copyright and digital rights where there are often competing proposals. The publication of the text by Wikileaks has created a rare and valuable opportunity to have a public debate on the merits of the agreement, and actions to fix, change or stop the agreement.

October 2013
updated version



Seattle to Brussels
Network



A transatlantic
CORPORATE
bill of rights

Investor privileges in EU-US trade deal threaten public interest and democracy

The EU negotiating mandate for a far-reaching free trade agreement with the US reveals the European Commission's plans to enshrine more powers for corporations in the deal. The proposal follows a persistent campaign by industry lobby groups and law firms to empower large companies to challenge regulations both at home and abroad if they affect their profits. As a result, EU member states could soon find domestic laws to protect the public interest challenged in secretive, offshore tribunals where national laws have no weight and politicians no powers to intervene.

The Commission's proposal for investor-state dispute settlement under the Transatlantic Trade and Investment Partnership (TTIP) would enable US companies investing in Europe to sue European courts and directly challenge EU governments at international tribunals, whenever they find that laws in the area of public health, environmental or social protection interfere with their profits. EU companies investing abroad would have the same privilege in the US.

Across the world, big business has already used investor-state dispute settlement provisions in trade and investment agreements to claim nizzing sums in compensation against democratically-made laws to protect the public interest (see Box 1). Sometimes the mere threat of a claim or its submission have been enough for legislation to be abandoned or watered down. In other cases tribunals – ad hoc three-member panels hired from a small club of private lawyers riddled with conflicts of interest² – have granted billions of Euros to companies, paid out of taxpayers' pockets.

Box 1

Some emblematic investor-state disputes

Corporations versus public health – Philip Morris v. Uruguay and Australia: Through bilateral investment treaties, US tobacco giant Philip Morris is suing Uruguay and Australia over their anti-smoking laws. The company argues that warning labels on cigarette packs and plain packaging prevent it from effectively displaying its trademark, causing a substantial loss of market share.³

Corporations versus environmental protection – Vattenfall v. Germany: In 2012, Swedish energy giant Vattenfall launched an investor-state lawsuit against Germany, seeking €3.7 billion in compensation for lost profits related to two of its nuclear power plants. The case followed the German government’s decision to phaseout nuclear energy after the Fukushima nuclear disaster.⁴

Corporations versus government action against financial crises – challenging Argentina & Greece: When Argentina froze utility rates (energy, water, etc.) and devalued its currency in response to its 2001–2002 financial crisis, it was hit by over 40 lawsuits from companies like CMS Energy (US) and Suez and Vivendi (France). By the end of 2008, awards against the country had totalled US\$1.15 billion.⁵ In May 2013, Slovak and Cypriot investors sued Greece for the 2012 debt swap which Athens had to negotiate with its creditors to get bailout money from the EU and the International Monetary Fund (IMF).⁶ Both, the UN and the IMF have warned that investment agreements can severely curb states’ abilities to fight financial and economic crises.⁷

Corporations versus environmental protection – Lone Pine v. Canada: On the basis of the North American Free Trade Agreement (NAFTA) between the US, Canada and Mexico, US company Lone Pine Resources Inc. is demanding US\$250 million in compensation from Canada. The ‘crime’: The Canadian province of Quebec had put a moratorium on ‘fracking’, addressing concerns about the environmental risks of this new technology to extract oil and gas from rocks.⁸

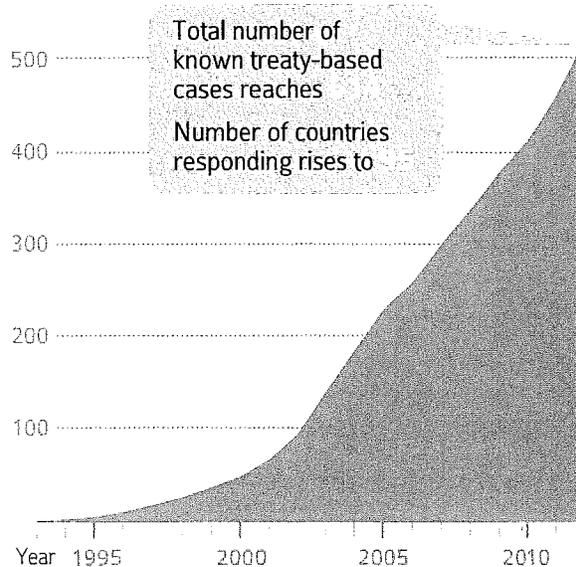
Corporations versus public health – Achmea v. the Slovak Republic: At the end of 2012, Dutch insurer Achmea (formerly Eureko) was awarded €22 million in compensation from Slovakia. In 2006, the Slovak government had reversed the health privatisation policies of the previous administration and required health insurers to operate on a not-for-profit basis.⁹

As the main users of existing international investment treaties, US and European companies have driven the investor-state litigation boom of the past two decades. By far the largest number of the 514 known disputes initiated by the end of 2012 were launched by US investors. They have filed 24% (123) of all cases. Next in line are investors from the Netherlands (50 cases), the UK (30) and Germany (27). Together, investors from EU member states have filed 40% of all known cases.¹⁰

EU and US companies have used these lawsuits to challenge green energy and medicine policies, anti-smoking legislation, bans on harmful chemicals, environmental restrictions on mining, health insurance policies, measures to improve the economic situation of minorities and many more. Now they are enthused about the prospect of an investment chapter in the EU-US free trade deal (TTIP), the biggest investment deal ever negotiated.

Deluge of disputes

Cumulative number of cases. Source: UNCTAD, Down to Earth



Lobbying for the corporate 'gold standard'

Investor-state dispute settlement under TTIP would empower EU and US-based corporations to engage in litigious wars of attrition to limit the power of governments on both sides of the Atlantic. The tremendous volume of transatlantic investment – both partners make up for more than half of foreign direct investment in each others' economies – hints at the sheer scale of the risk of such litigation wars. Additionally, thousands of EU and US companies have affiliates across the Atlantic; under TTIP they could make investor-state claims via these affiliates in order to compel their own governments to refrain from regulations they dislike.

Unsurprisingly, then, corporate lobby groups in both the EU and the US have pressured for the inclusion of investor-state arbitration in TTIP. The European employers' federation BusinessEurope, the US Chamber of Commerce, AmCham EU, the Transatlantic Business Council and other corporate lobby heavyweights all advocate such privileges for foreign investors. This is also part of a hope that an EU-US deal would set a global 'gold standard', a model for investment protection for other agreements around the world.¹¹ More and more countries are questioning and even abandoning investor-state arbitration globally precisely because of negative impacts against the public interest;¹² in response, business is demanding a "signal to the world of our willingness to commit" to their gold standard of investment protection.¹³

The investment chapter of the TTIP should eventually serve as the 'gold standard' for other investment agreements.

US Chamber of Commerce to US negotiators¹⁴

Ever since December 2009, when the EU got the power to negotiate investment protection issues through the Lisbon Treaty, industry associations have mobilised against any opportunity this might afford to institute a fairer balance of private and public interests.¹⁵ This is because the Treaty opened a window of opportunity for the EU to learn from the experience of existing investment agreements, address their flaws and develop a new generation of treaties – without investor-state dispute settlement, with investor obligations and more precise and restrictive language regarding their rights. Trade unions, public interest groups and academics from across the world called for such a U-turn.

Industry will oppose any deal in which investment protection is traded off against public policy objectives, including human and labour rights.

Pascal Kerneis, European Services Forum (ESF)

In numerous letters, seminars, breakfast debates and behind-closed-doors meetings with MEPs and the European Commission, corporate lobby groups such as BusinessEurope and national industry bodies such as the German industry federation BDI lobbied against that U-turn. They made clear that industry would oppose any deal in which investment protection was "traded off against public policy objectives, including human and labour rights", as Pascal Kerneis of the European Services Forum (ESF), a lobby outlet for global service players such as Deutsche Bank, IBM and Vodafone, told Commission officials during a meeting on transatlantic investment.¹⁶

While some argue that investor-state dispute settlement need not be part of the TTIP given the demonstrated US and EU commitment to the rule of law, the Chamber insists that the United States and the EU must include these provisions.

US Chamber of Commerce to US negotiators¹⁷

Expanding investor rights

If big business has its way, TTIP's investment protection provisions will be even more slanted in favour of corporations than current EU and US practice. While the European Parliament has repeatedly stressed governments' right to regulate in order to protect the environment, public health, workers and consumers, Peter Chase – a former US government official now with the US Chamber of Commerce in Brussels – has encouraged US negotiators to explain "the dangers of the unneeded social, environmental and 'right to regulate' provisions the European Parliament seeks".¹⁸

US energy giant Chevron, too, is lobbying for an investment chapter which goes beyond the current US model treaty. Having been sued several times by Canadian companies under NAFTA, the US has twice revised its template for international investment treaties to better protect its policy-space. Chevron wants a revival of some of these excessive

Box 2

Risky business: how vulnerable are US and EU governments?¹⁹

- Globally, **514** investor-state disputes were known by the end of 2012.
- **58** claims were launched in 2012 alone, the highest number of known disputes filed in one year.
- US and EU investors have initiated at least **329 (64%)** of all known disputes.
- The US has faced over **20** investment claims under NAFTA's investment chapter.
- **15** EU member states are known to have faced one or more investor-state challenges.²⁰
- The Czech Republic is the **fifth** most sued country in the world.
- **More than half** of foreign direct investment in the EU comes from the US; likewise over half the foreign direct investment in the US comes from the EU.
- Only **8** EU member states, all Eastern European, already have a bilateral investment treaty with the US²¹; TTIP would contain one of the **first** EU-wide investment protection chapters.
- Around **42%** of the known concluded investor-state cases were decided in favour of the state, **31%** in favour of the investor and **27%** of the cases were settled (many of the latter likely to involve payments or other concessions for the investor).
- The highest damages to date, **US\$1.77 billion**, were awarded to US oil company Occidental Petroleum against Ecuador.
- Legal costs in investor-state disputes average over **US\$8 million**, exceeding **US\$30 million** in some cases; they are not always awarded to the winning party.

investor rights such as the 'umbrella clause' in TTIP, which would considerably expand a state's obligations (see annex for more details). Chevron has also proposed that investments protected under TTIP should include "both existing and future investments".²² When an investor-state dispute mechanism is combined with such open-ended clauses, risks for costly legal proceedings grow considerably.

