CITIZEN TRADE POLICY COMMISSION
DRAFT AGENDA

Friday, March 22, 2013 at 9:30 A.M.
Room 214, Burton M. Cross State Office Building
Augusta, Maine

9:30 AM Meeting called to order

I. Welcome and introductions

II. Review of CTPC statutes (Lock Kiermaier, Staff)

III. PowerPoint presentation on TransPacific Partnership Agreement (Representative Sharon Treat, CTPC Chair)

IV. Review of current TPPA negotiations and status; "Overview of TransPacific Partnership Negotiations" (Representative Sharon Treat, CTPC Chair)

V. Review of previous CTPC letters (October 2012) to USTR about results of CTPC Assessment regarding Pharmaceuticals, Tobacco and Procurement (Lock Kiermaier, Staff)

VI. Articles of interest (Lock Kiermaier, Staff)

VII. Proposed next meeting date and suggestions for agenda topics

Adjourn

10 §11. MAINE JOBS, TRADE AND DEMOCRACY ACT

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1. Short title. This section may be known and cited as "the Maine Jobs, Trade and Democracy Act."

[2003, c. 699, §2 (NEW) .]

2. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Commission" means the Citizen Trade Policy Commission established in Title 5, section 12004-I, subsection 79-A. [2003, c. 699, §2 (NEW).]

B. "Trade agreement" means any agreement reached between the United States Government and any other country, countries or other international political entity or entities that proposes to regulate trade among the parties to the agreement. "Trade agreement" includes, but is not limited to, the North American Free Trade Agreement, agreements with the World Trade Organization and the proposed Free Trade Area of the Americas. [2003, c. 699, §2 (NEW).]

[2003, c. 699, §2 (NEW) .]

3. Purposes. The 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.

[2003, c. 699, §2 (NEW) .]

4. Membership. The commission consists of the following members:

A. The following 17 voting members:

(1) Three Senators representing at least 2 political parties, appointed by the President of the Senate;

(2) Three members of the House of Representatives representing at least 2 political parties, appointed by the Speaker of the House;

(3) The Attorney General or the Attorney General's designee;

(4) Four members of the public, appointed by the Governor as follows:

(a) A small business person;

(b) A small farmer;

(c) A representative of a nonprofit organization that promotes fair trade policies; and

(d) A representative of a Maine-based corporation that is active in international trade;

(5) Three members of the public appointed by the President of the Senate as follows:

(a) A health care professional;

(b) A representative of a Maine-based manufacturing business with 25 or more employees; and

(c) A representative of an economic development organization; and

(6) Three members of the public appointed by the Speaker of the House as follows:

(a) A person who is active in the organized labor community;

(b) A member of a nonprofit human rights organization; and

(c) A member of a nonprofit environmental organization.

In making appointments of members of the public, the appointing authorities shall make every effort to appoint representatives of generally recognized and organized constituencies of the interest groups mentioned in subparagraphs (4), (5) and (6); and [2003, c. 699, §2 (NEW).]

B. The following 4 commissioners or the commissioners' designees of the following 4 departments and the president or the president's designee of the Maine International Trade Center who serve as ex officio, nonvoting members:

(1) Department of Labor;

(3) Department of Environmental Protection;

(4) Department of Agriculture, Conservation and Forestry; and

(5) Department of Health and Human Services. [2003, c. 689, Pt. B, §6 (REV); 2007, c. 266, §1 (AMD); 2011, c. 657, Pt. W, §5 (REV).]

[2003, c. 689, Pt. B, §6 (REV); 2007, c. 266, §1 (AMD); 2011, c. 657, Pt. W, §5 (REV) .]

5. Terms; vacancies; limits. Except for Legislators, commissioners and the Attorney General, who serve terms coincident with their elective or appointed terms, all members are appointed for 3-year terms. A vacancy must be filled by the same appointing authority that made the original appointment. Appointed members may not serve more than 2 terms. Members may continue to serve until their replacements are designated. A member may designate an alternate to serve on a temporary basis.

[2003, c. 699, §2 (NEW) .]

6. Chair; officers; rules. The first-named Senate member and the first-named House of Representatives member are cochairs of the commission. The commission shall appoint other officers as necessary and make rules for orderly procedure.

[2003, c. 699, §2 (NEW) .]

7. Compensation. Legislators who are members of the commission are entitled to receive the legislative per diem and expenses as defined in Title 3, section 2 for their attendance to their duties under this chapter. Other members are entitled to receive reimbursement of necessary expenses if they are not otherwise reimbursed by their employers or others whom they represent.

[2003, c. 699, §2 (NEW) .]

8. Staff. The Office of Policy and Legal Analysis shall provide the necessary staff support for the operation of the commission. After one year, the commission shall assess the need for and qualifications of a staff person, for example, an executive director. If the commission determines that it requires such a person, it may request additional funds from the Legislature.

[2003, c. 699, §2 (NEW) .]

9. Powers and duties. The commission:

A. Shall meet at least twice annually; [2003, c. 699, §2 (NEW).]

B. Shall hear public testimony and recommendations from the people of the State and qualified experts when appropriate at no fewer than 2 locations throughout the State each year on the actual and potential social, environmental, economic and legal impacts of international trade agreements and negotiations on the State; [2003, c. 699, §2 (NEW).]

C. Shall every 2 years conduct an assessment of the impacts of international trade agreements on Maine's state laws, municipal laws, working conditions and business environment. The assessment must be submitted and made available to the public as provided for in the annual report in paragraph D; [2007, c. 266, §2 (AMD).]

D. Shall maintain active communications with and submit an annual report to the Governor, the Legislature, the Attorney General, municipalities, Maine's congressional delegation, the Maine International Trade Center, the Maine Municipal Association, the United States Trade Representative's Office, the National Conference of State Legislatures and the National Association of Attorneys General or the successor organization of any of these groups. The commission shall make the report easily accessible to the public by way of a publicly accessible site on the Internet maintained by the State. The report must contain information acquired pursuant to activities under paragraph B and may contain information acquired pursuant to activities under paragraph C; [2007, c. 266, §3 (AMD).]

E. Shall maintain active communications with any entity the commission determines appropriate regarding ongoing developments in international trade agreements and policy; [2003, c. 699, §2 (NEW).]

F. May recommend or submit legislation to the Legislature; [2003, c. 699, §2 (NEW).]

G. May recommend that the State support, or withhold its support from, future trade negotiations or agreements; and [2003, c. 699, §2 (NEW).]

H. May examine any aspects of international trade, international economic integration and trade agreements that the members of the commission consider appropriate. [2003, c. 699, §2 (NEW).]

[2007, c. 266, §§2, 3 (AMD) .]

10. Outside funding. The commission may seek and accept outside funding to fulfill commission duties. Prompt notice of solicitation and acceptance of funds must be sent to the Legislative Council. All funds accepted must be forwarded to the Executive Director of the Legislative Council, along with an accounting that includes the amount received, the date that amount was received, from whom that amount was received, the purpose of the donation and any limitation on use of the funds. The executive director administers any funds received.

[2003, c. 699, §2 (NEW) .]

11. Evaluation. By December 31, 2009, the commission shall conduct an evaluation of its activities and recommend to the Legislature whether to continue, alter or cease the commission's activities.

[2003, c. 699, §2 (NEW) .]

SECTION HISTORY
2003, c. 689, Pt. B, §6 (REV). 2003, c. 699, §2 (NEW). 2007, c. 266, §§1-3 (AMD). 2011, c. 657, Pt. W, §5 (REV).

OVERVIEW OF TRANS-PACIFIC PARTNERSHIP NEGOTIATIONS

Inside U.S. Trade - 03/15/2013

USTR Highlights Four TPP Areas Where Negotiations Mostly Wrapped Up

Posted: March 14, 2013

SINGAPORE -- According to the Office of the U.S. Trade Representative, Trans-Pacific Partnership (TPP) negotiations are so far advanced in the areas of customs, telecommunications, regulatory coherence, and development that these issues will not be taken up again by technical experts and future rounds and "any remaining work in these areas will be taken up in late-stage rounds as the agreement is finalized."

In a press release issued March 13 upon conclusion of the 16th round of TPP talks, USTR said that shelving technical talks in these advanced areas "will allow the TPP countries to concentrate their efforts on resolving the most challenging issues that remain, including related to intellectual property, competition and environment."

Singapore's Ministry of Trade and Industry (MTI) put forth a similar message in a separate March 13 press release. It said the 11 TPP members made the most progress in those same four areas. TPP negotiations on small and medium-sized businesses (SMEs) is also mostly concluded, sources have said previously.

On regulatory coherence, sources said New Zealand tabled a new proposal in Singapore, although the details remained unclear. The original U.S. proposal on regulatory coherence established an obligation for each TPP party to "endeavor" to set up a regulatory coordination mechanism at the central level of government, and to consider establishing a national coordinating body for this purpose, according to a version of the text leaked in October 2011.

But the New Zealand approach appears to focus more narrowly on the issue of notification requirements. Sources said it was unclear whether, under the New Zealand proposal, notifications would be required only if and when a TPP party establishes a regulatory coordination mechanism, or every time that mechanism reviews a regulation.

Sources also disagreed on whether the New Zealand language would be in lieu of text proposed by the United States, or in addition to it.

In the press release, MTI said other areas of the TPP talks where discussions "continued in earnest" were services, electronic commerce, sanitary and phytosanitary (SPS) measures, technical barriers to trade and government procurement.

In the area of SPS, negotiators here discussed a non-paper floated by USTR that proposes a "consultative mechanism" for resolving SPS disputes. This proposal, which sources said involves the appointment of a neutral facilitator to resolve SPS disputes, falls short of the full dispute settlement for SPS obligations that U.S. agriculture and food groups have demanded.

One informed source said the paper was not received well at the negotiating table by some TPP countries, including New Zealand, that want full dispute settlement for SPS obligations.

The USTR non-paper does not mention a rapid-response mechanism (RRM) for quickly resolving SPS problems for perishable goods that has been proposed by U.S. agriculture groups, according to another informed source.

According to the MTI release, TPP countries recognize that "further deliberation" will be required in the more challenging areas of the negotiations, which include intellectual property, environment, competition and labor.

Labor negotiators at this round continued to discuss an approach to dispute settlement that is favored by Canada and based on the side accord to the North American Free Trade Agreement (NAFTA), although Canada does not appear to have tabled legal text on this issue, according to an informed source. Canada first defended this approach at the December negotiating round in New Zealand (*Inside U.S. Trade*, Dec. 14).

The NAFTA side accord limits enforcement of trade or investment-related labor rights violations to monetary fines. That differs from the U.S. approach in the TPP labor text, which allows for penalties in the form of fines as well as trade sanctions based on the amount of trade affected by a given pattern of labor rights violations.

This reflects provisions in the U.S.-Peru free trade agreement, which applies the same enforcement mechanism to labor and environmental obligations as it does to commercial requirements.

According to MTI, TPP negotiators also continued efforts here to develop market access packages on goods, services, investment and government procurement.

MTI said Singapore, as host of the 16th round, aimed to invigorate the talks, including by exploring "fresh configurations" for the negotiations. "One innovation was for some working groups to break into smaller informal meetings as part of the official negotiation agenda to tease out the more difficult issues with fresh eyes," Singapore chief negotiator Ng Bee Kim said in the release. "We are glad that it worked well and helped move our negotiations along."

A wide range of sources here said chief negotiators during this round ramped up their

engagement with the chapter negotiators, in some cases meeting several times a day to provide further direction.

The MTI press release also noted that the next event on the TPP calendar is a meeting of trade ministers from the 11 participating countries that will occur on the sidelines of an Asia-Pacific Economic Cooperation ministerial meeting slated to take place in Indonesia April 20-21.

Inside U.S. Trade - 03/15/2013, Vol. 31, No. 11

Inside U.S. Trade, Daily News
News Analysis
TPP Talks Make Some Progress, But 2013 Conclusion Still Unlikely
Posted: March 14, 2013

The 16th round of Trans-Pacific Partnership (TPP) talks just wrapped up in Singapore, and although negotiators were able to make progress on some issues, the work on the toughest issues is only just beginning and questions abound as to if and when the 11-party negotiations will really start coming together.

Of course, meetings among TPP officials will continue. TPP trade ministers will meet on the margins of an Asia-Pacific Economic Cooperation (APEC) meeting in mid-April, and negotiators will then get together in Peru in May for the 17th formal round of talks.

Under the current schedule, there will then be one more round in September before a summit of APEC leaders in October, the informal goal for concluding the talks. But TPP countries may try to squeeze in an additional round in July to help achieve more progress before the summit.

As they move forward, negotiators will have to consider how elections in TPP countries could affect the ongoing talks. Elections are scheduled this year in Chile, Malaysia and Australia, although some believe the Australian election could make that country more flexible on the issue of investor-state dispute settlement.

Also complicating matters is the fact that the Office of the U.S. Trade Representative is faced with a restricted budget and the prospect of starting up massive new trade negotiations with the European Union this summer. USTR understands this is a crucial year to push forward on TPP to ensure the talks do not drift endlessly, sources say.

At the same time, few participants and private-sector stakeholders believe the talks are likely to wrap up this year – even if Japan does not join – because of all the unresolved issues. A quick

TPP conclusion is even more elusive if Japan joins, which is increasingly likely with an announcement by Prime Minister Shinzo Abe on Japan's interest in doing so expected tomorrow (March 15).

The Singapore round already highlighted the additional difficulties that can arise when new countries join. Stakeholders in Mexico, for instance, are pushing hard for exemptions from full tariff liberalization for a wide variety of items, including textiles, apparel, footwear and dairy products. While this may help provide cover for other TPP members who also want exemptions, it raises questions about whether the addition of Mexico and Canada will end up slowing down the talks, or lowering the overall level of ambition.

On the positive side, issues like customs, telecommunications, regulatory coherence and development are closed up, except for key political decisions that will be made later. USTR announced this week that negotiators will not return to these areas until "late-stage rounds."

One of the key issues to be resolved arises in the U.S.-Vietnam textile and apparel negotiations, where there were some positive signals in this round. USTR floated the concept of "short supply" deviations from the strict yarn-forward rule of origin that it has proposed, and Vietnam appears open to at least considering this approach. Vietnam made clear at this round that it wants to learn more about how these exceptions would work, and then see if it is a "good way forward."

On the other hand, USTR is still devising the exact parameters of its initial proposed list of short-supply exceptions, and industry sources said the exchanges on this issue in Singapore likely consisted of USTR briefing other countries about its process for doing so.

Some believe that USTR is unlikely to present a complete list of exceptions at the May round; once it does present a list, it will take considerable time for Vietnam to respond and for the two to work out a deal.

On the overall issue of goods market access, the U.S. and Vietnam have still not reached major breakthroughs. In fact, one source said the U.S. "undefined" basket, which covers those items that would have a phase-out period for tariffs of an indeterminate length, still included about 1,000 items going into the Singapore round. If that is true, it is another clear indication of how far off from agreement TPP partners are.