The US-side should clearly explain the dangers of the unneeded social, environmental, and 'right to regulate' provisions the European Parliament seeks.

Peter Chase, US Chamber of Commerce

Paving the way for dirty gas

Chevron is currently engaged in a controversial legal battle with Ecuador. The company initiated arbitration to avoid paying US\$18 billion to clean up oil-drilling-related

contamination in the Amazonian rainforest, as ordered by Ecuadorian courts. The case has been lambasted as "egregious misuse" of investment arbitration to evade justice.²³ No wonder Chevron dedicated its complete contribution to the US government's TTIP consultation to investment protection, "one of our most important issues globally" as they put it.²⁴

Chevron views investment protection as one of our most important issues globally.

Chevron to US trade negotiators

In Europe, Chevron wants the "the strongest possible protection" from government measures to "mitigate the risks associated with large-scale, capital intensive, and long term projects [...] such as developing shale gas". Because of its health and environmental impacts, several EU governments have decided to put a break on shale gas development ('fracking'). TTIP's proposed investment protection chapter would empower energy companies like Chevron to

challenge such precautionary measures because it would oblige governments “to refrain from undermining legitimate investment-backed expectations”, as Chevron demands (see Box 1 for a legal precedent under NAFTA). The mere threat of a million-Euro investor-state lawsuit could be enough to scare governments into submission and weaken or prevent fracking bans and strict regulation. In Chevron’s words: “Access to arbitration [...] increases the likelihood that investors and host states are able to resolve disagreements and negotiations in a successful and equitable manner.”²⁵

I’ve seen the letters from the New York and DC law firms coming up to the Canadian government on virtually every new environmental regulation [...]. Virtually all of the initiatives were targeted and most of them never saw the day of light.

Former Canadian government official, 5 years after NAFTA’s investor-state provisions came into force²⁶

Law firms lobbying for vested interests

Whenever policy-makers in the EU and the US have set out to change international investment treaties in recent years, law firms and investment arbitrators together with industry associations have mounted fierce lobbying campaigns to counter reforms to better balance public and private interests.²⁷ This is not surprising – investment arbitration is big business for them. The tabs racked up by elite law firms can be US\$1,000 per hour, per lawyer in investment treaty cases, with whole teams handling them. The private lawyers who decide these disputes, the arbitrators, also line their pockets, earning daily fees of US\$3,000 and more.²⁸ The more investment treaties and trade agreements with investor-state dispute settlement provisions exist, the more business for these lawyers.

EU and US lawyers dominate the field, seeking out every opportunity to sue countries. Nineteen of the top-20 law firms representing claimants and/or defendants in such disputes are headquartered in Europe or the US, the large majority of them (14) US firms. Out of the 15 arbitrators who have decided 55% of the total investor-state disputes known today, ten are from the EU or the US.²⁹

Since the entry into force of the Lisbon Treaty in Europe in 2009, law firms like Hogan Lovells and Herbert Smith Freehills have been keen to influence the debate, inviting

the European Commission, member state officials and MEPs to “informal but informed” roundtable discussions and webinars with their clients – including several who have sued countries under existing investment treaties such as Deutsche Bank, Shell and energy giant GDF Suez. Their message: there was a need for high standards of investor protection and in particular investor-state arbitration; and investment protection should not be linked to labour or environmental standards.³⁰

One of the main concerns put forward by lawyers was the politicisation of investment policy as a result of the Lisbon Treaty. The involvement of the European Parliament was a particular thorn in their side. At a conference in December 2009, Daniel Price, an ex-US trade negotiator and former co-chair of the Transatlantic Economic Council³¹ who now mainly works as lobbyist, investment lawyer and arbitrator, warned of the potential “steady deterioration” of investment treaties which he had witnessed in the US. The involvement of Congress had led to controversy and later to a review of the US investment policy which Price considered “unhelpful”. This review tried to better balance investor and state rights through more precise legal language. In January 2010, shortly after Price had walked through the revolving door from the Bush administration, he wrote to the Commission official responsible for the investment files and offered “to assist you in thinking through these issues.” He added: “As you know, my group has advised both outbound investors and governments on investment policy issues”.³²

A pure power grab

Some of Price’s arbitrator colleagues have already come out defending TTIP investor-state dispute settlement provisions against more cautious voices warning of litigation risks and questioning the need for extra-judicial enforcement in two sophisticated legal systems such as the US and the EU. Simon Lester, for example, policy analyst of the libertarian Cato Institute and usually a proponent of investor-state arbitration, has warned of the unprecedented litigation risks that such a dispute settlement system would create in the context of the enormous transatlantic investment flows.³³

With the amount of investment that would be covered in a US-EU agreement, US and EU leaders might have to start contemplating the impact of investor-state losses.

Simon Lester, Trade Policy Analyst, Cato Institute³⁴

One of the usual arguments for investor-state arbitration – the need to grant legal security to attract foreign investors to countries with weak court systems – turns to dust in the context of TTIP. If US and EU investors already make up for more than half of foreign direct investment in each others' economies, then it is clear that investors seem to be happy enough with the rule of law on both sides of the Atlantic. This is confirmed by an internal European Commission report from 2011 stating that "it is arguable that an investment protection agreement with the US would be needed with regard to the rule of law."³⁵

What possibly could be the explanation for why you would need extra-judicial enforcement and additional property rights with respect to an agreement with the European Union? Is it the US position that Europe's courts are crappy and that their property laws are scandalous? They are not. Investor-state in TTIP is a pure power grab from corporations.

Lori Wallach, Director Global Trade Watch at Public Citizen³⁶

Growing public outcry

Citizens and organised civil society, on the other hand, oppose investor-state dispute settlement. According to a statement by the Transatlantic Consumer Dialogue, supported by consumer groups from the EU and the US, TTIP "should not include investor-state dispute resolution. Investors should not be empowered to sue governments to enforce the agreement in secretive private tribunals, and to skirt the well-functioning domestic court systems and robust property rights protections in the United States and European Union."³⁷ The federation of US trade unions, AFL-CIO, similarly argues that "given the advanced judicial systems of both the US and EU", investor-state dispute settlement "is an unwarranted risk to domestic policy-making at the local, state and federal levels."³⁸ Digital rights activists, environmentalists and health groups have also come out against the threat of a corporate assault on democracy.

The US National Conference of State Legislators, which represents all 50 US state parliamentary bodies, has also

announced that it "will not support any [trade agreement] that provides for investor-state dispute resolution" because it interferes with their "capacity and responsibility as state legislators to enact and enforce fair, nondiscriminatory rules that protect the public health, safety and welfare, assure worker health and safety, and protect the environment."³⁹ MEPs from the Greens, Socialists and the Left Group in the European Parliament seem equally concerned.

It doesn't make any sense to apply this system in relations between the EU and the United States. Any claim should go through ordinary judicial system.

MEP David Martin, Socialists & Democrats⁴⁰

When US-Congressman Alan Grayson alerted the public that TTIP would include an investor-state system allowing consumer protection, environmental safeguards and labour laws to be "struck down by international tribunals", this generated nearly 10,000 angry comments from citizens in little more than 24 hours.⁴¹

Why are our representatives thinking about handing over our sovereign rights to huge corporations who care nothing about us?

One of many concerned citizens in her contribution to public TTIP consultation in US⁴²

Beware of the EU agenda

Some EU member states also seem to question the need for investment protection clauses between two legal systems which are as sophisticated as in the EU and the US. Some fear a flood of claims from the US with its more aggressive legal culture. There are concerns that the US financial sector could attack policies to tackle Europe's economic crisis such as bail-outs and debt restructuring. On the other hand, member states such as Germany and the Netherlands, which support far-reaching investor rights, rather want to avoid pro-public interest legal language which is more common in the US and which, in their view, would 'dilute' investment protections.

But the US government and the European Commission seem to be determined to use TTIP to empower foreign investors to bypass local courts and sue states directly at international tribunals when democratic decisions impede their expected profits. In its negotiation mandate, the Commission made detailed suggestions for a "state-of-the-art investor-to-state dispute settlement mechanism" and investor rights which mirror the proposals from business lobby groups.⁴³ The proposal will put many policies at risk and most likely create a chilling effect on governments looking to pass new rules to protect the environment and society (see annex).

It is high time that governments and parliaments on both sides of the Atlantic grasp the political and financial risks of investor-state dispute settlement and axe the plans for this looming transatlantic corporate bill of rights. The European Parliament in particular should put a leash on the Commission which is obviously disregarding MEPs' call for "major changes"⁴⁴ in the international investment regime (see annex).

Why on earth should legislators grant business such a powerful tool to rein in democracy and curb sound policies made in the interest of the public?

ANNEX:

The devil is in the (TTIP) detail

Trade speak: what the EU wants to negotiate⁴⁵

Translation: what it means in practice⁴⁶

The investment protection chapter “should cover a broad range of investors and their investments [...] whether the investment is made before or after the entry into force of the Agreement”.

Definitions of “investor” and “investments” are key because they determine who/what is covered by the chapter. A broad definition not only covers actual enterprises in the host state, but a vast universe ranging from holiday homes to sovereign debt instruments, exposing states to unpredictable legal risk. Broad definitions also open the door to mailbox companies abusing the treaty via “treaty shopping”, allowing, for example, a US firm to sue the US via a Dutch mailbox company.

Intellectual property rights (IPR) should be included in the definition of ‘investments’ to be protected by TTIP.

The investor-state disputes of tobacco company Philip Morris against Uruguay and Australia show the risks of this proposal (Box 1). In another IPR-based claim, US drug giant Eli Lilly is attacking patent laws in Canada whereby a medicine’s patentability must be demonstrated when filing a patent⁴⁷. Public health lawyers have lambasted TTIP-like deals a “booby trap for access to medicines”.⁴⁸

Investors should be treated in a “fair and equitable” (FET) way, “including a prohibition of unreasonable, arbitrary or discriminatory measures”.

A catch-all provision most relied on by investors when suing states. In 74% of the cases where US investors won, tribunals found an FET violation. In *Tecmed v. Mexico*, for example, the tribunal found that Mexico had not acted “free from ambiguity and totally transparently”. Due to environmental concerns, a local government had not relicensed an operating waste treatment plant.⁴⁹ The EU is likely to propose a broad version of the clause, even protecting what investors consider their ‘legitimate’ expectations from ‘unpredictable’ policy change. A ban on a chemical found to be harmful to public health could be considered a violation of this provision. Investors will also be enabled to challenge scientific justifications of a policy and ‘arbitrary’ or ‘unreasonable’ relationships between a policy and its objective.

Investors should be protected “against direct and indirect expropriation”, including the right to compensation.

From a certain, investor-friendly view, almost any law or regulatory measure can be considered an ‘indirect expropriation’ when it has the effect of lowering future expected profits. Several tribunals have interpreted legitimate environmental and other public policies in such a way.

The agreement should also include an “umbrella clause”.

This would bring all obligations a state assumed with regards to an investment under the TTIP ‘umbrella’ (like a contract with one investor), multiplying the risk of costly lawsuits.

The agreement should guarantee the “free transfer of funds of capital and payments by investors”.

This provision would allow the investor to always withdraw all investment-related monies, reducing the ability of countries to deal with sudden and massive out- and inflows of capital, balance of payment and other macroeconomic crises.

Investment protection “should be without prejudice to the right of the EU and the Member States to adopt and enforce [...] measures necessary to pursue legitimate public policy objectives such as social, environmental, security, stability of the financial system, public health and safety in a non-discriminatory manner”.

This paragraph provides false comfort. It links public policy to a necessity test, placing a big burden of proof on governments to justify their actions. Is Australia’s plain packaging law for cigarette packs necessary to protect public health? Was Germany’s exit from nuclear energy necessary? Might there not have been other, more effective measures? It would be up to an offshore tribunal of private lawyers with lack of accountability to decide.

<p>The arbitrators who decide investor-state claims should be independent.</p>	<p>This responds to widespread concerns about conflicts of interest among the 3-lawyer panels which ultimately decide investor-state disputes. Unlike judges, they have no flat salary but earn more the more claims they rule on. Existing codes of conduct have not prevented a small club of arbitrators from deciding on the majority of investor-state disputes, paving the way for more business in the future with expansive, investor-friendly interpretations of the law. Whether the EU will tackle the conflicts of interest of these 'entrepreneurial arbitrators' remains to be seen. Just claiming that they are independent clearly won't be enough.</p>
<p>There should be a "possibility of binding interpretation of the Agreement by the Parties".</p>	<p>This should allow governments to monitor and control how the law that they created is interpreted. Following a wave of investor claims under NAFTA, the US, Canada and Mexico have issued such joint clarifications of vaguely formulated investor rights. In practice, arbitrators have proven that they are willing to ignore these 'binding' interpretations.⁵⁰</p>
<p>Investors should be able to use "as wide a range of arbitration fora as is currently available under the Member States' bilateral investment agreements".</p>	<p>The institution that administers an investor-state dispute matters: for example, when it appoints arbitrators or resolves conflict of interest claims against them. A "wide range" of fora could include purely business-orientated organisations such as the Paris-based International Chamber of Commerce (ICC), one of the world's most influential corporate lobby groups. Can such a business site really be considered an independent forum for an investor-state dispute?</p>
<p>"The investor-to-state dispute settlement mechanism should contain safeguards against manifestly unjustified or frivolous claims".</p>	<p>Another paragraph providing false comfort. None of the controversial attacks on sound public policies mentioned in Box 1 would be dismissed under such a mechanism – because they are based on allegations of real violations of investment treaties as these tend to be so broad. Claims are only considered frivolous when there is a complete lack of legal merit. Under existing rules, states can already ask arbitrators to swiftly dispose of frivolous claims, but not a single such case is known.⁵¹</p>
<p>"Consideration should be given to the possibility of creating an appellate mechanism applicable to investor-to-state dispute settlement under the Agreement".</p>	<p>Unlike in proper court systems, decisions by investor-state arbitration panels are non-reviewable (except for annulment proceedings that address a narrow range of procedural errors and are not heard by judges but by another arbitration tribunal). An appeal mechanism could contribute to more coherent decisions, but as things currently stand, this is a long way from becoming a reality.</p>

Endnotes

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“ Why are our representatives thinking about handing over our sovereign rights to huge corporations who care nothing about us? ”

One of many concerned citizens in her contribution to the public TTIP consultation in the US



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Network**

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www.s2bnetwork.org



Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making. CEO works in close alliance with public interest groups and social movements in and outside Europe to develop alternatives to the dominance of corporate power.

www.corporateeurope.org



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TNI seeks to provide intellectual support to those movements concerned to steer the world in a democratic, equitable and environmentally sustainable direction.

www.tni.org

November 8, 2013

The President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

The organizations below are, like you, dedicated to ensuring the sustainability of public programs that provide access to affordable health care. But we write today to express our deep concern that provisions being advanced by the United States Trade Representative (USTR) for the Trans-Pacific Partnership (TPP) Agreement will undermine this goal by limiting the ability of states and the federal government to moderate escalating prescription drug, biologic drug and medical device costs in public programs. We are also concerned that the final trade agreement will bind the U.S. to a 12-year market exclusivity period for brand-name biologic drugs, contrary to the Administration's proposal in its most recent and previous budgets to reduce the exclusivity period.

With respect to policies used by public programs to manage spending on prescription drugs and medical devices, the following are examples of existing laws or proposals that could be subject to challenge by manufacturers under the Korea free trade agreement and the reported TPP proposals made by the USTR:

- The Affordable Care Act's discounts for prescription drugs under Medicare Part D;
- The Administration's proposal to save \$134 billion over 10 years through rebates under the Medicare program for low-income beneficiaries;
- Section 340B of the Public Health Services Act which includes a formula that the Department of Health and Human Services uses to set reduced prices for medicines supplied for outpatient care through nonprofit clinics, community health centers and safety net hospitals;
- Use of preferred drug lists and other mechanisms that state Medicaid programs have implemented to control costs;
- Application of comparative research funded by the Affordable Care Act, which will allow payers to make reimbursement decisions based on clinical comparisons of treatments; and
- Decisions by state Medicaid programs to remove drugs from their formularies, because they do not prove to be efficacious or because they have significant health risks.

While the free trade agreement with Korea included a footnote that excluded Medicaid from the pharmaceutical and medical device provisions in that agreement, there is at least one press report that New Zealand, one of the TPP countries, has told the United States that the reimbursement proposal is completely unacceptable unless the United States were to apply it to all U.S. federal or state-level drug pricing and reimbursement programs, including Medicaid.¹

We are also concerned that the reported U.S. proposal requires a lopsided appeals process that affords rights only to manufacturers and not to other stakeholders. Like the agreement reached with Korea, the reported U.S. proposal for TPP sets a standard for reimbursement amounts that is based on “competitive market-derived prices” or amounts that “appropriately recognize the value of the patented” products. Preferred drug lists, statutorily specified discounts or rebates would violate these standards, as would reimbursement policies that discourage the use of costlier new drugs or treatments that are not more effective than existing drugs or treatments.

Lastly, we urge the Administration to make the negotiating process transparent. While USTR proposals are developed in close and formal consultation with the pharmaceutical and medical device industries through the Industry Trade Advisory Committee, this process excludes health care advocates and the broader public. While the USTR may have a position that its TPP proposals will not affect existing U.S. laws or limit choices available to future lawmakers, the ultimate arbiter of these provisions will not be the USTR, but will be international arbitration forums. That makes it critical that negotiators have access to a full range of views and analysis through an open and public process.

We appreciate that international trade has the potential to raise the standard of living and quality of life for people in the United States and around the world. However, the proposals that have been advanced by the USTR related to the pharmaceutical, biologic and medical device industries could do the opposite by undermining access to affordable health care for millions in the United States and around the world. As trade negotiations move forward, we urge you to ensure that the TPP agreement and future trade agreements do not limit the tools available to states or the federal government to manage pharmaceutical and medical device costs in public programs and that agreements do not bind the U.S. to a 12-year exclusivity period for brand-name biologic drugs. We further urge that the process be made transparent to allow public input.

Thank you for considering our concerns.

Sincerely,

AARP
Alliance for Retired Americans
Alliance for a Just Society
American Federation of State, County and Municipal Employees
Center for Medicare Advocacy
Coalition on Human Needs
Community Catalyst
Consumers Union
Families USA
Health Care for America Now

Medicare Rights Center
National Association of Counties
National Committee to Preserve Social Security and Medicare
National Senior Citizens Law Center
National Women's Law Center

cc: The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services
Sylvia Mathews Burwell, Director, Office of Management and Budget
Ambassador Michael B.G. Froman, U.S. Trade Representative
Marilyn B. Tavenner, Administrator, Centers for Medicare and Medicaid Services
Cindy Mann, Director, Center for Medicaid and CHIP Services
Elizabeth Richter, Acting Director, Center for Medicare

¹ *Inside U.S. Trade*, November 4, 2011.

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the guardian

This transatlantic trade deal is a full-frontal assault on democracy

Brussels has kept quiet about a treaty that would let rapacious companies subvert our laws, rights and national sovereignty

• [Ken Clarke responds to this article](#)

Follow George Monbiot by email

BETA



George Monbiot

The Guardian, Monday 4 November 2013 15.31 EST



David Cameron with Barack Obama at a state dinner in Cameron's honour in 2012 at the White House. Photograph: Mandel Ngan/AFP/Getty Images

Remember that referendum about whether we should create a single market with the United States? You know, the one that asked whether corporations should have the power to strike down our laws? No, I don't either. Mind you, I spent 10 minutes looking

for my watch the other day before I realised I was wearing it. Forgetting about the referendum is another sign of ageing. Because there must have been one, mustn't there? After all that agonising over whether or not we should stay in the European Union, the government wouldn't cede our sovereignty to some shadowy, undemocratic body without consulting us. Would it?

The purpose of the Transatlantic Trade and Investment Partnership is to remove the regulatory differences between the US and European nations. I mentioned it a couple of weeks ago. But I left out the most important issue: the remarkable ability it would grant big business to sue the living daylights out of governments which try to defend their citizens. It would allow a secretive panel of corporate lawyers to overrule the will of parliament and destroy our legal protections. Yet the defenders of our sovereignty say nothing.

The mechanism through which this is achieved is known as investor-state dispute settlement. It's already being used in many parts of the world to kill regulations protecting people and the living planet.

The Australian government, after massive debates in and out of parliament, decided that cigarettes should be sold in plain packets, marked only with shocking health warnings. The decision was validated by the Australian supreme court. But, using a trade agreement Australia struck with Hong Kong, the tobacco company Philip Morris has asked an offshore tribunal to award it a vast sum in compensation for the loss of what it calls its intellectual property.