In other difficult areas -- including intellectual property (IP), state-owned enterprises (SOEs), environmental protections and goods market access -- the Singapore round offered somewhat modest results.

On pharmaceutical IP protections, negotiators at least resumed a conversation that has been dormant -- at formal TPP rounds, at least -- since March 2012. But that exchange in Singapore was general and focused on exchanging information to ensure all parties understand the way in which others handle IP issues. That level of generality may reflect the fact that Canada and Mexico were participating in talks on this subject for the first time.

The open question is when the U.S. will actually table a revised proposal and force TPP members to start making tough decisions, since it is already clear that it will not happen at the next round in Peru. Perhaps, as some stakeholders speculate, USTR will ultimately not alter its proposal to make it acceptable to all TPP participants. Alternatively, USTR could ask that its current proposal apply to developed TPP members, while developing TPP members can adhere to a lower standard of IP protection.

Another theory is that USTR prefers to build momentum in less controversial areas of the talks and return to IP later on, when the negotiations are closer to completion.

It may be taking that same strategy with other controversial proposals, including its "safeguard" for tobacco regulations, which it floated in mid-2012 but still has not tabled. USTR is also still hesitant to propose making sanitary and phytosanitary measures fully enforceable, as U.S. businesses want, and has floated a consultation mechanism instead.

On SOEs, negotiations also appear stuck at a pretty basic stage. Singapore, for instance, continues to argue that the very premise behind the U.S. proposal is misguided. Rather than focusing the application of rules on the issue of whether an entity is state-owned, disciplines should focus on anti-competitive behavior and seek to address that kind of behavior where it arises, it argues.

There are also no signs that any TPP countries have come back with textual amendments to the original U.S. proposal – which the U.S. tabled all the way back in the fall of 2011.

Australia was expected to formally table an SOE legal text at this round based on a "principles-based" approach it had floated earlier, but decided to hold off. But Australia clarified at this round that these principles would be enforceable and would extend to the sub-central level. Application of disciplines at the sub-central level could be difficult for the U.S., as the U.S. proposal only covers central government SOEs.

On the issue of Japan joining this year, TPP negotiators -- and many U.S. business groups -- are

striking a cautious note in public, saying the door is open to Japan if it is willing to meet the high standard of the agreement and can help bring about the goal of concluding the talks in 2013. Stakeholders in New Zealand and Australia also offered their views on this issue in Singapore.

If Japan were to join, the prospect of concluding this year will have evaporated, although there is always room for negotiators to get creative. One possibility would be to place Japan on a "separate track," such that negotiations with Japan would continue even if the overall TPP talks come to a close, as had been suggested at an earlier point when Japan signaled it was considering joining.

PROCUREMENT

Inside U.S. Trade - 03/15/2013

In TPP, Canada May Seek Bilateral Deals With U.S. On Procurement, Visas

Posted: March 14, 2013

In the Trans-Pacific Partnership (TPP) negotiations, Canada may seek to negotiate bilateral deals with the United States on some of its priority issues, including government procurement rules that would free it from any "Buy America" restrictions and rules that promote the movement of business professionals between the two North American countries, Canadian Trade Minister Ed Fast announced yesterday (March 14).

Speaking at an event at the Peterson Institute for International Economics (PIIE), Fast hinted that both areas could be worked out bilaterally between the U.S. and Canada within the TPP talks. While stressing the importance of "robust outcomes" in TPP chapters dealing with these two issues, Fast said it is "certainly possible that that could be done in a bilateral agreement" with the U.S., in reference to these two Canadian priorities.

More broadly, Fast argued that bilateral deals within the regional TPP negotiations are needed to accommodate those situations where "unique circumstances that exist between two trading partners make it impossible to expand the application of the goals of those countries to all of the members." Negotiating a deal with the U.S. on movement of business professionals is certainly one example, and is a key focus of Canada, Fast told reporters after this speech.

"The TPP negotiations offer us a chance to optimize the rules for the easy movement of professionals and business people across our border," he said at the event. Fast said U.S. companies like Microsoft, Warner Brothers, IBM and Cisco have told him that "their businesses suffer when they cannot get the people they need across the border."

Facilitating the movement of professionals would likely require negotiating new rules on visas. Generally speaking, that is difficult for the U.S. to do within the context of TPP, or any other trade

agreement, because many members of Congress consider it inappropriate to deal with U.S. visa policy in that context. However, it is unclear whether Congress may be more open to a deal on visas in TPP if it only applied to Canada, but not to other TPP partners.

Fast also stressed that Canada wants to negotiate procurement rules in the context of the TPP talks that would help avoid the imposition of "Buy America" restrictions that have cropped up in the past. These restrictions have been a "persistent irritant" for Canadian companies, he said.

He never specified exactly what Canada wants to achieve on government procurement, and instead stuck to general descriptions. "Instead of more 'buy local' policies, what we need are stronger rules on government procurement" to ensure a "level playing field" and to "drive efficiency and competitiveness," he said. Fast also said Canada wants "rules that enhance governments' abilities to obtain the best value for taxpayer money in their purchasing."

Last week, a U.S. trade official was more specific, saying that Canada tabled a proposal during the Singapore round of TPP talks -- which wrapped up this week -- that aims to ensure that projects carried out by sub-federal entities with money provided by the central government will be open to competition from firms within TPP countries (*Inside U.S. Trade*, March 8). Fast was asked if this was accurate at the event, but declined to respond.

Canadian industry groups like the Canadian Manufacturers and Exporters (CME) have long pushed for this language. They want to avoid repeating a situation that arose in the 2009 U.S. stimulus bill, which excluded Canadian companies from participating in some sub-federal U.S. procurements paid for with federal stimulus money. Canadian industry groups highlighted this as a potential demand in TPP last October (*Inside U.S. Trade*, Oct. 12).

In response to Canadian complaints, the U.S. and Canada inked a deal in 2010 under which the U.S. waived "Buy American" requirements in stimulus-funded projects for Canadian firms, while Canada gave U.S. firms guaranteed access to its sub-federal government procurement markets in its provinces and territories (*Inside U.S. Trade*, Feb. 19, 2010).

Fast appeared to be referencing that 2010 deal when he noted that the relationship between Canada and the U.S. "is unique to the point where, on government procurement, we really should be looking at expanding our current arrangements under the Canada-U.S. procurement agreement."

Despite his focus on a U.S.-Canada bilateral procurement arrangement, Fast also signaled the importance of strong procurement rules among all TPP members.

For instance, he hinted that strong procurement rules could help ensure that U.S. firms have the access they need to infrastructure contracts in Southeast Asia. Canada may seek "rules that provide secure access to opportunities created by the rapid development of public infrastructures

throughout the Asia-Pacific region."

Fast also touched on some key structural issues and challenges facing Canada as it participates in the TPPtalks, engages Japan bilaterally on a free trade agreement, tries to conclude FTA negotiations with the European Union, and contemplates the future of the North American Free Trade Agreement (NAFTA) in light of the fact that all three NAFTA partners are involved in TPP.

Fast said he expects NAFTA "will continue to be ... a key trilateral agreement amongst the three partner countries" even after TPP is concluded. But he cautioned that NAFTA partners would have to examine the final TPP outcome before deciding how TPP and NAFTA will relate to one another. Part of the reason NAFTA may still be valuable is because TPP may not be as ambitious across-the-board as NAFTA is, he signaled.

"I expect NAFTA will still exist because ... within a regional trade negotiation, you have the interests of ... different partners that have to be satisfied," meaning an individual country does not always get everything it wants, he said. "We would want to wait until we see the outcome" of TPP before deciding the fate of NAFTA, he added.

Concerning the possibility that Japan could join the TPP talks later this year, Fast conceded that that would add "another level of complexity" to the talks, although he said it would still be his goal to complete the negotiations by the end of the year, regardless of whether or not Japan joins.

But the Canadian trade minister also admitted that there are "many, many issues outstanding" among the current 11 participants and that completion of the TPP this year is "quite a daunting task."

Fast also signaled that Canada will continue its bilateral FTA talks with Japan even in the event that Japan were to join the TPP group. "We see them not being mutually exclusive in that perfect sense," he said, in reference to the Canada-Japan talks and the possibility of Japan joining TPP. He noted that the next negotiating round between Canada and Japan is scheduled to take place next month.

Overall, Fast signaled an openness to Japan joining TPP, saying Japan is a large economy and a "significant asset" to any trade negotiations.

The Canadian minister also stressed that Canada is watching the burgeoning U.S.-EU negotiations very carefully and mulling the impacts it could have on Canada. Gary Hufbauer, an expert at PIIE, asked Fast at the event if it is true that in the context of the Canada-EU negotiations, the EU has informally said that it will give Canada extra concessions beyond what was negotiated in their bilateral FTA to match what the EU ends up offering to the U.S. in any

U.S.-EU trade deal.

Fast declined to answer directly. "I can tell you that given the nature and the level of integration of the Canadian and American economies, obviously on the Canadian side, we have very clearly turned our minds to what happens beyond our agreement with the EU," he said. "We have to look to what happens between the U.S. and EU."

Moreover, he added that Canada has "taken extra care to ensure some of the opportunities we have to enhance even further our integration between [Canada and the U.S.] could take place ... if a U.S.-EU agreement is actually finalized." Fast also noted that some observers are speculating that once the U.S. and EU have a deal, it could "morph into a trans-Atlantic arrangement" incorporating the U.S., Canada, Europe and, presumably, Mexico.

Fast also touched on several other issues. For instance, he argued that sequestration -- and the budget cuts it enforced on U.S. agencies starting March 1 -- could hamper U.S.-Canada trade. "One of the concerns that I would express is that if sequestration is not addressed very soon, that we would see significant withdrawal of resources at our borders that would reinstate some of the very clear barriers that still exist at the border," he said.

This week, Fast met with business associations in Washington and also was slated to meet with various members of Congress, including Rep. Sander Levin (D-MI), the ranking member of the Ways and Means Committee. He was also scheduled to meet yesterday with Reps. Devin Nunes (R-CA) and Charles Rangel (D-NY), the chairman and ranking member, respectively, of the Ways and Means trade subcommittee.

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PHARMACEUTICALS

Inside U.S. Trade - 03/15/2013

TPP Countries Slowly Restart Formal Talks On Pharmaceutical IP Protections

Posted: March 14, 2013

SINGAPORE -- After roughly a year hiatus, countries participating in the Trans-Pacific Partnership (TPP) talks here restarted formal 11-party talks on pharmaceutical intellectual property rights (IPR), although the nature of that conversation was fairly basic. At the 16th round of negotiations, which wrapped up this week, as well as at the next formal round, TPP negotiators will focus on exchanging information, not text-based negotiations.

At a March 13 press conference, Singaporean chief negotiator Ng Bee Kim said negotiators will not discuss the existing U.S. proposal in this area, nor will they discuss any possible revision of

the U.S. proposal, at the next negotiating round, which is slated to take place May 15-24 in Lima, Peru. "For the coming round in Lima, there will continue to be discussion on this issue, but it will not be on textual proposals," Ng said.

The talks here on pharmaceutical IPR also did not delve into the specifics. "Countries shared respective information about their systems, and the delegations have also agreed to continue this exchange of information into the next round with a view to finding possible common grounds on this issue," Ng said. Before this week, TPP negotiators had not met formally to discuss pharmaceutical IPR since the Melbourne round back in March 2012.

Pharmaceutical IPR is one of the most contentious areas of the talks. The U.S. proposal, which focuses on the concept of an "access window," has been roundly rejected by many TPP partners. In response, the U.S. is now in a period of reviewing its proposal, and stakeholders are eager whether and how the U.S. opts to alter its proposal to make it more palatable to other TPP members.

While the comments by the chief Singaporean negotiator this week do not technically rule out the possibility that the U.S. could table a revised legal text prior to the Peru round but not discuss it there, one observer here said that scenario is highly unlikely. It is "impossible to believe" that TPP countries would avoid discussing a new legal text from the U.S. if it were on the table, this observer argued.

With negotiators saying they want to wrap up negotiations this year, however, this latest development does raise questions about when text-based negotiations will resume in this crucial area. After Lima, the next formal round that is now on the schedule will not take place until September, although there observers say TPP partners may schedule another round in July, after Lima and before that September round.

One observer offered several possible explanations for why the U.S. is apparently still holding off on tabling a revision. One possibility is that the administration simply needs more time in its deliberations. Another possible explanation is that Peru, which has the ability to set the agenda for the May round, has refused to allow a discussion on a revised U.S. proposal at that round, and wants to stick only to information exchange on this topic.

A third possible explanation is that TPP countries are aware that Japan may formally enter the negotiations sometime after the May round (see related story), and therefore want to ensure that Japan has the ability to negotiate on this sensitive issue, the observer said. The U.S. may believe that having Japan at the table could help drive a more favorable outcome on pharmaceutical IPR, this source speculated.

Speaking at the March 13 press conference, U.S. chief negotiator Barbara Weisel said the U.S.

internal review of its proposal has not yet concluded. "We have been internally discussing what approaches might be possible in the United States and those consultations ... are still underway, and until we conclude those discussions internally, we will not be prepared to put forward a proposal," she said.

Weisel did not give any indication as to when the U.S. would table a new proposal. She also clarified that the discussions on pharmaceutical IPR held in Singapore consisted only of an exchange of information to ensure that all parties understand the way in which others handle pharmaceutical intellectual property issues. That input will be valuable in informing the internal discussion in the U.S. about this issue in TPP, she maintained.

According to an industry source, most TPP countries have indicated that they will not be in a position to reply to the U.S. proposal until its missing pieces are tabled, including on biologic drugs. This source said it is unclear whether the U.S. internal review of the proposal will result in a revision, or merely a decision on how to fill in the missing pieces of the proposal as it now exists.

Sources said negotiators from other TPP countries are beginning to speculate that the U.S. may end up proposing some sort of "special and differential treatment" in a revised pharmaceutical IP proposal that would apply different standards to developing countries and developed ones.

Under this scenario, the U.S. could propose applying the stronger patent protections of the U.S.-Korea free trade agreement to developed countries in the TPP, while developing countries would be subject to the more flexible "May 10" standards included in U.S. FTAs with Peru, Panama and Colombia.

But this would require the U.S. to specify which TPP partners would be considered "developed" for the sake of the IP chapter, and sources said countries like Chile and Singapore would likely oppose being put in that category if it meant they had to adhere to the higher standard.

U.S. business groups, which favor the IP standards of the Korea FTA, in general oppose the idea of special and differential treatment although they support giving developing countries a transition period to phase in their TPP obligations, when necessary.

In general, the industry source said the U.S. has held bilateral consultations over the past several months with TPP partners on its proposal proposal, which has laid the groundwork for the U.S. to move forward in this area. Those consultations have yielded useful information in terms of what are the specific problems or sensitivities certain countries have regarding the proposal, as well as what sort of IP protections they already provide, this source said.