During its financial crisis, and in response to public anger over rocketing charges, Argentina imposed a freeze on people's energy and water bills (does this sound familiar?). It was sued by the international utility companies whose vast bills had prompted the government to act. For this and other such crimes, it has been forced to pay out over a billion dollars in compensation. In El Salvador, local communities managed at great cost (three campaigners were murdered) to persuade the government to refuse permission for a vast gold mine which threatened to contaminate their water supplies. A victory for democracy? Not for long, perhaps. The Canadian company which sought to dig the mine is now suing El Salvador for \$315m – for the loss of its anticipated future profits.

In Canada, the courts revoked two patents owned by the American drugs firm Eli Lilly, on the grounds that the company had not produced enough evidence that they had the beneficial effects it claimed. Eli Lilly is now suing the Canadian government for \$500m, and demanding that Canada's patent laws are changed.

These companies (along with hundreds of others) are using the investor-state dispute rules embedded in trade treaties signed by the countries they are suing. The rules are enforced by panels which have none of the safeguards we expect in our own courts. The hearings are held in secret. The judges are corporate lawyers, many of whom work for companies of the kind whose cases they hear. Citizens and communities affected by their decisions have no legal standing. There is no right of appeal on the merits of the case. Yet they can overthrow the sovereignty of parliaments and the rulings of supreme courts.

You don't believe it? Here's what one of the judges on these tribunals says about his work. "When I wake up at night and think about arbitration, it never ceases to amaze me that sovereign states have agreed to investment arbitration at all ... Three private individuals are entrusted with the power to review, without any restriction or appeal procedure, all actions of the government, all decisions of the courts, and all laws and regulations emanating from parliament."

There are no corresponding rights for citizens. We can't use these tribunals to demand better protections from corporate greed. As the [Democracy Centre](#) says, this is "a privatised justice system for global corporations".

Even if these suits don't succeed, they can exert a powerful chilling effect on legislation. One Canadian government official, speaking about the rules introduced by the North American Free Trade Agreement, remarked: "I've seen the letters from the New York and DC law firms coming up to the Canadian government on virtually every new environmental regulation and proposition in the last five years. They involved dry-cleaning chemicals, pharmaceuticals, pesticides, patent law. Virtually all of the new initiatives were targeted and most of them never saw the light of day." Democracy, as a meaningful proposition, is impossible under these circumstances.

This is the system to which we will be subject if the transatlantic treaty goes ahead. The US and the European commission, both of which have been captured by the corporations they are supposed to regulate, are pressing for investor-state dispute resolution to be included in the agreement.

The commission justifies this policy by claiming that domestic courts don't offer corporations sufficient protection because they "might be biased or lack independence". Which courts is it talking about? Those of the US? Its own member states? It doesn't say. In fact it fails to produce a single concrete example demonstrating the need for a new, extrajudicial system. It is precisely because our courts are generally not biased or lacking independence that the corporations want to bypass them. The EC seeks to replace open, accountable, sovereign courts with a closed, corrupt system riddled with

conflicts of interest and arbitrary powers.

Investor-state rules could be used to smash any attempt to save the NHS from corporate control, to re-regulate the banks, to curb the greed of the energy companies, to renationalise the railways, to leave fossil fuels in the ground. These rules shut down democratic alternatives. They outlaw leftwing politics.

This is why there has been no attempt by the UK government to inform us about this monstrous assault on democracy, let alone consult us. This is why the Conservatives who huff and puff about sovereignty are silent. Wake up, people we're being shafted.

Twitter: [@georgemonbiot](https://twitter.com/georgemonbiot). A fully referenced version of this article can be found at monbiot.com

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This EU-US trade deal is no 'assault on democracy'

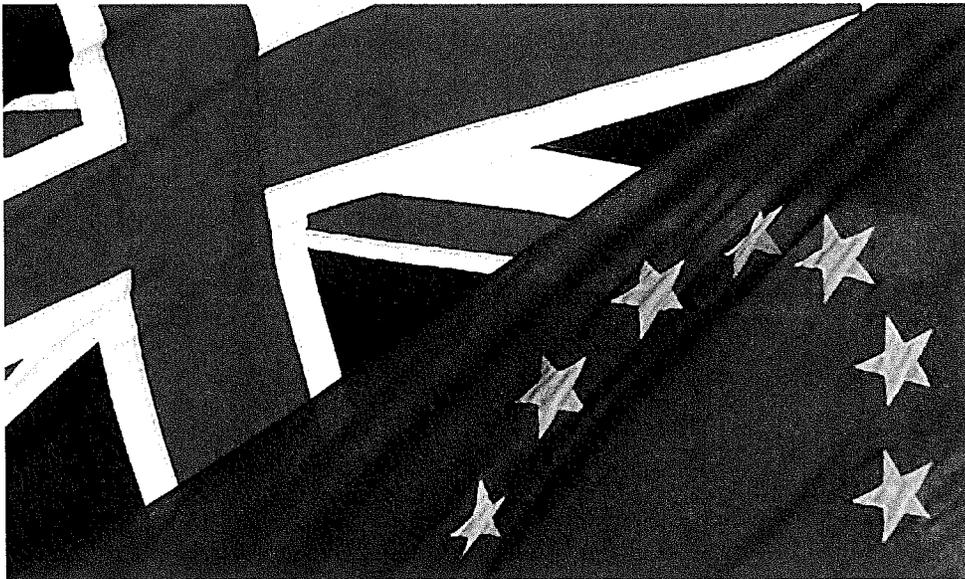
Ignore George Monbiot's polemic – the Transatlantic Trade and Investment Partnership is an astonishingly good deal for the UK economy

- George Monbiot: [This transatlantic trade deal is a full-frontal assault on democracy](#)



Ken Clarke

theguardian.com, Monday 11 November 2013 08.01 EST



The Transatlantic Trade and Investment Partnership would see the UK economy grow by an extra £10bn per annum'. Photograph: Stefan Wermuth/Reuters

On Monday, [EU and US negotiators are meeting in Brussels](#) for the second round of negotiations over what has become known as the [Transatlantic Trade and Investment Partnership \(TTIP\)](#).

Despite its byzantine name, the TTIP is in fact a trade deal between the EU and the US:

an astonishingly bold project which aims to create a free market encompassing the 800 million peoples of Europe and America, potentially boosting our collective GDP by £180bn.

Not that you would know that if you read George Monbiot's contribution on these pages a week ago. In one of the more conspiracy theorising polemics I have read in some while, he described this wealth-creating, free-trading, economic stimulus simply as "a monstrous assault on democracy" by institutions, "which have been captured by the corporations they are supposed to regulate". Monbiot is entitled to his view, but even on a highly selective reading of the facts, I cannot see how his argument stands up.

Take the effect we hope that the TTIP will have on the UK economy alone. According to the best estimates available, an ambitious deal would see our economy grow by an extra £10bn per annum. It could see a rise in the number of jobs in the UK car industry of 7%. British companies – of all sizes – currently pay £1bn to get their goods into the US – this cost could be removed altogether. Perhaps most importantly in the long-term, such a deal would safeguard the liberal trading rules which we British depend on – but which the growing economies of the east are less keen on – or generations to come.

I have never had Monbiot down as an ungenerous character, but to ignore all of this in favour of blowing up a controversy around one small part of the negotiations, known as investor protection, seems to me positively Scrooge-like. Investor protection is a standard part of free-trade agreements – it was designed to support businesses investing in countries where the rule of law is unpredictable, to say the least. Clearly the US falls in a somewhat different category and those clauses will need to be negotiated carefully to avoid any pitfalls – but to dismiss the whole deal because of one comparatively minor element of it would be lunacy.

This talk of shadowy corporations is all the more misleading given that, in my view, the deal's advantages will prove to be far more noticeable for smaller enterprises than for larger corporations. This is because the most important task for the regulators will be to establish that where a car part or a cake or a beauty product has been tested as safe in the EU, the US will allow its import without requiring a whole new series of similar-but-slightly different tests – and vice versa. This is not about reducing safety levels. It is simply common sense. Would any of us on holiday in the US decline to hire that all-American SUV, or say no to that unfeasibly enormous vat of fizzy pop on the grounds that the regulations "are not the same as the EU's"?

And while it is of course true to say that these changes will help big business, it is also true to say that big business often has a vested interest in overly complex regulation.

They can afford armies of staff to satisfy reams of regulation, but their smaller rivals cannot and so are squeezed out. So while leftwing radicals can attempt to skew the facts, it's my view that the TTIP is much more a deal for the small widget maker from the West Midlands than it is for the multinational corporate giant.

There is, of course, a long way to go if we are to make this a reality. Governments on both sides of the pond hope we will reach a conclusion on most aspects of a deal before 2014 is out. Meeting that target would be a major economic achievement. It would also be a serious political victory for Britain in Europe, demonstrating not only the enormously increased clout the UK enjoys on the world stage as part of the EU, but also that other EU leaders are heeding his calls for the institution to reform and focus on the vital issues of trade and competitiveness.

Far from carping from the sidelines, as advised by Monbiot, we British have a major part to play in what could be one almighty success story. We should knuckle down and get to it.

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November 12, 2013

General Keith Alexander
Director
National Security Agency
9800 Savage Rd.
Fort Meade, MD 20755

The Honorable Michael Froman
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear General Alexander and Ambassador Froman,

The New York Times reports on November 3 that wide-reaching efforts by the National Security Agency to collect data are driven in part by the agency's "customers" -- a range of other government agencies that includes the Office of the U.S. Trade Representative.

In light of this and other disclosures, we are writing to ask if the NSA, or other national security agencies, have surveilled any U.S. organizations or individuals advocating on U.S. trade policy. We ask you to disclose any such surveillance, whether or not it occurred at the request of USTR; whether or not it involved communications with foreign nationals; and whether or not it occurred within U.S. borders.

Core American principles ranging from the right to privacy to the right to petition our government are at stake. Simply put, we believe that our organizations -- as well as all others advocating on trade policy matters -- have right to an assurance that their operations are not under surveillance by U.S. government agencies. We trust you agree.

We look forward to your reply.