This will help U.S. negotiators see past the "rhetorical" opposition that was expressed by TPP countries when the proposal was discussed in earlier rounds, and to approach negotiations on this

issue pragmatically, this source said.

IPR negotiators discussed pharmaceutical issues on March 9 during a session in which Canada and Mexicofor the first time provided information about their regimes for protecting pharmaceutical intellectual property. It was the first time Canada and Mexico engaged in talks on pharmaceutical IPR since joined the talks in October. During the March 9 session, other TPP countries also discussed their systems, and some described how they would be negatively impacted by the U.S. proposal, sources said.

The U.S. proposal would allow brand-name drug companies to obtain stronger pharmaceutical patent protections if they sought marketing approval for a drug in a TPP country within a certain period of time after first obtaining marketing approval in another TPP country. The length of this so-called "access window" was never defined in the U.S. proposal, and was a key missing element along with the length of data exclusivity protections for biologic drugs.

In response to a question at the press conference, Weisel said the U.S. has not yet made a proposal on biologics, and the issue was not discussed here. Brand-name pharmaceutical companies are urging the U.S. to propose 12 years of data exclusivity for biologics in TPP, which is the current length of protection under U.S. law.

Malaysian chief negotiator J Jayasiri acknowledged that IP is a sensitive area for his country in the talks. When it comes to the wide range of disciplines being discussed in TPP, "there are areas where current proposals would cause some difficulties for Malaysia," he said. "We would like to see ... sufficient flexibilities to accommodate the kind of difficulties that we face, and this includes in areas like intellectual property."

Ng signaled that TPP countries have not yet made a decision on whether to schedule an additional round in July. The initial 2013 schedule agreed upon by TPP countries only called for rounds in March, May and September. "As to whether we will have another round in July, what we will do is, really, we have to consider this question even as we look to build on the positive momentum to try to conclude the [negotiations] in the course of a later date," she said.

TPP countries may want to hold a July round whether or not Japan enters the negotiations, the observer speculated. If Japan were to declare its intent to join TPP this week, and TPP countries then quickly concluded bilateral and group discussions with Tokyo, and the Obama administration were to send its notification to Congress, Japan could potentially be at the table by a July round. If Japan opts not to join the TPP talks, the current 11 partners may still want to hold a July round so they could bolster their chances of concluding a deal this year, the observer said.

The observer speculated that chief negotiators may not have been able to formally announce a July round here because they need to go back to their capitals to work out scheduling and budgetary details. Another observer pointed out that the Islamic holiday of Ramadan begins on

July 9 and last through Aug. 7, and that TPP countries would likely want to avoid scheduling a round during that period because Muslim negotiators would be fasting during daylight hours.

Inside U.S. Trade - 03/15/2013, Vol. 31, No. 11

Inside U.S. Trade
Daily News

TPP Countries Will Not Discuss New Pharmaceutical IPR Text At Next Round
Posted: March 13, 2013

SINGAPORE – Countries participating in the Trans-Pacific Partnership (TPP) negotiations will not discuss an existing U.S. proposal on pharmaceutical intellectual property rights (IPR) protection or a potential new U.S. proposal in this area at the next negotiating round that will take place May 15-24 in Lima, Peru, a Singaporean trade official said at a press conference here to conclude the 16th round of negotiations.

Singaporean chief negotiator Ng Bee Kim said TPP countries had informally exchanged general information and views on the issue of pharmaceutical IPR at the round here, and planned to do the same in Peru. "Countries shared respective information about their systems, and the delegations have also agreed to continue this exchange of information into the next round with a view to finding possible common grounds on this issue," she said.

She emphasized that the pharmaceutical IPR discussion in Lima will be based on "further clarification" and not on a proposed text. "For the coming round in Lima there will continue to be discussion on this issue, but it will not be on textual proposals," Ng said.

While her comments do not technically rule out the possibility that the United States could table a revised legal text prior to the Peru round but not discuss it there, one observer here said that scenario is highly unlikely. It is "impossible to believe" that that TPP countries would avoid discussing a legal text if it were already on the table, this observer argued.

A more likely scenario is that the U.S. somehow already knows that it will not be able to table a revised proposal in time for the Lima round, this observer said. Another possible explanation is that Peru, which has the ability to set the agenda for the May round, has refused to allow a discussion on a revised U.S. proposal at that round, and wants to stick only to information exchange on this topic.

A third possible explanation is that TPP countries are aware that Japan may formally enter the negotiations sometime after the May round, and therefore want to ensure that Japan has the ability to negotiate on this sensitive issue, the observer said. The U.S. may believe that having Japan at the table could help drive a more favorable outcome on pharmaceutical IPR, this source

speculated.

The U.S. "access to medicines" proposal on pharmaceutical IPR, originally tabled in September 2011, has met with criticism from many TPP countries. As a result, the U.S. government has undertaken an internal review of its proposal, which U.S. chief negotiator Barbara Weisel said has not yet concluded.

"We have been internally discussing what approaches might be possible in the United States and those consultations ... are still underway, and until we conclude those discussions internally, we will not be prepared to put forward a proposal," Weisel said at the closing press conference.

She did not give any indication as to when the U.S. would table a new proposal. Weisel clarified that the discussions on pharmaceutical IPR held in Singapore consisted only of an exchange of information to ensure that all parties understand the way in which others handle pharmaceutical intellectual property issues. That input will be valuable in informing the internal discussion in the U.S. about this issue in TPP, she said.

IPR negotiators discussed pharmaceutical issues on March 9 during a session in which Canada and Mexico for the first time provided information about their regimes for protecting pharmaceutical intellectual property. It was the first time TPP partners had discussed the pharmaceutical IPR issue in roughly a year, and the first since Canada and Mexico joined the talks in October. During the March 9 session, other TPP countries also discussed their systems, and some described how they would be negatively impacted by the U.S. proposal, sources said.

The U.S. proposal would allow brand-name drug companies to obtain stronger pharmaceutical patent protections if they sought marketing approval for a drug in a TPP country within a certain period of time after first obtaining marketing approval in another TPP country. The length of this so-called "access window" was never defined in the U.S. proposal, and was a key missing element along with the length of data exclusivity protections for biologic drugs.

In response to a question, Weisel said the U.S. has not yet made a proposal on biologics, and the issue was not discussed here. Brand-name pharmaceutical companies are urging the U.S. to propose 12 years of data exclusivity for biologics in TPP, which is the current length of protection under U.S. law.

Malaysian chief negotiator J Jayasiri acknowledged that IP is a sensitive area for his country in the talks. When it comes to the wide range of disciplines being discussed in TPP, "there are areas where current proposals would cause some difficulties for Malaysia," he said. "We would like to see ... sufficient flexibilities to accommodate the kind of difficulties that we face, and this includes in areas like intellectual property."

At the press conference, chief negotiators faced a barrage of questions from Japanese press about Tokyo's potential entry into the talks. But they were extremely cautious in their responses, and mainly reiterated the official position that any new country joining the negotiations has to commit to pursue an ambitious outcome in TPP and not slow down the talks.

"In the event that a ... country should join the TPP, what is important, as we have reiterated a few times here, is there must be a clear understanding that they share the goal of working to have an ambitious and comprehensive agreement, and two is that they will be able to contribute positively to the momentum of concluding the [negotiations] in 2013," Ng said.

She emphasized that if Japan announces it wants to join TPP, it will then have to enter into consultations bilaterally with separate TPP countries as well as collectively with the entire group. This is because a decision to allow a new country into TPP must be made by consensus by the current members.

Even if TPP countries reach a consensus to allow Japan to join the negotiations, individual TPP parties must then also carry out their own domestic consultations and legal procedures to integrate new members, Ng said. In the U.S., for instance, the Obama administration would likely follow the rules of an expired fast-track law by notifying Congress and entering into consultations with lawmakers for a period of 90 days before entering into new trade negotiations with Japan.

Ng also signaled that TPP countries have not yet made a decision on whether to schedule an additionalnegotiating round in July. The initial 2013 schedule agreed upon by TPP countries only called for rounds in March, May and September.
"As to whether we will have another round in July, what we will do is, really, we have to consider this question even as we look to build on the positive momentum to try to conclude the [negotiations] in the course of a later date," she said.

TPP countries may want to hold a July round whether or not Japan enters the negotiations, the observer speculated. If Japan were to declare its intent to join TPP this week, and TPP countries then quickly concluded bilateral and group discussions with Tokyo, and the Obama administration were to send its notification to Congress, Japan could potentially be at the table by a July round. If Japan opts not to join the TPP talks, the current 11 partners may still want to hold a July round so they could bolster their chances of concluding a deal this year, the observer said.

The observer speculated that chief negotiators may not have been able to formally announce a July round here because they need to go back to their capitals to work out scheduling and budgetary details. Another observer pointed out that the Islamic holiday of Ramadan begins on July 9 and last through Aug. 7, and that TPP countries would likely want to avoid scheduling a round during that period because Muslim negotiators would be fasting during daylight hours.

TOBACCO

Don't sell our health for foreign investment

Philip Pattemore is associate professor of paediatrics at the University of Otago in Christchurch.
11 Mar 2013, *Dominion Post* (Wellington, New Zealand)

MORE than 400 health professionals, mostly doctors and nurses, wrote to the prime minister this week expressing their concerns about the potential impact of the Trans-Pacific Partnership Agreement (TPPA) on smokefree legislation in New Zealand.

The TPPA has just entered another round of talks in Singapore. Negotiations are being held in secret and, though the signatories don't object to free trade and understand the need for confidentiality in financial negotiations, leaked information shows intellectual property rights of foreign investors are key issues.

Companies trading in tobacco, alcohol and pharmaceuticals may be able to use this agreement to protect their interests over ours.

The problem in relation to tobacco is that the New Zealand Government has already committed itself to reducing and eliminating tobacco smoking. Tobacco use comes at a huge cost to the health of the public – not only to people who smoke but to people and children near them.

The Government has obligations under the WHO Framework Convention on Tobacco Control to protect public health policies from the commercial and other vested interests of the tobacco industry.

But the TPPA may provide new protections to foreign investors operating in New Zealand via clauses relating to intellectual property. It may also provide foreign investors new avenues for disputing future health legislation through World Trade Organisation arbitration.

The 415 health professionals urged the Government to consider the impact of joining the TPPA on its commitments, and have demanded tobacco companies be excluded from participation in any negotiations of their investments or intellectual property.

Tobacco is no ordinary product like shoes or washing machines. When used as intended, it is harmful and addictive, killing more than 5000 New Zealanders a year and damaging the health of thousands of children.

That tobacco trade continues is a historical anomaly – a similar toxic product would never be licensed for consumers today. The Government should be aiming to eliminate it, not foster its trade interests.

The Government should be free to protect the public health interest in response to scientific medical evidence, rather than being chained up by the threat of legal or financial penalties. Corporations that have no interest in the health of New Zealanders should not be given leverage over our Government's health legislation.

In the letter, the Government is also urged to contest the inequity and undemocratic process of the TPPA negotiations. US Congress and more than 600 US trade corporations have been given access to drafts of the agreement, while the New Zealand public and health experts have been denied access, giving those corporations more leverage over our country's health than its own

citizens.

The Government has also expressed its commitment, under Te Tiriti o Waitangi, to reduce inequity by reducing supply and demand for tobacco.

There is well-documented evidence that Maori and Pacific communities in New Zealand carry a disproportionate burden of disease and lower life expectancy as a result of tobacco use.

The tobacco industry is using its dispute over plain packaging in Australia to discourage other countries from enacting similar legislation.

Our Government's intention to mandate plain packaging appears diluted by the move to delay it until we see the outcome of the challenges to the Australian legislation.

The industry has moved to delay the hearing in Australia, with a flow-on effect for New Zealand's legislation.

The health professionals who have signed the letter urged the Government not to enter into further trade provisions that may stall the goal of a smokefree Aotearoa by 2025. Our health should not be sold to strengthen trade.

TEXTILES/FOOTWEAR
Inside U.S. Trade, Daily News

Vietnam Signals Willingness To Work With U.S. On Short-Supply Proposal
Posted: March 13, 2013

SINGAPORE – Vietnam is open to working with the United States and the private sector to see whether a U.S. proposal aimed at resolving the controversial issue of rules of origin for apparel will lead to a solution that would be acceptable to both countries in a Trans-Pacific Partnership (TPP) agreement, according to a Vietnamese trade official.

In a press conference to mark the end of the 16th round of TPP talks here, Vietnamese chief negotiator Khanh Tran Quoc said Vietnam "welcomes any idea that can help us move forward, including the idea [of] a short-supply list."

The Office of the U.S. Trade Representative in December proposed the creation of permanent and temporary short-supply lists of items that could be sourced from outside the TPP region and still be made into apparel eligible for tariff benefits. These short-supply lists would serve as an exception to the restrictive yarn-forward rule of origin for apparel the U.S. has proposed in the talks.

Additional flexibility from the yarn-forward rule would be key for Vietnam, as that would make it easier for Vietnamese apparel products to qualify for reduced U.S. tariffs under TPP. But the U.S. wants to ensure that the TPP benefits accrue only to participating members, meaning it wants to

limit the number of exceptions to the yarn-forward rule.

In addition, U.S. textile manufacturers are worried that Vietnamese imports -- which are made with low labor costs and, according to U.S. manufacturers, benefit from a host of subsidies -- could displace apparel imports from Central America and other countries that are made with U.S. yarns and fabrics.

Khan said that Vietnam understands the importance of the textile issue for the U.S. and that he believes the U.S. recognizes its importance for Vietnam. "And that is why we've been working very closely, not only with the USTR but also with the business sector, in order to find all the possibilities that can help us to set up a formula that can be acceptable to both sides in this negotiation," he said.

But he emphasized that any potential solution to the rules of origin issue must meet two criteria. It must take into account the nature of the current globalized supply chain, and it must result in commercial benefits for businesses in the TPP region. "So in fact we are working and open to any proposal that can help us to move forward," Khan said.

After announcing its short-supply idea at the December TPP round, USTR began collecting suggestions for the lists from U.S. apparel importers and retailers as well as textile manufacturers through a complicated submission and vetting process on a White House website (*Inside U.S. Trade*, Feb. 7). That process is still ongoing.
USTR officials had hoped to present some initial proposals for items to include on the two lists at the round here, but apparel sector sources said they were not aware that this had occurred. They said the textile discussions held here on March 8 most likely consisted of USTR briefing other countries about the process it has set up for accepting proposals for the lists and vetting them with domestic industry.

Khan said his government had not yet decided whether Vietnam would consider coming up with its own proposals for items to be included on the short-supply lists. "We need to understand about the way to construct the list first, and then if we ... see that it could be a good way forward, then we might proceed to contribute to the list," he said.

In general, Khan stressed that Vietnam would prefer a more flexible rule of origin for apparel that would take into account the globalized nature of supply chains. "But at the same time, we understand it is a sensitive issue for a number of [countries], and that is why we are keen on working with them to find out a way, the best way, to ... move forward and to address the concern from each and every side," he said.

STATE OF MAINE

Citizen Trade Policy Commission

August 1, 2012

The Honorable Ronald Kirk
Trade Ambassador
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Mr. Probir Mehta
Deputy Assistant for Intellectual Property & Innovation
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: 2012 Trade Policy Assessment; commissioned by the Maine Citizen Trade Policy Commission

Dear Ambassador Kirk and Mr. Mehta:

As you may know, the Citizen Trade Policy Commission (CTPC) is required by current Maine Law (10 MRSA Chapter 1-A) to provide an ongoing state-level mechanism to assess the impact of international trade policies and agreements on Maine's state and local laws, business environment and working conditions. An important part of the CTPC mandate is to conduct a biennial assessment on the impacts of international trade agreements on Maine.

We have enclosed a copy of our recently completed 2012 Trade Policy Assessment. In a process that is more fully described in an addendum included within the printed document, the Citizen Trade Policy Commission contracted with Professor Robert Stumberg of Georgetown University to conduct this assessment.

We believe that the 2012 Trade Policy Assessment is an invaluable tool for a more complete understanding of both the proposed TransPacific Partnership Agreement (TPPA) which is currently being negotiated and other international trade treaties and their current and potential effects on Maine. As a specific result of the 2012 Trade Policy Assessment, the CTPC has voted unanimously to make a number of recommendations regarding the potential treatment of *pharmaceuticals* within the TPPA and other international trade agreements:

- CTPC members voted to cite previous communications to the USTR regarding the treatment of pharmaceuticals in international trade treaties. In particular, we have also enclosed a letter dated February 12, 2010 which was addressed to Ms. Jennifer Choe Groves within the USTR. In that letter, the CTPC:
    - Voiced its support for evidence-based reimbursement decisions to restrain pharmaceutical prices;
    - Endorsed the continued state use of Preferred Drug Lists to also reduce pharmaceutical prices; and
    - Opposed any promotion of international restrictions on domestic pharmaceutical pricing programs.
- More specifically, the CTPC is unanimous in our support for the inclusion of a footnote in the TPPA and other trade agreements which "carves out" federal reimbursement programs such as Medicaid, 340 B and Medicare Part B;
- The CTPC also voted unanimously to support provisions in the TPPA and other international trade agreements which emphasize, allow for and encourage the overall affordability of pharmaceuticals in each affected country; and
- Finally, the CTPC requests that the USTR develop a clear public statement on the specific elements of a pharmaceuticals-related provision, as they are proposed by the USTR for consideration as a part of the TPPA.

In making these and other recommendations, members of the CTPC expressed a clear desire to further discuss these subjects in detail with either of you in the context of a public meeting held by the CTPC. We invite you to appear at such a public meeting at a date that is mutually satisfactory and as an alternative to you traveling to Maine, we suggest that a conference call could be arranged on a date to be determined in the near future.

On behalf of the CTPC, we thank you for your attention to the issues we have raised regarding any pharmaceutical-related provisions to be included in the TPPA and other international trade agreements and we look forward to discussing these issues with you in more detail.

Sincerely,

Roger Sherman

Senator Roger Sherman, Chair

Joyce Maker

Representative Joyce Maker, Chair

c: Governor Paul LePage
Senator Olympia Snowe
Senator Susan Collins
Representative Michael Michaud
Representative Chellie Pingree
Maine State Representative Sharon Treat, member of Intergovernmental Policy Advisory Committee

STATE OF MAINE

Citizen Trade Policy Commission

August1, 2012

The Honorable Ronald Kirk
Trade Ambassador
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Ms. Jean Grier
Senior Procurement Negotiator
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: 2012 Trade Policy Assessment; commissioned by the Maine Citizen Trade Policy Commission

Dear Ambassador Kirk and Ms. Grier:

As you may know, the Citizen Trade Policy Commission (CTPC) is required by current Maine Law (10 MRSA Chapter 1-A) to provide an ongoing state-level mechanism to assess the impact of international trade policies and agreements on Maine's state and local laws, business environment and working conditions. An important part of the CTPC mandate is to conduct a biennial assessment on the impacts of international trade agreements on Maine.

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We believe that the 2012 Trade Policy Assessment is an invaluable tool for a more complete understanding of both the proposed TransPacific Partnership Agreement (TPPA) which is currently being negotiated and other international trade treaties and their current and potential effects on Maine. As a specific result of the 2012 Trade Policy Assessment, the CTPC has voted unanimously to make a number of recommendations regarding the potential treatment of *procurement* within the TPPA and other international trade agreements:

- We favor an approach represented by procurement provisions in other previously negotiated trade agreements such as the World Trade Organization's Agreement on Government Procurement which allow state governors to decide whether to be subject to the procurement chapters of different Free Trade Agreements that have been negotiated between the U.S. and individual nations. The CTPC strongly believes that it is essential to a state's sovereignty to be able to decide whether to be subject to certain procurement provisions;
- The CTPC also is unanimous in our support for the inclusion of provisions in the TPPA and other trade agreements which allow for laws and regulations which permit "Buy America" procurement requirements and
- Finally, the CTPC requests that the USTR develop a clear public statement on the specific elements of a procurement-related provision, as they are proposed by the USTR for consideration as a part of the TPPA.

In making these and other recommendations, members of the CTPC expressed a clear desire to further discuss these subjects in detail with either of you in the context of a public meeting held by the CTPC. We invite you to appear at such a public meeting at a date that is mutually satisfactory and as an alternative to you traveling to Maine, we suggest that a conference call could be arranged on a date to be determined in the near future.

On behalf of the CTPC, we thank you for your attention to the issues we have raised regarding any procurement-related provisions to be included in the TPPA and other international trade agreements and we look forward to discussing these issues with you in more detail.

Sincerely,

Roger Sherman AM

Senator Roger Sherman, Chair

Joyce Maker AM

Representative Joyce Maker, Chair

c: Governor Paul LePage
Senator Olympia Snowe
Senator Susan Collins
Representative Michael Michaud
Representative Chellie Pingree
Maine State Representative Sharon Treat, member of Intergovernmental Policy Advisory Committee

STATE OF MAINE

Citizen Trade Policy Commission

August 1, 2012

The Honorable Ronald Kirk
Trade Ambassador
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Ms. Barbara Weisel
Assistant U. S. Trade Representative for Southeast Asia and the Pacific
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: 2012 Trade Policy Assessment; commissioned by the Maine Citizen Trade Policy Commission

Dear Ambassador Kirk and Ms. Weisel:

As you may know, the Citizen Trade Policy Commission (CTPC) is required by current Maine Law (10 MRSA Chapter 1-A) to provide an ongoing state-level mechanism to assess the impact of international trade policies and agreements on Maine's state and local laws, business environment and working conditions. An important part of the CTPC mandate is to conduct a biennial assessment on the impacts of international trade agreements on Maine.

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We believe that the 2012 Trade Policy Assessment is an invaluable tool for a more complete understanding of both the proposed TransPacific Partnership Agreement (TPPA) which is currently being negotiated and other international trade treaties and their current and potential effects on Maine. As a specific result of the 2012 Trade Policy Assessment, the CTPC has voted unanimously to make a number of recommendations regarding the potential treatment of *tobacco* within the TPPA:

- We favor 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, we favor 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 making these and other recommendations, members of the CTPC expressed a clear desire to further discuss these subjects in detail with either of you in the context of a public meeting held by the CTPC. We invite you to appear at such a public meeting at a date that is mutually satisfactory and as an alternative to you traveling to Maine, we suggest that a conference call could be arranged on a date to be determined in the near future.

On behalf of the CTPC, we thank you for your attention to the issues we have raised regarding the treatment of tobacco-related provisions in the TPPA and we look forward to discussing these issues with you in more detail.

Sincerely,

Roger Sherman ttm
Senator Roger Sherman, Chair

Joyce Maker ttm
Representative Joyce Maker, Chair

c: Governor Paul LePage
Senator Olympia Snowe
Senator Susan Collins
Representative Michael Michaud
Representative Chellie Pingree
Maine State Representative Sharon Treat, member of Intergovernmental Policy Advisory Committee

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

OCT 26 2012

Senator Roger Sherman, Chair
Representative Joyce Maker, Chair
State of Maine
Citizen Trade Policy Commission
c/o Office of Policy & Legal Analysis
State House Station #13
Augusta, ME 04333-0013

Dear Senator Sherman and Representative Maker:

Thank you for the recent letters you sent on behalf of the Citizen Trade Policy Commission (CTPC) and for sending a copy of your 2012 Trade Policy Assessment. I appreciate receiving your input on the possible impacts of international trade agreements generally and the Trans-Pacific Partnership (TPP) specifically, including the potential coverage of procurement by state governments and the potential treatment of tobacco and pharmaceuticals. In addition, you asked several questions regarding the status of the dispute in the World Trade Organization (WTO) regarding the Country of Origin Labeling Act (COOL).

With regard to your concerns with the potential coverage of state procurement under the TPP, let me assure you that the United States will only cover the state procurement of Maine or any other state where that state has expressly authorized such coverage. This is our long-established practice, which dates back to the inclusion of state procurement under the WTO Agreement on Government Procurement. With respect to your interest in further discussions of these issues, I understand our government procurement negotiator, Jean Grier, has been in contact with you.

In one of your letters you also outlined a number of CTPC recommendations regarding the treatment of tobacco in the TPP negotiations. We have heard from many stakeholders in recent months, with a number of perspectives on this issue and the draft tobacco proposal we developed. We are considering this wide-ranging input before determining how to move forward in the TPP negotiations. It is important to ensure we strike the right balance on an issue that is important to so many Americans. As we move forward in our review of the input we have received, we look forward to further discussion with interested stakeholders, including members of the CTPC.

Regarding your concern on the reimbursement of pharmaceutical products and medical devices, USTR is seeking TPP transparency provisions to ensure transparency and procedural fairness for pharmaceutical products and medical devices. This is a significant area of concern for U.S. exporters, including those in the innovative and generic pharmaceutical industries and the medical device industry. Our emphasis on transparency and fairness preserves flexibility for all TPP governments to design evidence-based pricing and reimbursement programs at the national level, while ensuring respect for the rights of stakeholders of all viewpoints through basic norms of transparency and procedural fairness. We will continue to negotiate these provisions carefully with the concerns of state government authorities in mind. As USTR has indicated previously, it remains our view that corresponding provisions of existing agreements are not applicable to Medicaid or health care programs at non-central levels of government.

NOV 05 2012

Finally, you asked about the status of the WTO dispute settlement proceedings regarding COOL. The United States has stated that it intends to comply with the recommendations and rulings of the WTO in the COOL dispute. We are continuing to consult internally within the U.S. Government on this matter, and no decision has yet been made as to how we will implement the WTO's recommendations and rulings.

Thank you again for sharing your views on the TPP negotiations and other trade issues of interest to the CTPC. We appreciate this input and your active engagement with us, and we will continue to consult closely with stakeholders, including members of the CTPC, as we formulate and implement U.S. trade policy.

Sincerely,

Ambassador Ron Kirk

STATE OF MAINE

Citizen Trade Policy Commission

October 4, 2012

Ms. Jean Grier
Senior Procurement Negotiator
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ms. Grier,

Please accept our sincere appreciation for your participation at the meeting held by the Maine Citizen Trade Policy Commission (CTPC) on September 19, 2012. Your comments were timely, informative, helpful and clear. We feel very fortunate that you were able to take the time to speak with us over the phone in spite of what we assume is an incredibly demanding schedule.

As you know, the CTPC dedicates itself to staying informed about international trade policy and how it impacts our state. We conduct biennial assessments of specific areas of interest with regard to trade policy; our most recent dealt with the Trans Pacific Partnership Agreement (TPPA) and was completed this summer. A copy of that assessment can be found on our website at: http://www.maine.gov/legis/opla/citpolassessments.htm

In addition to expressing our gratitude for your participation at our last meeting, we wanted to point out statements that we found particularly helpful and informative.

- In response to our question as to the potential negotiations for state-level procurement provisions in the TPPA, you stated that the USTR is committed to the same process of consulting with the states that has been used in other trade agreements. You assured us that USTR will seek state input if TPPA includes sub-federal level procurement provisions. We've established our strong support for state input. Not only are we one of the 37 states which have stated we want to be consulted with regard to procurement, we have also enacted legislation that requires the Governor to receive approval from the Maine Legislature to either opt in or opt out of the procurement provisions in international trade agreements. That requirement can be found at 10 MRSA §13. Subsection 5 of this law reads:

5. Legislative approval of trade agreement required. *Unless the Legislature by proper enactment of a law authorizes the Governor or another official of the State to enter into the specific proposed trade agreement, the State may not be bound by that trade agreement.*

- You also spoke to our concerns regarding potential changes to the WTO Agreement on Government Procurement (GPA), stating that any changes to that umbrella agreement will only apply to procurement on the federal level. We have been aware of the pressure being applied by the European Union with regard to changes to the GPA in order for them to have greater access to state-level procurement opportunities. We are relieved to know that the USTR will support maintaining the provisions of the GPA that enable states to opt in or opt out of procurement provisions in trade agreements and that the USTR won't bind states in any way unless they opt-in.

- We understand that the trigger for seeking input from the states is procurement activity that equals or exceeds $500,000 in value. It was reassuring to hear that there are no plans to reduce that threshold.

- You were helpful in pointing out that the Davis Bacon Act, which requires a prevailing wage be paid for federal projects, and the Berry Amendment, which requires the Department of Defense to give procurement preference to domestically made goods for the military, will not be impacted by procurement provisions negotiated in the TPPA.

The Commission is so fortunate to have access to and input from people directly involved with the important responsibility of negotiating international trade agreements. Please accept our sincere gratitude for your thoughtful and helpful participation at our September meeting.

Sincerely,

Roger Sherman (DDF)
Senator Roger L. Sherman, Co-chair
Maine Citizen Trade Policy Commission

Joyce Maker CDDF
Representative Joyce A. Maker, Co-chair
Maine Citizen Trade Policy Commission

Article notes: 3/22/13 CTPC agenda:

Senate Finance Committee holds Hearing on the President's Trade Agenda, Asks Questions on TPP and Trade Promotion Authority

- Senate Finance Committee held a hearing on the President's Trade Agenda on 3/20/13
- Sole witness was Acting USTR Deetrios Marantis
- Senate Chair Baucus supports renewal of the Trade Promotion Authority (TPA) and urges ratification of TPPA in 2013
- USTR Marantis stated that TPPA negotiations are intensifying, Trans Atlantic Free Trade Agreement negotiations are about to begin, and stated his intent to work with the committee on TPA

USTR Announcement: Obama Administration Notifies Congress of Intent to Negotiate Transatlantic Trade and Investment Partnership

- USTR sent a notification to Congress on 3/20/13 of its intent to negotiate TATIP agreement with leaders of the European Union
- TATIP to address issues of mutual job creation, growth and increased competiveness

Japan to Join the Trans-Pacific Partnership – Finally!