Access (AccessNow.org)
American Medical Student Association
Center for Digital Democracy
Center for Effective Government
Center for Financial Privacy and Human Rights
Center for Food Safety
Center for International and Environmental Law
Center for Media and Democracy
Center for Rights
Citizens for Ethics and Responsibility in
Washington (CREW)
Citizens Trade Campaign
Coalition for Sensible Safeguards
Communications Workers of America
Consumer Action
Consumer Federation of America
Consumer Watchdog
Defending Dissent Foundation
Electronic Frontier Foundation
Fight for the Future

Food & Water Watch
Friends of the Earth, U.S.
Friends of Privacy USA
Government Accountability Project
Greenpeace
Health GAP
Institute for Agriculture and Trade Policy
Just Foreign Policy
Knowledge Ecology International
National Legislative Association on Prescription
Drug Prices
Openthegovernment.org
Organic Consumers Association
Privacy Times
Project On Government Oversight (POGO)
Public Citizen
Public Knowledge
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WikiLeaks publishes secret draft chapter of Trans-Pacific Partnership

Treaty negotiated in secret between 12 nations 'would trample over individual rights and free expression', says Julian Assange

Alex Hern and Dominic Rushe

theguardian.com, Wednesday 13 November 2013 13.12 EST



Demonstrators protest against the Trans-Pacific Partnership (TPP) after the May Day rally in Tokyo, Japan. Photograph: EPA/Kimimasa Mayama

WikiLeaks has released the draft text of a chapter of the Trans-Pacific Partnership (TPP) agreement, a multilateral free-trade treaty currently being negotiated in secret by 12 Pacific Rim nations.

The full agreement covers a number of areas, but the chapter published by WikiLeaks focuses on intellectual property rights, an area of law which has effects in areas as diverse as pharmaceuticals and civil liberties.

Negotiations for the TPP have included representatives from the United States, Canada, Australia, New Zealand, Japan, Mexico, Malaysia, Chile, Singapore, Peru, Vietnam, and Brunei, but have been conducted behind closed doors. Even members of the US

Congress were only allowed to view selected portions of the documents under supervision.

"We're really worried about a process which is so difficult for those who take an interest in these agreements to deal with. We rely on leaks like these to know what people are talking about," says Peter Bradwell, policy director of the London-based Open Rights Group.

"Lots of people in civil society have stressed that being more transparent, and talking about the text on the table, is crucial to give treaties like this any legitimacy. We shouldn't have to rely on leaks to start a debate about what's in them."

The 30,000 word intellectual property chapter contains proposals to increase the term of patents, including medical patents, beyond 20 years, and lower global standards for patentability. It also pushes for aggressive measures to prevent hackers breaking copyright protection, although that comes with some exceptions: protection can be broken in the course of "lawfully authorised activities carried out by government employees, agents, or contractors for the purpose of law enforcement, intelligence, essential security, or similar governmental purposes".

WikiLeaks claims that the text shows America attempting to enforce its highly restrictive vision of intellectual property on the world – and on itself. "The US administration is aggressively pushing the TPP through the US legislative process on the sly," says Julian Assange, the founder and editor-in-chief of WikiLeaks, who is living in the Ecuadorean embassy in London following an extradition dispute with Sweden, where he faces allegations of rape.

"If instituted," Assange continues, "the TPP's intellectual property regime would trample over individual rights and free expression, as well as ride roughshod over the intellectual and creative commons. If you read, write, publish, think, listen, dance, sing or invent; if you farm or consume food; if you're ill now or might one day be ill, the TPP has you in its crosshairs."

Just Foreign Policy, a group dedicated to reforming US foreign policy, managed to crowdfund a \$70,000 (£43,700) bounty for Wikileaks if the organisation managed to leak the TPP text. "Our pledge, as individuals, is to donate this money to WikiLeaks should it leak the document we seek." The conditions the group set have not yet been met, however, because it required the full text, not individual chapters.

Related to the TPP is a second secret trade agreement, the Transatlantic Trade and Investment Partnership (TTIP), which ties together regulatory practices in the US and

EU. George Monbiot, [writing in this paper](#), referred to the treaty as a "monstrous assault on democracy". Ken Clarke, the minister without portfolio, [replied](#) that it "would see our economy grow by an extra £10bn per annum".

Campaign group Fight for the Future has already collected over 100,000 signatures in an [online petition](#) against what it calls the "extreme Internet censorship plan: contained in the TPP.

Evan Greer, campaign manager for Fight for the Future, said: "The documents revealed by WikiLeaks make it clear why the US government has worked so hard to keep the TPP negotiations secret. While claiming to champion an open Internet, the Obama administration is quietly pushing for extreme, SOPA-like copyright policies that benefit Hollywood and giant pharmaceutical companies at the expense of our most basic rights to freedom of expression online."



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The New York Times

November 12, 2013

House Stalls Trade Pact Momentum

By ANNIE LOWREY

WASHINGTON — The Obama administration is rushing to reach a new deal intended to lower barriers to trade with a dozen Pacific Rim nations, including Japan and Canada, before the end of the year.

But the White House is now facing new hurdles closer to home, with nearly half of the members of the House signing letters or otherwise signaling their opposition to granting so-called fast-track authority that would make any agreement immune to a Senate filibuster and not subject to amendment. No major trade pact has been approved by Congress in recent decades without such authority.

Two new House letters with about 170 signatories in total — the latest and strongest iteration of long-simmering opposition to fast-track authority and to the trade deal more broadly — have been disclosed just a week before international negotiators are to meet in Salt Lake City for another round of talks.

“Some of us have opposed past trade deals and some have supported them, but when it comes to fast track, members of Congress from across the political spectrum are united,” said Representative Walter B. Jones Jr. of North Carolina, who circulated the Republican letter.

Without fast-track authority, however, the other countries in the negotiations might balk at American requests since they wouldn't be sure the final deal would remain unchanged. And getting both houses of Congress to agree to the final deal might be close to impossible without the fast-track authority, which the Obama administration has requested and which is being pursued in the Senate by Max Baucus, Democrat of Montana and the chairman of the Senate Finance Committee, along with the top Republican on the committee, Orrin G. Hatch of Utah.

“This could be the end of T.P.P.,” said Lori Wallach of Public Citizen, a watchdog group that has opposed the deal, formally called the Trans-Pacific Partnership. “All these other countries are like, ‘Wait, you have no trade authority and nothing you've promised us means anything? Why would we give you our best deal?’ Why would you be making concessions to the emperor who has no clothes?”

Michael B. Froman, the United States trade representative, said that he continued to work with Congress on fast-track authority, also known as trade promotion authority.

“We believe that Congress should have a strong role in determining U.S. trade policy — and one of the best ways they can do that is to pass a law codifying their direction to the administration for negotiating trade agreements,” Mr. Froman said. “We will continue to consult with Congress on the importance of T.P.A. as a longstanding tool for shaping U.S. trade policy on behalf of the American people.”

The Obama administration has conducted a behind-the-scenes campaign to win over congressional offices and keep members — in particular, key committee members — informed.

“Everything we do with trade policy is done hand-in-glove with Congress,” Mr. Froman said in recent remarks, where he also emphasized that there was no trade agreement yet, and that the administration continued to get feedback from Congress about what to include in the deal.

But coming to an agreement at home might be as much of a hurdle as doing so internationally. Senate aides said that the overloaded congressional calendar posed a challenge to passing fast-track authority by the end of the year, but that they thought it still had enough bipartisan support to win passage in the Senate.

“The legislative window is closing,” said Sean Neary, a spokesman for Senator Baucus. “This is a priority.”

The greater challenge lies in the House, where opposition to the fast-track authority comes from both policy and process concerns, and from a range of liberals, conservatives and moderates.

Many members have had a longstanding opposition to certain elements of the deal, arguing it might hurt American workers and disadvantage some American businesses. Those concerns are diverse, including worries about food safety, intellectual property, privacy and the health of the domestic auto industry.

Others say that they are upset that the Obama administration has, in their view, kept Congress in the dark about the negotiations, by not allowing congressional aides to observe the negotiations and declining to make certain full texts available.

“We remain deeply troubled by the continued lack of adequate congressional consultation in many areas of the proposed pact that deeply implicate Congress’ constitutional and domestic

policy authorities,” said the House Democrats’ letter, circulated by Representative Rosa DeLauro of Connecticut and George Miller of California.

The House Democratic letter has about 151 signatories. On the Republican side, 22 lawmakers signed a similar letter. Other members have signaled their opposition independently, meaning that roughly 40 percent to 50 percent of House members have signaled that they have concerns about, or oppose, the use of fast-track authority.

The T.P.P. as outlined is aimed at reducing barriers, cutting red tape and harmonizing international regulations, though it is also expected to include numerous provisions protecting a wide variety of interests, both at home and abroad, from increased competition.

This article has been revised to reflect the following correction:

Correction: November 13, 2013

An earlier version of this article referred incorrectly to the position of roughly 40 to 50 percent of House members on a pending issue involving a trade agreement with Pacific Rim nations. They have signaled that they have concerns about, or oppose, the use of fast-track authority to push through such an accord, not that they do not support the pact itself.

PLEASE NOTE: Legislative Information **cannot** perform research, provide legal advice, or interpret Maine law. For legal assistance, please contact a qualified attorney.

JOINT RESOLUTION MEMORIALIZING THE PRESIDENT OF THE UNITED STATES, THE UNITED STATES CONGRESS AND THE UNITED STATES TRADE REPRESENTATIVE REGARDING THE USE OF TRADE PROMOTION AUTHORITY IN INTERNATIONAL TRADE POLICY

WE, your Memorialists, the Members of the One Hundred and Twenty-sixth Legislature of the State of Maine now assembled in the First Regular Session, most respectfully present and petition the President of the United States, the United States Congress and the United States Trade Representative as follows:

WHEREAS, the State strongly supports international trade when fair rules of trade are in place and seeks to be an active participant in the global economy, and the State seeks to maximize the benefits and minimize any negative effects of international trade; and

WHEREAS, existing trade agreements have effects that extend significantly beyond the bounds of traditional trade matters, such as tariffs and quotas, and can undermine Maine's constitutionally guaranteed authority to protect the public health, safety and welfare and its regulatory authority; and

WHEREAS, a succession of federal trade negotiators from both political parties over the years have failed to operate in a transparent manner and have failed to meaningfully consult with the State on the far-reaching effect of trade agreements on state and local laws, even when obligating the State to comply with the terms of these agreements; and

WHEREAS, Article II, Section 2 of the United States Constitution empowers the President of the United States "...by and with the advice and consent of the Senate, to make treaties, provided two thirds of Senators present concur..."; and

WHEREAS, the trade promotion authority implemented by the United States Congress and the President of the United States with regard to international trade and investment treaties and agreements entered into over the past several years, commonly known as fast-track negotiating authority, does not adequately provide for the constitutionally required review and approval of treaties; and

WHEREAS, the United States Trade Representative, at the direction of the President of the United States, is currently negotiating or planning to enter into negotiations for several multilateral trade and investment treaties, including the Trans-Pacific Partnership Agreement and the Trans-Atlantic Trade and Investment Partnership; and

WHEREAS, proposals are under consideration to review these and future trade and investment agreements pursuant to a fast-track model; and

WHEREAS, the current process of consultation with states by the Federal Government on trade policy fails to provide a way for states to meaningfully participate in the development of trade policy, despite the fact that trade rules could undermine state sovereignty; and

HP1129, , 126th Maine State Legislature
JOINT RESOLUTION MEMORIALIZING THE PRESIDENT OF THE UNITED STATES, THE UNITED STATES CONGRESS
AND THE UNITED STATES TRADE REPRESENTATIVE REGARDING THE USE OF TRADE PROMOTION AUTHORITY
IN INTERNATIONAL TRADE POLICY

WHEREAS, under current trade rules, states have not had channels for meaningful communication with the United States Trade Representative, as both the Intergovernmental Policy Advisory Committee on Trade and the state point of contact system have proven insufficient to allow input from states, and states do not always seem to be considered as a partner in government; and

WHEREAS, the President of the United States, the United States Trade Representative and the Maine Congressional Delegation will have a role in shaping future trade policy legislation; now, therefore, be it

RESOLVED: That We, your Memorialists, respectfully urge and request that future trade policy include reforms to improve the process of consultation both between the Executive Branch and Congress and between the Federal Government and the states; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the fast-track model of consultation and approval of international treaties and agreements be rejected with respect to pending agreements and agreements not yet under negotiation; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the President of the United States, the United States Congress and the United States Trade Representative seek to develop a new middle ground approach to consultation that meets the constitutional requirements for treaty review and approval while at the same time allowing the United States Trade Representative adequate flexibility to negotiate the increasingly complicated provisions of international trade treaties; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the President of the United States, the United States Congress and the United States Trade Representative seek a meaningful consultation system that increases transparency, promotes information sharing, allows for timely and frequent consultations, provides state-level trade data analysis, provides legal analysis for states on the effect of trade on state laws, increases public participation and acknowledges and respects each state's sovereignty; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that each instance in which trade promotion authority is authorized by the United States Congress be limited to a specific trade agreement to help ensure the adequate review and approval of each international trade treaty; and be it further

RESOLVED: That suitable copies of this resolution, duly authenticated by the Secretary of State, be transmitted to the Honorable Barack H. Obama, President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, to the United States Trade Representative and to each Member of the Maine Congressional Delegation.

PLEASE NOTE: Legislative Information **cannot** perform research, provide legal advice, or interpret Maine law. For legal assistance, please contact a qualified attorney.

JOINT RESOLUTION MEMORIALIZING THE PRESIDENT OF THE UNITED STATES, THE UNITED STATES CONGRESS AND THE UNITED STATES TRADE REPRESENTATIVE REGARDING STATES' RIGHTS IN FUTURE INTERNATIONAL TRADE POLICY

WE, your Memorialists, the Members of the One Hundred and Twenty-fifth Legislature of the State of Maine now assembled in the First Regular Session, most respectfully present and petition the President of the United States, the United States Congress and the United States Trade Representative as follows:

WHEREAS, Maine strongly supports international trade when fair rules of trade are in place and seeks to be an active participant in the global economy; and

WHEREAS, Maine seeks to maximize the benefits and minimize any negative effects of international trade; and

WHEREAS, existing trade agreements have effects that extend significantly beyond the bounds of traditional trade matters, such as tariffs and quotas, and that can undermine Maine's constitutionally guaranteed authority to protect the public health, safety and welfare and its regulatory authority; and

WHEREAS, a succession of federal trade negotiators from both political parties over the years has failed to operate in a transparent manner and has failed to meaningfully consult with states on the far-reaching effect of trade agreements on state and local laws, even when obligating the states to the terms of these agreements; and

WHEREAS, the current process of consultation with states by the Federal Government on trade policy fails to provide a way for states to meaningfully participate in the development of trade policy, despite the fact that trade rules could undermine state sovereignty; and

WHEREAS, under current trade rules, states have not had channels for meaningful communication with the United States Trade Representative, as both the Intergovernmental Policy Advisory Committee on Trade and the state point of contact system have proven insufficient to allow input from states and states do not always seem to be considered as a partner in government; and

WHEREAS, the President of the United States, the United States Trade Representative and the Maine Congressional Delegation will have a role in shaping future trade policy legislation; now, therefore, be it

RESOLVED: That We, your Memorialists, respectfully urge and request that future trade policy include reforms to improve the process of consultation between the Federal Government and the states; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the President of the United States, the United States Congress and the United States Trade Representative seek a

HP1152, , 125th Maine State Legislature
JOINT RESOLUTION MEMORIALIZING THE PRESIDENT OF THE UNITED STATES, THE UNITED STATES CONGRESS
AND THE UNITED STATES TRADE REPRESENTATIVE REGARDING STATES' RIGHTS IN FUTURE INTERNATIONAL
TRADE POLICY

meaningful consultation system that increases transparency, promotes information sharing, allows for timely and frequent consultations, provides state-level trade data analysis, provides legal analysis for states on the effect of trade on state laws, increases public participation and acknowledges and respects each state's sovereignty; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the Federal Government reform the system of consultation with states on trade policy to more clearly communicate and allow for states' input into trade negotiations by allowing a state to give informed consent or to opt out if bound by nontariff provisions in a trade agreement and by providing that states are not bound to these provisions without consent from the states' legislatures; to form a new nonpartisan federal-state international trade policy commission to keep states informed about ongoing negotiations and information; and to provide that the United States Trade Representative communicate with states in better ways than the insufficient current state point of contact system; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that state laws that are subject to trade agreement provisions regarding investment, procurement or services be covered by a positive list approach, allowing states to set and adjust their commitments and providing that if a state law is not specified by a state as subject to those provisions, it cannot be challenged by a foreign company or country as an unfair barrier to trade; and be it further

RESOLVED: That We, your Memorialists, respectfully urge and request that the United States Congress fund a center on trade and federalism to conduct legal and economic policy analysis on the effect of trade and to monitor the effectiveness of trade adjustment assistance and establish funding for the Department of Commerce to produce state-level service sector export data on an annual basis, as well as reinstate funding for the Bureau of Economic Analysis's state-level foreign direct investment research, both of which are critical to state trade offices and policy makers in setting priorities for market selection and economic impact studies; and be it further

RESOLVED: That suitable copies of this resolution, duly authenticated by the Secretary of State, be transmitted to the Honorable Barack H. Obama, President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, to the United States Trade Representative Ambassador Ron Kirk and to each Member of the Maine Congressional Delegation.

Sen. Troy Jackson, Chair
Sen. John Patrick
Sen. Roger Sherman
Rep. Sharon Treat, Chair
Rep. Jeff McCabe
Rep. Bernard Ayotte

Robert Umphrey
Stephen Cole
Michael Herz
Dr. Joel Kase



John Palmer
Linda Pistner
Harry Ricker
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Staff:
Lock Kiermaier

STATE OF MAINE

Citizen Trade Policy Commission

August 22, 2013

Ambassador Michael Froman
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Dear Ambassador Froman:

The Maine Citizen Trade Policy Commission (CTPC) is authorized by Maine State law [10 MRSA §11(3)] "... to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment; to provide a mechanism for citizens and Legislators to voice their concerns and recommendations; and to make policy recommendations designed to protect Maine's jobs, business environment and laws from any negative impact of trade agreements." In carrying out its statutory mission, the CTPC has closely been following various developments relating to the proposed Transpacific Partnership Agreement (TPPA).

As chairs of the CTPC, we write to inform you of our deep concern about the new text concerning tobacco and public health measures under consideration by the USTR for tabling in the TPPA negotiations currently underway. This proposal is a major retreat from the policy that was drafted and widely shared in great detail by USTR in 2012, which would have created a "safe harbor" for some tobacco control regulations, and which the USTR itself stated would "explicitly recognize the unique status of tobacco products from a health and regulatory perspective".

Based on our most recent understanding, the current USTR proposal on tobacco as it relates to the TPPA is to reaffirm that existing language in the General Agreement on Tariffs and Trade (GATT) which establishes a nation's right to enact health and safety measures includes tobacco measures. While the Maine CTPC had reservations about the earlier USTR proposal, which failed to recognize and protect the central role of U.S. state governments in enacting and enforcing tobacco control regulations and which contained numerous loopholes, the new proposal is so weak that it fails to be legally significant.

Citizen Trade Policy Commission
c/o Office of Policy & Legal Analysis
State House Station #13, Augusta, ME 04333-0013 Telephone: 207 287-1670
<http://www.maine.gov/legis/opla/citpol.htm>

First, USTR's proposal is not legally significant because it simply states the obvious. As the WTO dispute panel noted in the Indonesia clove cigarettes dispute, "It is self-evident that measures to reduce youth smoking are aimed the protection of human health ..." Second, it is not legally significant because as a general exception, it does not cover the investment chapter – where the greatest litigation threat to tobacco-control measures is posed, as litigation against Uruguay and Australia demonstrates. Also, assuming that TPPA drafters follow the KORUS model, general exceptions do not apply to the chapter on intellectual property and perhaps other new chapters such as those on regulatory coherence and state-owned enterprises.

We want to particularly emphasize our grave concern that the current USTR proposal on tobacco for the TPPA leaves the door wide open for the future use of Investor-State Dispute Resolution (ISDR) mechanisms by large international corporations to challenge and overturn federal, state and local laws and regulations which govern tobacco control measures. It is our strongly held view that the tenants of the proposed TPPA should not be used by the tobacco industry to circumvent existing or evolving public health law – either in the United States or in other TPPA member nations. We note that tobacco control measures are a firmly established tenant of current U.S. law and continue to receive the broad support of elected officials on every level regardless of political affiliation.

Further, we are not impressed with the consultation provision proposed by USTR as we understand it. This provision has no teeth in that even if the consulting parties agree, consultation cannot block a challenge to a tobacco regulation. In any event, this consultation is irrelevant to an investor-state challenge, wherein lies the greatest threat to chill or prevent regulation. In addition, from a U.S. state perspective, this provision is useless in that state health or other sub-federal tobacco regulatory authorities are not included in any consultation.