- After nearly 2 years of discussions, Japan has agreed to become part of the TPPA

From Negotiation to Policy: the Power of a Trade Pact

- Useful overview of the process used to negotiate international trade treaties
- Advantages of trade agreements like TPPA include useful environmental, consumer and trade protections
- Disadvantages of trade agreements like TPPA include usurpation of meaningful Congressional oversight through the use of "Fast Track Authority" and the possibility of having trade agreements override federal, state and local laws for any participating nation

Senate Finance Committee Holds Hearing on the President's Trade Agenda, Asks Questions on TPP and Trade Promotion Authority

http://infojustice.org/archives/29049 March 20, 2013

Mike Palmedo

Today the Senate Finance Committee held a hearing on "The President's 2013 Trade Agenda." Opening statements, a webcast, and instructions for submitting comments to the record are all here.

AUSTR Demetrios Marantis

The sole witness at the hearing was Acting United States Trade Representative Demetrios Marantis.

There was much discussion of Trade Promotion Authority (TPA) – which many Senators want to see move forward. TPA legislation will include the defining of negotiating objectives for USTR. Senators also asked about the Trans Pacific Partnership (TPP) and the Trans Atlantic Free Trade Agreement negotiations. Most of the discussions about intellectual property and trade were about data exclusivity for biopharmaceuticals, which Sen. Hatch and Menendez want included in the TPP.

Prepared statements

Sen. Baucus called for the renewal of Trade Promotion Authority (TPA) in his opening statement, and said he would work to get it passed. He said that he wants the TPP to be concluded this year. Baucus said that China's "wholesale theft" of U.S. intellectual property "must be fought."

Sen. Hatch said that the TPP and TAFTA hold great promise, but that tough issues need to be resolved. The TPP must include strong IP protection for biologics, and TAFTA must include the "highest levels" of IPR protection in order to win his support.

Acting USTR Demetrios Marantis gave a very short prepared statement, in which he reported that USTR is intensifying TPP negotiations, preparing to begin negotiations for TAFTA, preparing to begin negotiating a services agreement in Geneva, and looking forward to "beginning" to work with the committee on Trade Promotion Authority. He also discussed enforcement activities, and warned that funding cuts have complicated USTR's efforts to fulfill its responsibilities.

Q&A

At the beginning of Q&A Baucus asked Marantis to discuss TPA. He brought up the fact that the law will define USTR's trade objectives going forward, and that the world economy has changed since the last time goals were legislated. Marantis reaffirmed that USTR is going to move forward on TPA, and he said that there is a diversity of interests on the committee and in general about what the negotiating objectives should be

Sen. Hatch said that the pharmaceutical industry is the biggest driver of innovation in the US economy, and that under U.S. law, biopharmaceuticals now have 12 years of data exclusivity. Therefore, he is "perplexed" that the administration has not sought 12 years of data protection for biopharmaceuticals in the TPP negotiations. Marantis answered that USTR is discussing data protection with committee and with the TPP partners, and that it is a "tough issue." Hatch asked him how it is his position to "ignore U.S. law."

Sen. Brown asked how a re-articulated TPA bill could "ensure that the benefits of trade are shared more broadly than they have in the past." He asked if there are any particular new negotiating objectives that the administration would seek. He suggested that more trade adjustment assistance could be included in a TPA bill. Marantis assured Brown that USTR would consult him and others on the committee about the negotiating objectives in new TPA legislation.

Sen. Menendez said that any 21st century agreement needs strong intellectual property protection, and that protections for biologics enjoy strong bipartisan support in Congress. He asked if it is the administration's plan to table a proposal for 12 years of data exclusivity for biopharmaceuticals in the TPP, and noted that it is the standard in US law. Marantis answered that USTR is not sure what it will table yet, and he said against that USTR has been discussing the issue with trading partners and with the Members of the Committee. Biopharmaceuticals are a new area of innovation. Some trading partners provide for this type of protection, and some do not. Menendez said that he will be looking for a 12 year term of data exclusivity when deciding whether or not to do support the final agreement.

Senators Portman, Grassley, and Thune also stressed their desire to see TPA move forward.

USTR NEWS

UNITED STATES TRADE REPRESENTATIVE

www.ustr.gov Washington, D.C. 20508 202-395-3230

For Immediate Release: **Contact:** Carol Guthrie

March 20, 2013
cguthrie@ustr.eop.gov

Obama Administration Notifies Congress of Intent to Negotiate Transatlantic Trade and Investment Partnership

Washington, D.C. – The Obama Administration today notified the U.S. Congress of its intent to enter into negotiations on a comprehensive trade and investment agreement with the European Union. Today's notification follows a joint announcement last month by President Obama and the Leaders of the European Union indicating their intent to pursue talks toward a Transatlantic Trade and Investment Partnership. Acting United States Trade Representative Demetrios Marantis noted in a letter to lawmakers that an ambitious, comprehensive, and high-standard agreement could significantly expand trade and investment between the United States and the European Union, generating new business and job opportunities.

"The decision to launch negotiations on the Transatlantic Trade and Investment Partnership reflects the broadly shared conviction that transatlantic trade and investment can be an even stronger driver of mutual job creation, growth, and increased competitiveness," the letter read. **"The support for a comprehensive agreement that has been offered by a significant and diverse set of stakeholders boosts our confidence that it will be possible to find mutually acceptable solutions on difficult issues and conclude an agreement that will benefit U.S. workers. With average U.S and EU tariffs already quite low, new and innovative approaches to reducing the adverse impact on transatlantic commerce of non-tariff barriers must be a significant focus of the negotiations. The Administration will hold regular and rigorous consultations with Congress and stakeholders on all elements of the agreement."**

The transatlantic economic relationship is already the world's largest, accounting for one third of total goods and services trade and nearly half of global economic output. Transatlantic trade and investment currently supports 13 million jobs on both sides of the Atlantic.

To view a copy of the notification letter to Congress, click here. For more information on America's trade with the European Union, please visit the European Union page of USTR's website.

BROOKINGS

UP FRONT

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Joshua Meltzer | March 18, 2013 10:27am

Japan to Join the Trans-Pacific Partnership – Finally!

Japanese Prime Minister Abe's statement of his country's willingness to join the Trans-Pacific Partnership (TPP) negotiations is good for the U.S., Japan and the TPP. It follows former Japanese Prime Minister Noda's announcement at the Asia-Pacific Economic Conference (APEC) in 2011 of Japan's interest in the TPP negotiations and almost two years of discussions between the Japanese government and the other TPP parties on their expectations should Japan join the trade agreement. The TPP parties currently include the U.S., Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.

Japan's participation in the TPP will boost the agreement's economic and strategic significance. The TPP aims to be the 21st century trade agreement that sets the rules for trade and investment in the Asia-Pacific region going forward. Achieving this goal will require other major economies in the Asia-Pacific region to join the agreement with the intention of the TPP ultimately becoming a Free Trade Agreement of the Asia-Pacific (FTAAP), and Japan's participation in the TPP will give added momentum towards this goal. For one, with Japan the TPP will cover 8.6 percent of global trade and almost 40 percent of global GDP. Japan's entry into the TPP is also likely to give further impetus to other countries joining the TPP. In particular South Korea, which already has an FTA with the U.S., should now see the TPP as a key opportunity to negotiate new market access opportunities with Japan, with which it has a $108 billion trading relationship. Other countries such as Colombia, the Philippines and Thailand are also watching the TPP negotiations careful with an eye to joining.

Japan's participation in the TPP is also of economic significance for the U.S. Without Japan's participation in the TPP the market access opportunities for the U.S. are limited because the U.S. has FTAs with six of the 10 TPP parties. Should the TPP lead to new market liberalization beyond what has already been promised in their current FTAs with the U.S., the already significant liberalization committed to under these FTAs means that any new market access gains for the U.S. will be minimal.

In contrast, the U.S. does not have an FTA with Japan, which is the world's third largest economy with significant tariff and nontariff barriers in areas of key export interest for the U.S., ranging from agriculture to automobiles to financial services. As a result, an ambitious outcome in the TPP could provide the U.S. with important new markets. Its potential economic value is highlighted by the size of total bilateral trade of $220 billion in 2012 and a trade deficit of $80 billion. But this understates the size of the trading relationship as many Japanese goods and services are now inputs into final goods exported from countries such as China and South Korea. Value-added trade data more accurately captures these dimensions, and on a value-added basis the U.S. trade deficit with Japan increases by approximately 60 percent. Additionally, there is a significant bilateral investment

Fear of Lowering Standards

TPP disputes might follow a similar path and serve as an alternative to revamping domestic laws and regulations to change their effect.

"An agreement like the TPP becomes a mechanism for a broad array of industry interests to re-litigate policies that they lost when the debate occurred in the sunshine of public scrutiny and the open congressional process," says Lori Wallach, director of Public Citizen's Global Trade Watch, who kept an eye on the negotiations unfolding in Singapore and whose group opposes the free-trade pact. "It can become a backdoor strategy for changing domestic policy."
That prospect isn't lost on Congress. Rep. Rosa DeLauro says she is worried that food and agriculture interests will weaken the 2010 food safety law, which she helped write, while the Obama administration continues to implement its provisions.
"It's my fear," the Connecticut Democrat says, that "it would mean we would have to lower our standards."

Vessels for Grievances
Congress typically takes up trade agreements under presidential fast-track authority, which forces lawmakers to vote up or down on the whole deal without being able to amend it. (The president's fast-track authority has expired, but the administration is expected to seek its renewal.)

The Obama administration rejects the notion that the trans-Pacific talks could gut portions of statutes such as the Dodd-Frank financial overhaul, the 2010 health care law or DeLauro's measure.
"Only Congress changes U.S. law, period," Carol Guthrie, spokeswoman for the U.S. Trade Representative, wrote in an email, "and only administrations, in consultation with Congress, change U.S. policies and regulations."

Lobbyists and representatives of several corporations deny that the trade talks could be an opportunity for U.S. policy do-overs.

One longtime lobbyist and expert in trade pacts calls the legislating-via-trade-deal route an "unusual strategy." He says that companies and other groups weighing in on negotiations are more likely to use their muscle to raise other countries' standards so that they are in harmony with those of the United States.

But the complex nature of the TPP negotiations coupled with the reach of those countries involved with the United States - Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and, perhaps in the future, Japan - fuel speculation about the deal's eventual impact on the policies of individual countries.

David Thomas, the Business Roundtable's vice president for trade, says the TPP agreement "creates an opportunity to sort of knit together a regional free-trade area that can allow companies to more efficiently do business across those countries as well as within those countries."

There is precedent for trade-driven changes to U.S. laws. When Congress two decades ago passed the Uruguay Round Agreement Acts, transforming the General Agreement on Tariffs and Trade into the World Trade Organization, lawmakers approved a change in patent law that extended market exclusivity for U.S. products from 17 years to about 20 years. Trade and patent law experts say the change harmonized U.S. and international patent laws and benefited, in particular, big companies that file patents in multiple countries.

The North American Free Trade Agreement that Congress approved in 1993, "downwardly harmonized" federal rules for interstate trucking, says Mike Dolan, the legislative representative who handles trade policy for the International Brotherhood of Teamsters, which complained about NAFTA provisions giving Mexican trucks access to U.S. highways.

"The free-trade lobby," Dolan says, "uses these trade deals to enact a kind of domestic regulatory agenda that they can't get otherwise."

Inside Track

With the TPP talks, an immediate concern for Dolan is the "Buy American" policies that give preferential treatment to U.S. goods in federal procurement contracts. Negotiators could give that same preferred status to goods made in the 10 other countries.

Several senators late last year spelled out their Buy American concerns in a letter to President Barack Obama. Ohio Democrat Sherrod Brown, who signed the letter, has been a critic of pacts such as the Central American Free Trade Agreement and says he wants to use his position on the Finance Committee, which has jurisdiction over international trade matters, to illuminate the otherwise secretive process of trade negotiations such as the TPP.

"Corporate CEOs often have better access to information on trade negotiations than Congress does," Brown says. "These trade agreements are often good for large corporations and not so good for American workers."

Rep. Zoe Lofgren, a California Democrat and free-trade supporter who backs the TPP generally, is especially concerned about what might be in the copyright provisions of a deal.

Lofgren opposed legislation aimed at curbing online piracy - known by its acronym, SOPA - which was backed by the movie industry and other sectors that rely on copyright protections, because it would, she said, hamper Internet freedom. Technology giants such as Google Inc. led a lobbying and grass-roots effort in 2012 that derailed the legislation. Movie executives and other content providers, she says, have looked to trade pacts such as the Anti-Counterfeiting Trade Agreement as a back channel to resurrect some of SOPA.

"In the past, there have been efforts by Big Content to get in a trade agreement what they could not get through the Congress," Lofgren says, noting that ACTA had stalled.

Lofgren says she warned U.S. Trade Representative Ron Kirk, "Look at what happened to ACTA. ACTA went down because of a perception that it was delivering SOPA-like rules to the Internet. If there's overreach in the TPP, the entire trade agreement could go down just as ACTA went down." (Kirk stepped down March 15.)

A spokesman for the Motion Picture Association of America declined to comment, referring questions to the USTR and the U.S. Chamber of Commerce, which led a delegation to Singapore.

Richard Bates, senior vice president of government relations for Walt Disney Co., says movie studios would like to see in the TPP the same level of protections for intellectual-property rights as are included in a congressionally approved free-trade agreement with South Korea.

One entertainment industry executive, who declined to speak on the record because of the sensitivity of the talks, says allegations that content providers are trying to get SOPA policies into the TPP deal are "scare tactics."

On the flip side of this debate, some content providers and entertainment industry lobbyists say that technology companies are eying TPP as a way to weaken existing intellectual-property laws. Not surprisingly, both camps are watching the unfolding negotiations with immense interest. "Generally," says one lobbyist familiar with the issue, "the approach in the United States to these trade agreements has been to get other countries to adopt stronger intellectual-property rights so our movies, our products, aren't ripped off around the world."
Lawmakers gave corporate interests a say in trade talks in the Trade Act of 1974, which created industry trade-advisory committees that give feedback on relevant issues to trade negotiators. AFL-CIO President Richard Trumka has the same privilege.

"The purpose of a trade agreement is to help the U.S. economy," says one entertainment industry official, who was not authorized to discuss the talks. "The U.S. exporters have an important role to play in understanding what the barriers are."

This lobbyist added, though, that openness in negotiations often falls victim to the "horse trading" that goes on behind closed doors to arrive at a final deal.

Potential Complications

The secrecy of the deal-making may well provide lobbyists with an opportunity, but it can just as easily get in their way.

Because the draft text of any agreement is secret, lobbyists with the best access to officials on the inside must be careful to not reveal too much in public while also figuring out how to press their cases.

In Singapore, for example, the USTR hosted a "stakeholder engagement event" on March 6, at which business and other interests had "the opportunity to raise questions and share views directly with negotiators and other stakeholders," according to the USTR website.