Under the circumstances, it would be better to not offer this text at all than to give the false impression that the United States is serious about protecting government authority within the TPPA to regulate tobacco to protect health.

In a previous letter dated August 1, 2012, the CTPC wrote to your predecessor Ambassador Ron Kirk, regarding our strongly held convictions about how tobacco should be treated in the TPPA. Among other things, we stated the following:

- The CTPC favors a complete "carve out" of tobacco from the trade provisions of the TPPA; in other words, we would prefer that any regulations or laws pertaining to tobacco be completely excluded from the TPPA. The CTPC believes strongly that the efforts of individual nations to control tobacco and combat its adverse health effects should not be interfered or impeded in any way by provisions of the TPPA or any other international trade agreement;
- Absent a complete "carve out" of tobacco from the TPPA, the CTPC favors an approach which modifies the purported compromise proposal being made by the USTR; more specifically, the CTPC favors an approach which ensures that all federal and state laws and regulations pertaining to tobacco regulation are not subject to jurisdiction under the TPPA and further that any tobacco-related provisions of the TPPA embrace an approach which minimizes potential litigation be it through local, state or federal court and the possible use of "investor-state" dispute settlement systems; and

- Finally, the CTPC requests that the USTR develop a clear public statement on the specifics on the specific elements of a tobacco-related provision, as they are proposed by the USTR for consideration as a part of the TPPA.

In speaking for the CTPC, we can safely say that our position has not changed and that we are concerned that the current alternative being proposed by the USTR is woefully inadequate and may in fact be counterproductive towards achieving the goal of protecting the public health and welfare through our federal, state and local laws and regulations which govern tobacco control measures. Given the about-face represented by the USTR's current tobacco proposal, we urge you to consult widely before tabling any text on this topic, and suggest that a public hearing on the treatment of tobacco in the TPPA would be an effective way to convene the relevant parties and gather the information needed to draft an effective proposal that truly protects public health and in particular, the health of our youth.

In closing, at the very least, we favor returning to the earlier USTR "safe harbor" proposal as at least a starting point for further negotiations, although we would prefer a more comprehensive approach which goes further to exempt or "carve out" tobacco control measures from the proposed TPPA.

Please feel free to call on either of us for further information regarding our position on this vitally important public policy issue.

Sincerely,



Senator Troy Jackson, Chair



Representative Sharon Anglin Treat, Chair

c.c. President Barack Obama
Senator Susan Collins
Senator Angus King
Representative Michael Michaud
Representative Chellie Pingree
Maine Attorney General Janet Mills
David Agnew, Deputy Assistant to the President and Director of Intergovernmental Affairs

United States Senate

WASHINGTON, DC 20510

November 12, 2013

Ambassador Michael Froman
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20208

Dear Ambassador Froman:

We write to express our concerns about the tobacco provisions proposed by the United States during the most recent Trans-Pacific Partnership (TPP) trade negotiations in Brunei. While we would prefer an exclusion for all tobacco products from the TPP, we strongly believe TPP should, at the very least, include language that recognizes tobacco as a unique consumer product and ensures TPP nations are able to fully implement and enforce strong nondiscriminatory tobacco control legislation to protect public health and reduce tobacco-related deaths.

Tobacco use is the leading preventable cause of deaths worldwide, taking 6.3 million lives a year, including 1,200 Americans daily. The United States spends nearly \$200 billion a year for tobacco-related illness and injury, and lost productivity. Unless serious, urgent action is taken, tobacco will kill one billion people worldwide this century.

Tobacco companies and governments supporting tobacco companies have a history of aggressively using trade law to subvert domestic tobacco control measures. Indonesia, on behalf of Kretek International, an Indonesian tobacco company that sells a clove-flavored cigarette that is attractive to children, used provisions in several World Trade Organization agreements to challenge a provision in the Family Smoking Prevention and Tobacco Control Act that bans candy-like flavorings that appeal to youth smokers. Philip Morris International filed a Bilateral Investment Treaty dispute against Uruguay because of the country's graphic warning labels. The company is also using Australia's Bilateral Investment Treaty with Hong Kong to challenge an Australian ban on color and images on tobacco packages. These efforts by tobacco companies and governments supporting tobacco companies to use trade laws to subvert public health measures are deplorable and a serious threat to global public health.

The current tobacco proposal states that tobacco control measures are measures "to protect human health," and as such would fall under a "general exceptions" chapter of the TPP analogous to Article XX(b) of the General Agreement on Tariffs and Trade (GATT). It has long been assumed that tobacco control measures fall under this provision, and yet, we have seen repeated legal challenges to these measures. The provisions proposed by the United States would not exempt tobacco control measures from other TPP obligations and do not prevent nations, on behalf of tobacco companies,

from using TPP as a basis for threatening or following through with legal action to prevent the enforcement of nondiscriminatory tobacco control legislation.

We appreciate that the current tobacco proposal allows the health ministers of the two countries to have an opportunity to discuss any challenged tobacco control measure before legal action commences. However, even if the consulting parties agree, consultation cannot block a challenge to tobacco control regulation. We are concerned that this provision will simply delay, but will not prevent, tobacco companies and governments supporting tobacco companies from using TPP as a basis for preventing domestic enforcement of sensible non-discriminatory tobacco control legislation.

We also appreciate efforts to find consensus on this issue. However, tobacco companies and governments supporting tobacco companies have proven they are willing to use trade laws as a basis to challenge domestic tobacco control legislation. The final TPP language should recognize this dangerous trend and prevent further abuses of trade laws related to domestic tobacco control legislation.

The United States should be leading the fight against death and disease from tobacco products, which are a uniquely dangerous threat to public health. We urge you to work with TPP participating nations to include language in TPP that recognizes tobacco as a unique consumer product and ensures TPP nations are able to fully implement and enforce strong non-discriminatory tobacco control legislation to protect public health and reduce tobacco-related deaths.

Sincerely,



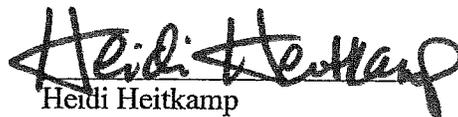
Richard J. Durbin
United States Senator



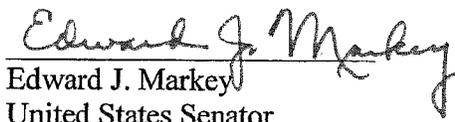
Richard Blumenthal
United States Senator



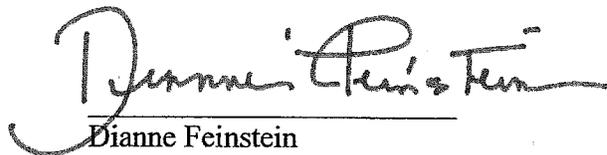
Tom Harkin
United States Senator



Heidi Heitkamp
United States Senator



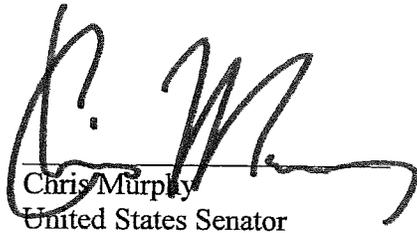
Edward J. Markey
United States Senator



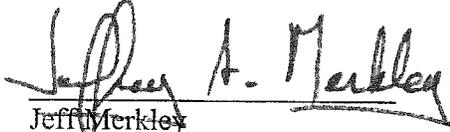
Dianne Feinstein
United States Senator



Benjamin L. Cardin
United States Senator



Chris Murphy
United States Senator



Jeff Merkley
United States Senator



Elizabeth Warren
United States Senator



Al Franken
United States Senator



Sherrod Brown
United States Senator

Sen. Roger Sherman, Chair
Sen. Thomas Martin Jr.
Sen. John Patrick
Rep. Joyce Maker, Chair
Rep. Bernard Ayotte
Rep. Margaret Rotundo

Heather Parent
Stephen Cole
Michael Herz
Michael Hiltz
Connie Jones



Wade Merritt
John Palmer
Linda Pistner
Harry Ricker
Michael Roland
Jay Wadleigh
Joseph Woodbury

Staff:
Lock Kiermaier

STATE OF MAINE

Citizen Trade Policy Commission

March 23, 2012

The Honorable Ron Kirk
Trade Ambassador
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Dear Mr. Ambassador:

The Maine Citizen Trade Policy Commission "... is established to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment; to provide a mechanism for citizens and Legislators to voice their concerns and recommendations; and to make policy recommendations designed to protect Maine's jobs, business environment and laws from any negative impact of trade agreements."

We recently sent you a letter on March 6, 2012 stating our concerns about the manner in which international trade treaties are currently negotiated and the overall need for greater transparency and meaningful congressional consultation and review. Since that time, the Commission met on March 9, 2102 and unanimously voted to send you this additional letter of concern.

The Commission strongly supports the recently stated position of the Australian government in opposition to inclusion of investor-state dispute settlement (ISDS) clauses in the TPPA. As you know, ISDS clauses give businesses from one country the power to take international legal action against the government of another country over breaches in an international trade treaty. The practical effect of ISDS clauses is the possible abrogation of federal, state and municipal law due to certain interpretations of foreign trade treaties like the TPPA. The Commission believes that, regardless of the particular national perspective in question, that the

use of ISDS clauses undermines federal, state and municipal sovereignty and should not be included in international trade treaties like the TPPA.

Please contact us with any questions that you may have regarding the Commission's position on these issues.

Sincerely,

Senator Roger L. Sherman, Chair

Representative Joyce Maker, Chair

Cc: Governor Paul R. Lepage
Senator Olympia J. Snowe
Senator Susan M. Collins
Representative Michael H. Michaud
Representative Chellie Pingree
State Representative Sharon Treat

Sen. Troy Jackson, Chair
Sen. Stan Gerzofsky
Sen. Roger Sherman
Rep. Margaret Rotundo, Chair
Rep. Jeffery A. Gifford
Rep. Sharon Anglin Treat

Jane Ajudi
Malcolm Burson
Leslie Manning
Wade Merritt
Linda Pistner
Barbara VanBurgel



Sarah Adams Bigney
Carla Dickstein
Michael Herz
Michael Hiltz
John Palmer
John L. Patrick
Cynthia Phinney
Paul Volckhausen
Joseph Woodbury

Curtis Bentley, Legislative Analyst

STATE OF MAINE

Citizen Trade Policy Commission

February 17, 2010

Jennifer Choe Groves
Senior Director for Intellectual
Property and Innovation and Chair of the Special 301 Committee
Office of the United States Trade Representative

Re: Submission of Written Testimony and Notice of Intent to Testify at a Public Hearing
Concerning the 2010 Special 301, Docket #USTR-2010-0003

Dear Ms. Groves:

On behalf of the Maine Citizen Trade Policy Commission (CTPC or Commission), we write to oppose the recent and disturbing expansion of the Special 301 report into the realm of disciplining countries for implementing effective and non-discriminatory pharmaceutical pricing policies. This letter, and our request to testify orally at the hearing that will be held in on Wednesday, March 3, 2010, is pursuant to the unanimous vote of the Commission at our January 8, 2010 meeting.