Such out-in-the-open discussion is not the only way to try to influence the deal, however. The American Chamber of Commerce in Singapore hosted a March 8 reception for diplomats and outside interests in the grand ballroom of the hotel where negotiations were being held.

Corporate representatives also book suites where they can huddle with their counterparts and with government officials. Even public interest groups get in on the lobbying: Wallach of Public Citizen said that during a previous TPP round in New Zealand she took to standing outside, in the rain, trying to persuade negotiators to chat about her concerns.

Catherine Mellor, a trade policy expert with the U.S. Chamber of Commerce, says the group regularly keeps in touch with the USTR's office, administration officials and members of Congress. But the negotiations offer a potentially one-stop opportunity for face time with foreign officials too.

"We do meet with the foreign negotiators," explains Mellor, whose subtle accent in a reminder of her Australian roots. "A lot of these companies have real-market examples of why these policies are needed."

Banking-industry insiders say privately that the talks may be an opportunity to clarify "international, cross-border applications" of the "Volcker rule" in the Dodd-Frank law, which restricts banks from making speculative investments and is much maligned by the industry, one banking source says.

High stakes ensure that business will be engaged in future deal-making on trade, even when negotiators rebuff their input. "They might publicly say they don't want this, but they might give in if they need something else," says Mark Grayson of the Pharmaceutical Research and Manufacturers of America. Industry groups hang around so "they know you're there, in case they have some questions."

FOR FURTHER READING: Changing dynamics on congressional trade policy, 2008 Almanac, p. 6-18; World Trade Organization approval (PL 103-465), 1994 Almanac, p. 123; NAFTA approval (PL 103-182), 1993 Almanac, p. 171; Uruguay Round approval, 1993 Almanac, p. 171.

Source: CQ Weekly
The definitive source for news about Congress.

CITIZEN TRADE POLICY COMMISSION
DRAFT AGENDA

Friday, April 26, 2013 at 9:30 A.M.
Room 214, Burton M. Cross State Office Building
Augusta, Maine

9:30 AM Meeting called to order

I. Welcome and introductions

II. Update of CTPC contact information

III. PowerPoint presentation on Maine International Trade Center (Wade Merritt, CTPC member)

IV. Review of past Legislative Resolution on "Fast Track Authority" (Lock Kiermaier, Staff)

V. Update on IGPAC/USTR activity (Representative Sharon Treat, CTPC Chair)

VI. Review of Legislative Bills of Interest (Lock Kiermaier, Staff)

VII. Articles of interest (Lock Kiermaier, Staff)

VIII. Proposed next meeting date and suggestions for agenda topics

Adjourn

Citizen Trade Policy Commission

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For Immediate Release: April 23, 2013
Contact: Adrienne Bennett, Communications Director (207) 287-2531

Governor LePage travels to Montreal to encourage economic growth between Maine and Quebec

AUGUSTA – Governor Paul R. LePage signed a memorandum of agreement yesterday with Premier of Quebec Pauline Marois to encourage economic development and support job creation between Maine and Province of Quebec. The Premier invited the Governor to Montreal to sign the agreement, which she described as an important collaboration between Maine and Quebec.

Although Maine and Quebec share a border, as well a common history and culture, this is the first time that the state has entered into such an MOU to strengthen relations with Quebec.

"I was pleased to meet with Premier Marois to discuss how Maine and Quebec can work together to create jobs and cooperate in the areas of energy, natural resources transportation, border security and culture," the Governor said. "And I know she was pleased to converse with me in French, which is my native language, and to talk about our shared French-Canadian heritage."

The MOU encourages Maine and Quebec to coordinate with their business communities to set up partnerships and implement economic development initiatives. The agreement also encourages an exchange of cross-border solutions for clean energy, such as hydropower and bioenergy, which could lower home heating costs for Maine people".

"Le Québec et le Maine partagent non seulement une histoire et un patrimoine, mais également des enjeux et des défis qui présentent des occasions de collaboration importantes. Je me réjouis de la signature de cet accord qui témoigne de notre volonté à travailler ensemble pour assurer le développement de relations qui nous seront mutuellement bénéfiques," said Premier Marois.

A Quebec-Maine Joint Committee will be responsible for implementing the agreement.

In addition to signing the agreement with the Premier, Governor LePage spoke to 150 business leaders at luncheon conference sponsored by The Montreal Council on Foreign Relations. Titled "Maine and Quebec: Opportunities to Stimulate our Economic Relations," the Governor spoke about economic agenda of Maine, strengthening of business relations with Quebec and business opportunities that Maine can offer Quebec.

ATTACHED PHOTOS

LePage CORIM.jpg: Governor Paul R. LePage speaks at The Montreal Council on Foreign Relations

Marois LePage 003.jpg: Governor Paul R. LePage signs an agreement with Premier of Quebec Pauline Marois

JOINT RESOLUTION MEMORIALIZING THE MAINE DELEGATION, THE CONGRESS OF THE UNITED STATES AND THE PRESIDENT TO SAFEGUARD THE STATE'S ROLE IN INTERNATIONAL TRADE AGREEMENTS

WHEREAS, the State of 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, the State of Maine seeks to maximize the benefits and minimize any negative impacts of international trade; and

WHEREAS, existing trade agreements have impacts which 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 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 states on the far-reaching impact of trade agreements on State and local laws, even when binding the State of Maine to the terms of these agreements; and

WHEREAS, existing trade agreements have not done enough to ensure a level playing field for Maine workers and businesses, or to include meaningful human rights, labor, and environmental standards, which hurts Maine businesses, workers, and communities; and

WHEREAS, the negative impact of existing trade agreements on the State's constitutionally guaranteed authority to protect the public health, safety and welfare, and regulatory authority has occurred in part because U.S. trade policy has been formulated and implemented under the Trade Promotion Authority (Fast Track) process; and

WHEREAS, Trade Promotion Authority (Fast Track) eliminates vital checks and balances established in the U.S. Constitution by broadly delegating to the Executive Branch authority reserved for Congress to set the terms of international trade; and

WHEREAS, Trade Promotion Authority (Fast Track) circumvents normal congressional review and amendment committee procedures, limits debate to 20 hours total, forbids any floor amendments to the implementing legislation that is presented to Congress, and generally creates a non-transparent trade policymaking process; and

WHEREAS, Trade Promotion Authority (Fast Track) is not necessary for negotiating trade agreements, as demonstrated by the existence of scores of trade agreements, including major pacts such as the agreements administered by the WTO, implemented without use of Fast Track; and

WHEREAS, the current grant of Trade Promotion Authority (Fast Track) expires in July 2007; now, therefore be it

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
171	An Act To Facilitate the Licensing of International Mail Order Prescription Pharmacies by the Maine Board of Pharmacy	Sen. Troy Jackson	Labor, Commerce, Research, and Econ. Dev	2/19/2013	not yet scheduled	Not reported out	No Fiscal Impact	The purpose of this bill is to facilitate the licensing of international mail order prescription pharmacies by the Maine Board of Pharmacy. See detailed summary on CTPC WORD document	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
449	An Act To Ensure Consumer Choice in the Purchase of Prescription Drugs	Sen. Doug Thomas	Labor, Commerce, Research, and Econ. Dev	3/13/2013	not yet scheduled	Not reported out	Not yet determined	This bill clarifies and affirms the ability of Maine consumers to purchase mail order prescription drugs from licensed pharmacies that are located in certain nations specified under federal law.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
813	An Act To Promote the Sale of Maine Milk	Rep. Joseph Brooks	State & Local Gov	3/27/2013	4/8/2013	Not reported out	Not yet determined	This bill requires a state-owned or state-operated facility that sells or contracts with a person to sell beverages directly to the public, including a facility on the Maine Turnpike, to have available for sale milk processed at a milk plant in the State. This bill exempts facilities in an institutional setting in which sales of beverages to the public are incidental, including a state-owned postsecondary institution or correctional facility.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
1326	An Act To Prevent Youth Tobacco Use	Rep. Megan Rochelo	Taxation	not yet scheduled	not yet scheduled	Not reported out	Not yet determined	This bill requires that all tobacco products be taxed at rates equivalent to the current tax on cigarettes. The bill provides an appropriations and allocations section to fund anticipated increased demand on the tobacco hotline for those people who are seeking to quit tobacco use.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1338	An Act To Prohibit State and Local Governments from Contracting with Corporations That Engage in Business in Known Terrorist States	Rep. Teresea Hayes	State & Local Gov	4/22/2013	not yet scheduled	Not reported out	Not yet determined	This bill requires that, beginning January 1, 2014, the State, the University of Maine System, the Maine Community College System, the Maine Maritime Academy and municipalities exclude any business entity or individual from doing business with the State, the University of Maine System, the Maine Community College System, the Maine Maritime Academy or a municipality if that business entity or individual does business with any company, or any subsidiary, affiliate or parent of any company, that does business with a country designated by federal law as a state sponsor of terrorism. It also requires that counties and school boards adopt policies by January 1, 2014 that require counties and school boards to exclude any business entity or individual from doing business with a county or school board if that business entity or individual does business with any company, or any subsidiary, affiliate or parent of any company, that does business with a country designated as a state sponsor of terrorism.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1381	An Act To Promote Rural Job Creation and Workforce Development	Sen. Troy Jackson	Labor, Commerce, Research, and Econ. Dev	4/22/2013	not yet scheduled	Not reported out	Not yet determined	This bill gives a preference in state contracting to bidders who primarily employ residents of the State and to bidders who coordinate with regional workforce development programs and who fill at least 20% of positions on the project with low-income or long-term unemployed people. The bill requires that successful bidders on public building or public works contracts with the State, counties, cities and towns and every charitable or educational institution that is supported in whole or in part by aid granted by the State or by a municipality commit to coordinate with regional workforce development programs and make best efforts to hire low-income and long-term unemployed people. The bill also requires state public works programs to give hiring preference to residents of the county where the work is being performed.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1254	An Act To Increase Consumption of Maine Foods in All State Institutions	Rep. Craig Hickman	State & Local Gov	4/22/2013	not yet scheduled	Not reported out	Not yet determined	Current law requires state and school purchasers to buy meat, fish, dairy products, excluding milk and eggs, and species of fruits and fresh vegetables directly from Maine food producers or from food brokers. This bill establishes a minimum percentage of Maine foodstuffs that must be purchased, requiring at least 15% for the 10 years beginning January 1, 2014, at least 25% for the next 10 years and at least 35% beginning in 2034.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
1103	An Act To Encourage Development in the Logging Industry	Sen. Troy Jackson	State & Local Gov	4/8/2013	4/12/2013	Not reported out	Not yet determined	This bill would withhold a tax incentive, eliminate General Fund money for forest fire protection, and would proscribe a tax penalty for individuals who, either directly or through a contracting entity, hire foreign H-2A visa workers for timber harvesting operations or fail to give required notice concerning their use of H-2A foreign workers for timber harvesting on their land.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1151	An Act Regarding the Administration and Financial Transparency of the Citizen Trade Policy Commission	Rep. Joyce Maker	Labor, Commerce, Research, and Econ. Dev	4/8/2013	4/12/2013	OTP as Amd	Appropriations to a new Citizen Trade Policy Commission program in the Legislature and offsetting deappropriations	This bill modifies the law governing the Citizen Trade Policy Commission to provide that: 1. To the extent funding permits, the Legislature, through the commission, must contract for year-round staff support for the commission. To the extent the commission lacks adequate staff support, the commission may request staff support from the Legislative Council, except that Legislative Council staff support is not authorized when the Legislature is in regular or special session; and 2. All funds appropriated, allocated or otherwise provided to the commission must be separately accounted for and used solely for the purposes of the commission and are nonlapsing. At the beginning of each fiscal year, and at any other time at the request of the cochairs of the commission, the Executive Director of the Legislative Council must provide to the commission an accounting of all funds available to the commission, including funds for staff support. The bill is designated an emergency to ensure that the limited funding available to the commission does not lapse at the end of the current fiscal year.	

Article notes: 4/26/13 CTPC agenda

TPPA/Japan Articles

Japan's Possible Entry Into the Trans-Pacific Partnership and Its Implications

- The TPPA is the Obama administration's most significant trade policy initiative and represents a an effort to "rebalance" the US relationship with its Asia-pacific trading partners;
- Japan has the second largest economy in Asia and the third largest economy in the world so inclusion of Japan is crucial to a meaningful and comprehensive TPPA ;
- Inclusion of Japan into the TPPA will represent a de facto free trade agreement between the U.S. and Japan and has the potential to reinvigorate the economic relationship between the two countries. On the downside, failure to include Japan in a meaningful TPPA could result in a failure to establish a more open free trade and prosperous economic relationship between the two countries.

Japan wins spot in mega trade pact

- Japan has been accepted into the proposed 11 nation trade pact referred to as the Trans-pacific Partnership Agreement (TPPA);
- Canada had been the sole remaining nation opposed to Japan's inclusion in the TPPA;
- The U.S. had formally agreed to Japan's inclusion earlier in April;
- As a condition of inclusion in the TPPA, Japan agreed that "US tariffs on its cars would be phased out at the latest time allowed by a future accord".

TPPA Articles

Baucus Sees Trans-Pacific Partnership Agreement as Major Spark to U.S. Economy

- Senator Max Baucus, Chair of the Senate Finance Committee, has endorsed the proposed TPPA by stating that "The TPP presents tremendous opportunities to expand U.S. exports and support hundreds of thousands of good-paying jobs here in America. The Asia-Pacific economies are some of the fastest growing in the world, and Asia is importing more and more goods from around the world. The United States needs to share in that growth, and the TPP offers the way to do so,";
- Senator Baucus also endorsed a "fast track approach" by which Congress could approve the TPPA.

Safeguards for Tobacco Control: Options for the TPPA

- As a useful follow-up to his 2013 Assessment for the CTPC, Dr. Robert Stumberg has prepared an article on the latest implications of how tobacco may be treated in the TPPA;
- The tobacco industry continues to use international trade agreements like the TPPA to "chill, divert or delay" national tobacco-control policies. Specifically, the tobacco industry makes use of the following strategies:
    - The expansion of investor-state arbitration process to circumvent local regulation through the Investment Chapters of agreements like the TPPA;
    - The Intellectual Property Chapter is used to expand on the ability to use a Trade name that indicates a location for a particular product;
    - The Cross Border Services Chapter expands service sectors to which trade rules apply thereby providing another opportunity for tobacco companies to circumvent local regulation;

    - The Regulatory Coherence Chapter promotes tobacco industry representation in the stakeholder process enabling the industry to have more control over regulatory impact assessments;
    - The Technical Barriers to Trade Chapter has the potential to limit how governments can cooperate with each other with regards to tobacco control measures; and
    - The use of Tariff Schedules for tobacco control measures is undermined by increased market access by the tobacco industry.
- Dr. Stumberg also states that the proposed USTR "carve out' for tobacco in the TPPA is still under consideration. This carve-out provides for a limited regulation of tobacco products.