The Maine Citizen Trade Policy Commission was established by the Legislature in 2003 to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment; to provide a mechanism for citizens and Legislators to voice their concerns and recommendations; and to make policy recommendations designed to protect Maine's jobs, business environment and laws from any negative impact of trade agreements. We have members representing the Maine House of Representatives, and Senate, the Maine International Trade Center, various state agencies, and members affiliated with citizen constituencies including small businesses, manufacturers, labor, environmental organizations, and small farmers.

Pursuant to our statutory mission, we have included a focus on health policy and trade issues, including pharmaceutical policy and in particular, the impact of that policy on Medicaid implementation and costs in the state. Our membership is determined by statute and includes a health professional. We have previously written to the U.S. Trade Representative concerning carving out Medicaid from free trade agreement provisions relating to pharmaceuticals. Legislative members of the commission have also met with USTR staff on these issues, and we were gratified that the Korea FTA included a footnote recognizing the role of the states implementing and paying for Medicaid and explicitly carving out these state programs.

Despite this past advocacy and the at least tacit recognition by the USTR that when trade agreements address pharmaceutical policy, there can be unintended and deleterious consequences for state health policy and access, it appears that the USTR has nevertheless embarked on an even broader effort to promote a new international trade framework to restrict domestic regulatory responses to excessive pricing by monopoly pharmaceutical suppliers.

This new direction concerns us greatly, because it will increase state health care costs and significantly reduce access to health care. The timing of this initiative is particularly questionable given the multi-million dollar deficits in state Medicaid budgets caused by the ongoing worldwide recession. The consequence of its implementation will be to reduce access to affordable health care at the very time the Administration is pushing for universal health coverage in partnership with the States.

Maine relies on evidence-based reimbursement decisions to restrain pharmaceutical prices. Like other states, Maine uses a wide variety of regulatory tools and policies to control excessive pricing by medicine suppliers. These are often the same tools used by foreign governments that USTR lists as “unreasonable” under Special 301 and has sought to restrict or eliminate in recent trade agreements. One of the most important of these state mechanisms is the Preferred Drug Lists (PDLs) in the Medicaid program.

More than forty states use PDLs for Medicaid and other programs. These are programs that, like those in other countries, use the bulk purchasing and reimbursement power of governments to pressure drug companies to accept steep reductions in their reimbursement prices as a condition for gaining preferred access to a large market. The industry calls these “price controls,” governments call them “negotiation.” Regardless, these are the same tools that USTR for several years has been highlighting as in need for a new international standard setting exercise to restrict domestic policy options.

Use of PDLs by Maine and other U.S. states has resulted in tremendous savings; eliminating or restricting this tool will have serious negative repercussions. The prices paid by the state of Maine for prescription drugs in its Medicaid program average around 50% of the “Average Wholesale Price” (AWP) as a result of both the federal Medicaid rebate, rebates through the state’s supplemental rebate program, and a tiered PDL. The state also has improved its bargaining power while maintaining this basic approach by expanding the size of its

purchasing pool. At a time when brand-name drug prices and spending has increased in the double digits over a decade, Maine has been able to keep its drug spend relatively flat.

Maine's approach to drug pricing is consistent with the approach taken in the majority of states. Indeed, the President's budget for 2008 specifically noted that Medicaid "allows states to use [such] private sector management techniques to leverage greater discounts through negotiations with drug manufacturers."¹ Maine's current Supplemental Budget as proposed by Governor John E. Baldacci would already cut back on pharmaceutical access programs such as Drugs for the Elderly,² a program initiated in the early 1970's – the first such program in the Nation – in an effort to balance the budget in light of reduced revenues due to the economy.

Although it is commonly posited by industry that foreign countries "free ride" on U.S. pharmaceutical prices, U.S. governments that use policy tools that are similar to foreign governments pay similar prices. The prices paid by state Medicaid programs or the Veterans Administration hospitals, for example, are frequently *lower* than Canadian and European prices.³ Similar tools are used by almost every bulk purchaser of drugs – including private insurance companies, branches of the U.S. federal government and most other industrialized countries.

The Maine Citizen Trade Policy Commission opposes USTR's promotion of international restrictions on domestic pharmaceutical pricing programs. As noted above, we are concerned about a recent and disturbing trend of the United States Trade Representative using trade agreements and pressure, including through Special 301, to push for the international regulation of *domestic* pharmaceutical reimbursement programs.

Maine and other states have repeatedly raised concerns about USTR's recent use of Free Trade Agreements with Australia and Korea to begin establishing international disciplines on pharmaceutical pricing programs. In several submissions to USTR and Congress we have warned that U.S. states already use the same tools that USTR was attempting to restrict abroad. The Korea agreement included a radical provision appearing to allow industry appeals of government pharmaceutical reimbursement decisions on whether they adequately respected the "value" of patented pharmaceutical products. Such provisions, if applied to state pharmaceutical pricing programs, would significantly hamper the operation of important public health programs.

The 2009 Special 301 Report contains additional evidence of USTR's shift of its negotiating priorities into the arena of restricting evidence based pricing programs. The Report singles out Japan, Canada, France, Germany, New Zealand, Taiwan and Poland for administering "unreasonable . . . reference pricing or other potentially unfair reimbursement policies." The Report further states that:

¹ Budget of the United States Government, FY 2008. Available at www.whitehouse.gov.

² See information posted at: <http://www.maine.gov/dhhs/mainerx/del.htm>

³ See the 2004 Annual Report of the West Virginia Pharmaceutical Cost Management Council, available at <http://www.wvc.state.wv.us/got/pharmacycouncil/>.

The United States also is seeking to establish or continue dialogues with Organization for Economic Cooperation and Development (OECD) members and other developed economies to address concerns and encourage a common understanding on questions related to innovation in the pharmaceutical sector.

It appears to the Commission that USTR is targeting the same policies that it has in the past – i.e. innovative reimbursement policies that effectively restrain medicine pricing in a manner similar to state preferred drug lists and other public policies. *We oppose this use of Special 301. The U.S. should not be negotiating for the limitation of programs abroad that are the best practices in the field right now here at home*

Finally, we are concerned that the actions of USTR threaten best practices needed for health reform. Maine has been a leader in expanding access to health care for its residents and identifying and implementing best practices to rein in excessive medical cost and promote public health.⁴ Pharmaceutical policy in the U.S. is a major component of health policy – and costs – and is no less in need of reform. We spend more on pharmaceuticals than any other country in the world. Maine and other U.S. states are effectively using policies to reduce costs and promote public health by influencing prescribing decisions with evidence. As the federal government continues working on health reform, we strongly urge that it learn from these examples, and not allow its USTR to negotiate them out of existence.

Thank you for your consideration.

Yours sincerely,

Senator Troy Jackson, Chair

Representative Margaret Rotundo, Chair

cc: Ron Kirk, USTR
John Baldacci, Governor
Member of Maine's Congressional Delegation

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⁴ Initiatives include Dirigo Health, the Maine Quality Forum, increased transparency of medical pricing and quality (including a first-in-nation web-based disclosure) and the Advisory Council on Health Systems Development which just issued a draft report on payment reform. See http://www.maine.gov/governor/baldacci/policy/health_care.html

Sen. Troy Jackson, Chair
Sen. Stan Gerzofsky
Sen. Roger Sherman
Rep. Margaret Rotundo, Chair
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Jane Aludi
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Sarah Adams Bigney
Carla Dickstein
Michael Herz
Michael Hiltz
John Palmer
John L. Patrick
Cynthia Phinney
Paul Volckhausen
Joseph Woodbury

Curtis Bentley, Legislative Analyst

STATE OF MAINE

Citizen Trade Policy Commission

June 23, 2010

The Honorable Max Baucus
Chairman
Committee on Finance
U.S. Senate
Washington, D.C. 20515

The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
U.S. Senate
Washington, D.C. 20515

Dear Chairman Baucus and Ranking Member Grassley:

The Maine Citizen Trade Policy Commission is a bipartisan commission established in 2003 to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment, and to make policy recommendations to the Legislature and the Governor concerning the impact of trade agreements and trade-related policies.

The Maine Citizen Trade Policy Commission voted unanimously to express its strong support of Congressional efforts to preserve jobs in Maine that are threatened as a result of some foreign companies manipulating our tariff system to gain an unfair economic advantage over our domestic manufacturers. If left uncorrected, this situation will encourage other foreign manufactures to manipulate their products for the purposes of avoiding tariffs to which they should be subject.

Genfoot, Inc. and New Balance are among the few remaining domestic shoe manufacturers. New Balance employs roughly 1,000 individuals at their three manufacturing facilities in Maine in skilled, middle class jobs that have brought a direct economic benefit to the State of Maine during this time of high unemployment. The viability of this company has depended on duty rates Congress adopted years ago on the recommendation of the U.S. Trade

Representative. These duty rates help level the playing field and are essential to the preservation of jobs at this facility. However, some international manufacturers have found a way around these tariffs by implanting a small amount of textile material onto the sole of their footwear causing that footwear to be reclassified as a textile product subject to a lower duty rate.

We cannot afford to lose these valuable jobs in our state to unfair tariff practices especially during this time of high unemployment. We strongly urge Congress to close the loophole that allows importers to evade duties that help domestic manufacturers compete in the U.S. and global markets.

We urge you to take action to save Maine jobs and prevent importers from avoiding tariff rates that protect domestic footwear.

Sincerely,

Senator Troy Jackson, co-chair

Representative Peggy Rotundo, co-chair

cc:

Senator Susan M. Collins
Senator Olympia J. Snowe
The Honorable Michael Michaud
The Honorable Chellie M. Pingree