With TPP Tobacco Proposal On Hold, Stakeholders Eye Impact On EU FTA

- The fate of the USTR "carve out" proposal for the treatment of tobacco in the TPPA will have a significant bearing on how tobacco is treated in the upcoming EU FTA negotiations;
- The lack of current action by the USTR to "table" the carve out provision for the TPPA has led to a certain amount of uncertainty about how tobacco will ultimately be treated in either agreement;
- The U.S. is likely to have a greater ability to influence the possible inclusion of a tobacco carve out provision in the TPPA then in the EU FTA agreement where the European Union members are perceived as having a more equal ability to influence events.

USTR Still Mulling Two Possible Approaches For Next TPA Bill

- The USTR is still considering what legislative approach to take with Congress regarding approval on international trade treaties like the TPPA;
- The two options under consideration both involve renewal of Trade Promotion Authority (TPA); the first involves a TPA timeline approach which establishes a timeframe for congressional oversight and the second approach tethers TPA to a particular treaty such as the TPPA.

U.S. struggles with pharmaceutical goals in Asia trade talks

- The USTR is striving for a balance in the manner in which pharmaceuticals are handled in the TPPA ;
- One goal is to ensure strong patent and data protections for US drug manufacturers and the other competing goal is to ensure that developing countries have affordable access to medicine;

Miscellaneous Articles

Free trade versus food democracy

- Recent trends in worldwide agriculture places a new emphasis on healthier, locally grown produce with fewer pesticides;
- This trend towards local agricultural sustainability necessarily involves a series of local decisions which should be reflected in national trade policy;
- However, as reflected in the recent actions of the USTR, U.S. trade policy seems to ignore these trends, opting instead for a position which opposes "localization barriers to trade" and favors the removal of trade barriers which impede the free flow of goods and services;
- The USTR opposition to the realities of sustainable local (re:national) agriculture in favor of free flowing international agricultural trade fits in with the market demands of large international food corporations but contradicts the recent success of nations that have built domestic agricultural production;
- Proposed free trade provisions within the TPPA not only work against the agricultural success of small nation states but also work against the local interests of U.S. dairy farmers that worry about the free trade impact of dairy imports from countries like New Zealand.

India Takes Aim at U.S. State, Local Incentives for Renewable Energy Sector

- India has formally challenged a number of state and local renewable energy sector incentive programs by maintaining that these programs may be in violation of global trade rules;
- The formal objection lodged by India with the WTO, challenges these programs on the basis of incentives that are contingent upon the use of of "domestic or state specific products";
- In particular, India's allegations are based on the provisions of Article III:4 of GATT which states that WTO members must treat imported goods the same as domestic goods with respect to all applicable federal, state and local regulations;
- The five programs challenged by India are offered in Michigan, California (2) and Texas (2);
- The U.S. has also filed a formal complaint against India for its requirement that alternative energy equipment manufactured in India must contain certain technical components manufactured in India.

Tar sands oil pipeline bill advances in Vermont Senate, in spite of warning from petroleum industry

- The Vermont Legislature is considering a bill which would increase the regulatory oversight of the expanded use of an existing oil pipeline running from Vermont to Maine to allow for the transmission of heavier tar sands oil;
- Among the several objections to this proposed legislation is the contention that such regulation would impose an "unconstitutional barrier" on foreign and interstate commerce.

Testing the Right to Frack

- Canada's ability to initiate legislation to regulate the practice of "fracking" is being challenged by international corporations from the US and China under the provisions of international trade treaties like NAFTA;
- The article suggests that treaties like NAFTA "actually give foreign firms more rights and legal protections than local companies";
- International companies can use the arbitration process provided by NAFTA to bypass local, provincial and federal regulations.

Japan's Possible Entry Into the Trans-Pacific Partnership and Its Implications

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Summary

On March 15, 2013, Prime Minister Abe announced that Japan would formally seek to participate in the negotiations to establish the Trans-Pacific Partnership (TPP). In taking this step, Prime Minister Abe has had to confront influential domestic interests that argued against the move. Among the most vocal have been Japanese farmers, especially rice farmers, and their representatives. In his March 15 statement, Prime Minister Abe acknowledged these domestic sensitivities, but also insisted that Japan needed to take advantage of "this last window of opportunity" to enter the negotiations, if it is to grow economically. Other Japanese business interests, including manufacturers, strongly support the TPP.

The TPP would be a free trade agreement (FTA) among at least the current 11 participants—Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. The United States and its TPP partners envision the agreement as "a comprehensive, next-generation regional agreement that liberalizes trade and investment and addresses new and traditional trade issues and 21st century challenges."

The 11 countries must still reach a consensus, if Japan is allowed to join the negotiations. As part of the process, Japan has been discussing conditions for its entry into the negotiations with each of the 11 countries. It has completed discussions with six countries, while continuing discussions with the United States, Australia, Canada Mexico, and New Zealand. The United States has identified issues regarding autos, insurance, and beef that need to be addressed.

Congress has a direct and oversight role in the issue of U.S. participation in the TPP. It must approve implementing legislation, if the TPP is to apply to the United States. Some Members of Congress have already weighed in on whether Japan should be allowed to participate in the TPP and under what conditions. More may do so as the process proceeds.

The TPP is the leading U.S. trade policy initiative of the Obama Administration and a core component of Administration efforts to "rebalance" U.S. foreign policy priorities toward the Asia-Pacific region by playing a more active role in shaping the region's rules and norms. As the second largest economy in Asia, the third largest economy in the world, and a key link in global supply/production chains, Japan's participation would be pivotal to enhancing the credibility and viability of the TPP as a regional free trade arrangement.

Japan's membership in the TPP with the United States would constitute a *de facto* U.S.-Japan FTA. A large segment of the U.S. business community has expressed support for Japanese participation in the TPP, if Japan can resolve long-standing issues on access to its markets for U.S. goods and services. However, the Detroit-based U.S. auto industry and the UAW union have expressed strong opposition to Japan participating in the TPP negotiations.

The TPP issue presents both risks and opportunities for the United States and Japan. On the one hand, if successful, it could reinvigorate an economic relationship that has remained steady but stagnant, by forcing the two countries to address long-standing, difficult issues, and allowing them to raise their relationship to a higher level. On the other hand, failure to do so could indicate that the underlying problems are too fundamental to overcome and could set back the relationship. It could signify the failure of the United States and/or Japan to deal with domestic opposition to a more open trade relationship.

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Introduction

The United States is engaged in negotiations with 10 other countries to form a regional free trade agreement (FTA)—the Trans-Pacific Partnership Agreement (TPP).[1] In the negotiations, the United States and the other TPP partner-countries seek to build "a comprehensive, next-generation regional agreement that liberalizes trade and investment and addresses new and traditional trade issues and 21st century challenges."[2] The TPP partners also envision the agreement to be a building block towards the establishment of a broader, Asian-Pacific regional FTA, sometimes referred to as the Free Trade Area of the Asia- Pacific (FTAAP).

On March 15, 2013, Japanese Prime Minister Shinzo Abe announced on March 15, 2013, that Japan would formally seek to participate in the negotiations to establish the TPP. The announcement followed an initial expression of interest in November 2011 by then-Prime Minister Noda. In the intervening months, Japanese supporters of the TPP, including representatives of major companies, and TPP opponents, including representatives of the very vocal and politically influential agricultural sector engaged in debate. In addition, lower house parliamentary elections led to the formation of a new government under the Liberal Democratic Party (LDP) and Abe as prime minister. In his March 15 statement, Prime Minister Abe acknowledged the interests and sensitivities of the agricultural groups, but he also insisted that Japan needed to take advantage of "this last window of opportunity" to enter the negotiations, if it is to grow economically.

U.S. and Japanese trade officials are engaged in preliminary discussions on conditions for Japanese entry into the discussions. The Obama Administration has identified issues regarding autos, insurance, and beef, which need to be addressed.

Congress has a direct and oversight role in U.S. participation in the TPP. It must approve implementing legislation, if a final TPP agreement is to apply to the United States. Some Members of Congress have already weighed in on whether Japan should be allowed to participate in the TPP and under what conditions. More may do so as the process proceeds.

The Obama Administration has been proceeding in negotiating the TPP as if trade promotion authority (TPA), which expired on June 30, 2007, were in force. TPA is the authority that Congress gives to the President to enter into trade agreements that can receive expedited legislative consideration. The Administration has been adhering to consultation requirements and notification deadlines that have been an integral part of previous TPA or fast-track statutes. To maintain this practice, the Obama Administration would have to notify both Houses of Congress 90 calendar days before it begins official negotiations (as opposed to preliminary discussions) with Japan on the TPP.

The TPP is the leading U.S. trade policy initiative of the Obama Administration and a pillar of its efforts to "rebalance" U.S. foreign policy priorities toward the Asia-Pacific region by playing a more active role in shaping the region's rules and norms. As the second largest economy in Asia,

[1] The eight countries are: Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam. The governments of Mexico and Canada also expressed interest and, after a series of consultations, were formally invited to join by the nine TPP partners on June 18 and June 19, 2012, respectively. They will join the negotiations officially in the fall of 2012.

[2] Trans-Pacific Partnership Leaders Statement, November 11, 2011.

the third largest economy in the world, and a key link in the global supply chain, Japan's participation would be pivotal to the credibility and viability of the TPP as a regional trade arrangement. The inclusion of Japan would expand the amount of U.S. trade and foreign investment that the TPP would cover if implemented.

For Japan, participation in the TPP could potentially transform its economy by providing unprecedented access to the Japanese market for foreign exporters and investors. It could also force Tokyo to confront structural economic problems that have long impeded economic growth. It would also symbolize Japan's continued position as an economic power in East Asia, an image that has been tarnished by decades of economic stagnation and the growth of China.

Japan's participation in the TPP would have important implications for the U.S.-Japan relationship. For example, it already has renewed a focus on long-standing issues, such as access to Japan's markets for autos, agricultural products, and insurance, which have remained irritants in the relationship. These issues will likely have to be addressed in one form or another, perhaps even before Japan is approved as a full-fledged TPP participant. New issues will undoubtedly also be raised in the process.

An Overview of the TPP

The TPP is an evolving regional free trade agreement (FTA). It was originally formed as the Trans-Pacific Strategic Economic Partnership—an FTA now in effect among Singapore, New Zealand, Chile, and Brunei (the so-called "P-4"). In the fall of 2008, the United States, along with Australia, Peru, and Vietnam, joined the negotiations to accede to the arrangement. Malaysia joined as the ninth negotiating partner in October 2010.

On November 14, 2009, President Obama committed the United States to engage with the TPP countries to transform the original P-4 pact into a regional arrangement with broad-based membership and "the high standards worthy of a 21st century trade agreement."[3] After several months of discussions, the nine partners announced a framework for the agreement in time for the ministerial meeting of the Asia-Pacific Economic Cooperation (APEC) forum in Honolulu, Hawaii, which was held November 8-13, 2011. The TPP partners conducted a series of rounds since that time and are aiming to complete the agreement by the end of 2013.

As reflected in the framework, the TPP partners envision a comprehensive arrangement covering a broad range of trade and trade-related activities, similar in structure to a number of recently concluded U.S. FTAs. These activities include market access for goods and services; government procurement; foreign investment; technical barriers to trade; trade remedies; sanitary and phytosanitary measures;[4] intellectual property rights; worker rights; and environmental protection. The TPP countries also agreed to pursue cross-cutting issues such as regulatory coherence, competitiveness and business facilitation, also known as transnational supply and production chains; the participation of small and medium-sized companies; economic development; and potential disciplines on the state-owned enterprises (SOEs).

[3] Remarks of President Obama at Suntory Hall, Tokyo, Japan, November 14, 2009.

[4] Sanitary and Phytosanitary measures are procedures used by government agencies to ensure the animal and plant products are safe for consumption.

The TPP participants also envision the TPP to go beyond typical FTAs by being:

- a regional agreement that facilitates trade by minimizing the "noodle bowl" effect that has been created by different sets of rules under the more than 100 bilateral and regional FTAs that exist in the Asia Pacific-region;
- an agreement that addresses trade challenges that are emerging in the 21st century, for example, cloud computing and SOEs, that have not been addressed in previous FTAs nor not fully in the World Trade Organization (WTO) because they did not exist or were considered not as important; and
- a "living agreement" that will not restrict its membership to the 11 countries but will be open to other countries acceding to it as long as they are willing to commit to its provisions and will take on new issues as they arise.

The leaders of the nine TPP countries instructed their negotiators to develop a completed legal text as soon as possible. The complexity of the issues at hand, the diversity of the membership, and the possibility of new members, such as, Japan, and newly invited Canada and Mexico, suggest challenges ahead for the negotiators.

U.S.-Japan Economic Ties

A brief overview of U.S.-Japan economic ties can provide context for understanding U.S. and Japanese interests in the TPP and the potential implications from various perspectives. It could also shed light on opportunities and challenges presented by an FTA that includes the United States and Japan. A U.S.-Japan FTA is not a new idea, but it is a policy option that has failed to take hold in the past because of some fundamental issues which have been seemingly intractable.

U.S.-Japan Trade Trends

The United States and Japan are the world's first and third largest economic powers. Together they account for over 30% of gross world product.[5] The two countries remain very important economic partners, accounting for large shares of each other's foreign trade and investment, even though their relative economic significance to one another has declined over the last few years. In 1999, Japan slipped from being the second largest U.S. trading partner to the third largest. In 2004, it slipped to number 4, where it has remained. Until 2007, the United States was Japan's largest trading partner, but it slipped to number 2 since 2007.[6]

The global financial crisis and economic downturn added another dimension to the relationship as the two countries have grappled with the severe impact of the crisis on their respective economies, while working with their partners in the G-20 to coordinate a multilateral response.[7] The impact of the March 11, 2011 earthquake and subsequent tsunami and nuclear accidents in northeast Japan also affected trade, although not as much as originally anticipated.

[5] CRS calculation based on data in CIA, *World Factbook*, http://www.CIA.gov.

[6] Global Trade Atlas.

[7] The G-20 countries are: Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, the United Kingdom, the United States, and the European Union.

U.S.-Japanese bilateral trade in goods and services declined significantly in 2009 over 2008 levels because of the global economic downturn but has picked up since. (See **Table 1** and **Table 2**.)

Table 1. U.S.-Japan Merchandise Trade, 2004-2012

($ billions)

Year	U.S. Exports	U.S. Imports	Total Trade	U.S. Trade Balances
2004	54.4	129.6	184.0	-75.2
2005	55.4	138.1	193.5	-82.7
2006	59.6	148.2	207.8	-88.6
2007	62.7	145.5	208.2	-82.8
2008	66.6	139.2	205.8	-72.3
2009	51.2	95.9	147.1	-44.8
2010	60.5	120.3	180.8	-59.8
2011	66.2	128.8	195.0	-62.2
2012	70.0	146.4	216.4	-76.3

Source: U.S. Department of Commerce, U.S. Census Bureau.

Table 2. U.S.-Japan Trade in Services, 2004-2012

($ billions)

Year	U.S. Exports	U.S. Imports	Total Trade	U.S. Trade Balances
2004	36.0	21.3	57.3	14.8
2005	42.5	23.8	66.3	18.7
2006	42.0	25.5	67.5	16.5
2007	41.2	26.2	67.4	15.0
2008	42.3	25.7	68.0	16.6
2009	41.4	22.9	64.3	18.5
2010	45.1	25.9	71.0	19.2
2011	44.9	27.5	72.4	17.4
2012*	47.1	29.4	76.5	17.7

Source: U.S. Department of Commerce, Bureau of Economic Analysis.

Note: * Preliminary.

Raw trade data likely underestimate Japan's importance because they do not readily measure Japan's role in the East Asian supply and production networks that produce goods exported to the United States. The two countries are also economically tied through investment flows. For example, Japanese investors are the second largest group (next to China) of foreign holders of U.S. treasury securities and, therefore, U.S. government debt and of direct investments in the U.S. economy.

In the 1980s and 1990s, the bilateral economic relationship was the centerpiece of U.S. and Japanese foreign economic agendas. Persistent and increasing U.S. merchandise trade deficits with Japan, sharp increases in Japanese exports to the United States of high-value manufactured products, such as cars, and large volumes of Japanese investments in the United States (including purchases of high-profile properties, such as the Empire State Building) stoked fears in the United States of Japan as an economic threat to the United States. Many scholarly and popular books and journal articles were written on the subject.[8]

However, since the mid-1990s, the trade relationship with Japan has been a lower priority for U.S. officials. One reason for the shift may be the rise of China as a global trade and economic power, and source of challenges and opportunities to U.S. trade policymakers. Symbolic of this rise are the relative merchandise trade balances with Japan and China. While U.S. merchandise trade deficits with Japan have remained relatively constant in recent years, the U.S. deficits with China have risen significantly. In 2012, the U.S. trade deficit with Japan was $76.3 billion, while the trade deficit with China was $315.1 billion.[9]

Another reason may have been that Japan's economic problems over the last two decades have made it seem less of a competitive "threat."[10] In addition, the level of Japanese foreign direct investments in the United States has declined. Furthermore, security issues, such as North Korea's nuclear program (the United States and Japan are parties to talks on North Korea's fledgling nuclear program) and the relocation of U.S. troops in Japan, have overshadowed bilateral trade relations as a priority.[11] Nevertheless, trade-related tensions remained, albeit below the surface.

Managing the Trade Relationship

Over the years, U.S.-Japan economic relations have experienced degrees of friction, sometimes to the point of threatening the stability of the alliance. The United States dominated the economic relationship with Japan for many years after World War II. The United States was by far the largest economy in the world, and Japan was dependent on the United States for national security. The United States set the agenda, and the issues on the agenda were driven by the U.S. demands for Japan to curb exports to the United States and/or to remove barriers to U.S. exports and investments.

In the 1960s and 1970s, the primary issues were Japan's perceived protectionist economic policies that it implemented through high tariffs and other border restrictions. As Japan's economy became more developed and competitive and as it negotiated reductions in its tariffs with other members of the General Agreement on Tariffs and Trade (GATT)—now the World Trade Organization (WTO)—the United States focused on non-tariff barriers, including "behind the border" measures, such as government regulations that, while not ostensibly protectionist, may be applied in a way that restricts trade. Certain measures are not covered by WTO

[8] For example, Clyde V. Prestowitz, *Trading Places: How We Allowed Japan to Take the Lead*, New York: Basic Books, 1988.

[9] For more information on the rise of China in U.S. economic relations, see CRS Report RL33536, *China-U.S. Trade Issues*, by Wayne M. Morrison.

[10] For more information on Japan's economic problems, see archived CRS Report RL30176, *Japan's "Economic Miracle": What Happened?*, by William H. Cooper.

[11] For more information on the overall U.S.-Japan relationship, see CRS Report RL33436, *Japan-U.S. Relations: Issues for Congress*, coordinated by Emma Chanlett-Avery.

agreements and are currently not readily addressed in trade negotiations since they serve non-trade functions. Examples of such measures include

- domestic taxes on car purchases and other regulations said to discriminate against sales of imported vehicles;
- a government contract bidding system that favors certain domestic providers of construction services;
- zoning regulations that discourage the establishment of large retail stores that are more likely to sell imported products than the smaller stores the regulations are designed to protect;
- government health insurance reimbursement regulations that discourage the purchase of newer, leading-edge pharmaceuticals and medical devices, many of which are imported; and
- government subsidies for the production of semiconductors.

To address these non-tariff barriers Japan and the United States employed, largely at the latter's instigation, special bilateral frameworks and agreements to conduct their government-to-government economic relations. These arrangements included

- the Market-Oriented Sector-Specific (MOSS) talks started in 1985;
- the Structural Impediments Initiative (SII), begun in March 1989;
- the United States-Japan Framework for a New Economic Partnership, begun in 1993;
- the Enhanced Initiative on Deregulation and Competition Policy (the Enhanced Initiative), begun in 1997;
- the U.S.-Japan Economic Partnership for Growth (The Economic Partnership) begun in 2001; and
- the United States-Japan Economic Harmonization Initiative, launched in 2010, which now operates as the primary bilateral forum for bilateral discussions.

The two countries also concluded bilateral agreements or memoranda of understanding (MOUs), whereby Japan agreed to address U.S. concerns about its trading practices for specific products, including autos and semiconductors.

These arrangements varied in their approaches. However, they shared some basic characteristics: they were bilateral; were designed to remedy U.S. - Japan trade problems by focusing on regulations and other fundamental barriers; and were typically initiated by the United States. However, these arrangements were only of limited success, judging by the fact that many of the issues they were supposed to address remain.

Pending Challenges and the TPP

Many of that issues that have continually irritated the U.S.-Japan economic relationship could be addressed within the TPP. U.S. policymakers and other stakeholders have identified three issues that, if resolved, would be considered "confidence-building measures" that could boost U.S.

support of Japan's inclusion in the TPP. The issues relate to: Japanese restrictions on imports of U.S. beef; market access in Japan for cars made by Detroit-based U.S. manufacturers; and preferential treatment for insurance and express delivery subsidiaries of state-owned Japan Post.[12]

Market Access for U.S. Beef

In December 2003 when Japan imposed a ban on imported U.S. beef (as did some other countries) in response to the discovery of the first U.S. case of bovine spongiform encephalopathy (BSE or "mad cow disease") in Washington State. In the months before the diagnosis in the United States, nearly a dozen Japanese cows infected with BSE had been discovered, creating a scandal over the Agricultural Ministry's handling of the issue (several more Japanese BSE cases have since emerged). Japan had retained the ban despite ongoing negotiations and public pressure from Bush Administration officials, a reported framework agreement (issued jointly by both governments) in October 2004 to end it, and periodic assurances afterward by Japanese officials to their U.S. counterparts that it would be lifted soon.

In December 2005, Japan lifted the ban after many months of bilateral negotiations, but reimposed it in January 2006 after Japanese government inspectors found bone material among the initial beef shipments. The presence of the bone material violated the procedures U.S. and Japanese officials had agreed upon. The then-U.S. Secretary of Agriculture Johanns expressed regret that the prohibited material had entered the shipments.

In July 2006, Japan announced it would resume imports of U.S. beef from cattle 20 months old or younger. The first shipments arrived in August 2006. Members of Congress had pressed Japan to lift restrictions on imports of U.S. beef from even older cattle. U.S. officials met with Japanese agricultural officials September 14-15, 2010, for technical discussions but produced no clear indication of resolution of the issue. On August 4, 2011, a bipartisan group of Senators sent a letter to Secretary of Agriculture Vilsack and to USTR Ron Kirk, urging them to press Japan (and China) to end restrictions on imports of U.S. beef. In December 2011 Japan announced that it was reassessing its BSE-related restrictions with the objective to raise the maximum age of cattle from which U.S. beef can be exported to Japan.

On February 1, 2013, the Japanese government loosened its restrictions on beef imports from the United States to allow beef from cattle 30 months or younger for the first time since December 2003. According to a joint press release from the Office of the United States Trade Representative and the Department of Agriculture, the Japanese government's Food Safety Commission would continue to monitor shipments of U.S. beef and would consider the possibility of allowing U.S. beef from cattle of any age to be imported into Japan.

Market Access for U.S.-Made Autos

Auto and auto-parts-related trade and investment have been a very sensitive set of issues in the U.S.-Japan economic relationship. The issue has its roots in the late 1970s and early 1980s, when U.S. imports of Japanese-made vehicles surged as a result of the increase in U.S. consumer

[12] Office of the USTR, *U.S., Japan Hold High-Level Discussions on the Trans-Pacific Partnership,* http://www.ustr.gov/about-us/press-office/press-releases/2012/february/us-japan-hold-high-level-consultation-trans-pacif.

demand for smaller vehicles, largely in response to the rapid increase in gasoline prices, while demand for U.S.–manufactured cars plummeted. Facing pressure from the U.S. auto industry and pressure from Congress in the form of limits on imports of Japanese made cars, the Reagan Administration persuaded Japan to agree in 1981 to voluntary export restraints. Japanese manufacturers responded to the restraints by establishing manufacturing facilities in the United States and exporting high-valued, passenger cars. U.S. manufacturers asserted that Japan employed various measures to restrict sales of foreign-made cars in Japan and the use of U.S.-made parts in Japanese cars manufactured in the United States. These issues were the subject of bilateral negotiations and agreements through the 1990s. The agreements were mostly in the form of Japanese government pledges to ensure that government regulations did not impede the sale of U.S.-made cars in Japan and voluntary efforts on the part of Japanese manufacturers to increase the use of U.S.-made auto parts in cars made in the United States. The U.S. government pledged to implement programs to promote the export of U.S.-made cars in Japan.

The intensity of the issue had subsided somewhat but has regained attention in the context of Japan's possible participation in the TPP negotiations. (See TPP discussion below.) The three Detroit-based car manufacturers—Chrysler, Ford, and General Motors—charge that Japanese government regulations continue to prevent them from obtaining their fair share of Japanese domestic vehicle sales. They cite the traditionally small share of total cars sales in Japan that consist of imported cars—around 7.4%. U.S. manufacturers account for a small share of sales of imported cars in in Japan—2.1% in 2011. [13]

Insurance, Express Delivery, and Japan Post

Japan is the world's second largest insurance market, next to the United States. U.S.-based insurance providers have found it difficult to enter the market, especially in life and annuity insurance. They have been concerned about favorable regulatory treatment that the government gives to the insurance subsidiary Japan Post Insurance of Japan Post, the national postal system, which holds a large share of the Japanese domestic insurance market. Japan Post subsidizes the insurance operations from revenues from its other operations. Also, Japan Post Insurance is not subject to the same regulations as other, privately owned insurance providers, both domestic and foreign-owned. Similarly, U.S. express delivery providers have charged that Japan Post's express delivery company obtains subsides from the government-owned parent agency that gives it an unfair competitive advantage.

On October 1, 2007, the Japanese government of then-Prime Minister Junichiro Koizumi introduced reforms to privatize Japan Post and a major objective of his administration. The Bush Administration and many U.S. companies, particularly insurance companies, supported these reforms. However, successor governments led by the Democratic Party of Japan (DPJ) have taken steps to roll back the reforms. On March 12, 2012, the government introduced, and on April 27, 2012, Japan's legislature passed, a bill into law to loosen regulatory requirements. According to industry reports and other commentaries, the bill reverses the reforms that the Koizumi government introduced.[14]

[13] Japan Automobile Manufacturers Association, http://www.jama.org/pdf/MVS2011.pdf.

[14] Coalition of Service Industries, *Proposed Japanese Legislation Complicates Entry in to the TPP,* press release, April 6, 2012. Also, Parker, David A. and Matthew P. Goodman, *Japan Post Reform: Return to Sender*, commentary from Center for Strategic and International Studies, May 30, 2012.

Among other things, the United States wants the Japanese government to refrain from allowing Japan Post to expand its coverage of services until a "level playing field" for competition between its services and those offered by privately owned providers. In addition, the U.S. government wants enhanced transparency in the development and implementation of regulations pertaining to Japan Post-provided services. The U.S. government and U.S.-based providers have had similar concerns about insurance services sold by cooperatives (kyosai) that are not subject to the same regulatory authorities as private insurers and have argued give them an unfair advantage over U.S. and other privately owned and operated companies.[15]

Overall U.S. Objectives

Japan's possible entry into the TPP touches on a range of U.S. trade and foreign policy objectives. Acting USTR Demetrios Marantis greeted positively Prime Minister Abe's March 15, 2013 statement but stipulated:

> Since early last year, the United States has been engaged with Japan in bilateral TPP consultations on issues of concern with respect to the automotive and insurance sectors and other non-tariff measures, and also conducting work regarding meeting TPP's high standards. While we continue to make progress in these consultations, important work remains to be done. We look forward to continuing these consultations with Japan as the 11 TPP countries consider Japan's candidacy for this vital initiative in the Asia-Pacific region.[16]

The United States is also working with Japan on "gap issues," to make sure that Japan would be prepared to take steps to meet goals of the TPP in areas that Japan has not addressed in its previous FTAs.[17]

Market Access

Japan's entry into TPP negotiations could likely expand U.S. trade and investment opportunities in Japan. The target for the United States would be to get Japan to liberalize non-tariff measures, such as certain government regulations, which have been a more significant irritant than tariffs in U.S.-Japan trade relations. The TPP, as envisioned and being negotiated by the current set of 11countries, would cover at least some of these non-tariff measures that Japan maintains. If Japan enters the TPP negotiations, the United States and Japan would have a framework within which to address these long-standing market access issues.

Rules-based Trade Framework and Impartial Dispute Settlement

One drawback of bilateral frameworks that the United States and Japan have used in the past is that they have had no formal dispute settlement mechanism. For example, a number of trade

[15] United States Trade Representative, *National Trade Estimates Report on Foreign Trade Barrier, 2013.*

[16] United States Trade Representative, *Statement by Acting U.S. Trade Representative Demetrios Marantis on Japan's Announcement Regarding the Trans-Pacific Partnership,* March 15, 2013.

[17] *World Trade Online,* March 21, 2013.

disputes in the 1980s and 1990s—including on market access for U.S.-made autos and autoparts in Japan, Japanese trade practices in semiconductors, and access to Japanese markets for construction services—became highly politicized with threats of U.S. unilateral action, potentially undermining the overall relationship. Disputes usually were resolved through brinkmanship but often did not produce meaningful changes in Japan's trade practices or a significant increase of U.S. exports of the products in question. The TPP would provide a set of mutually agreed-upon rules that go beyond the WTO but would likely use an impartial, multi-party dispute settlement mechanism like that used in the WTO that would reduce the role of one-on-one confrontations in resolving issues.

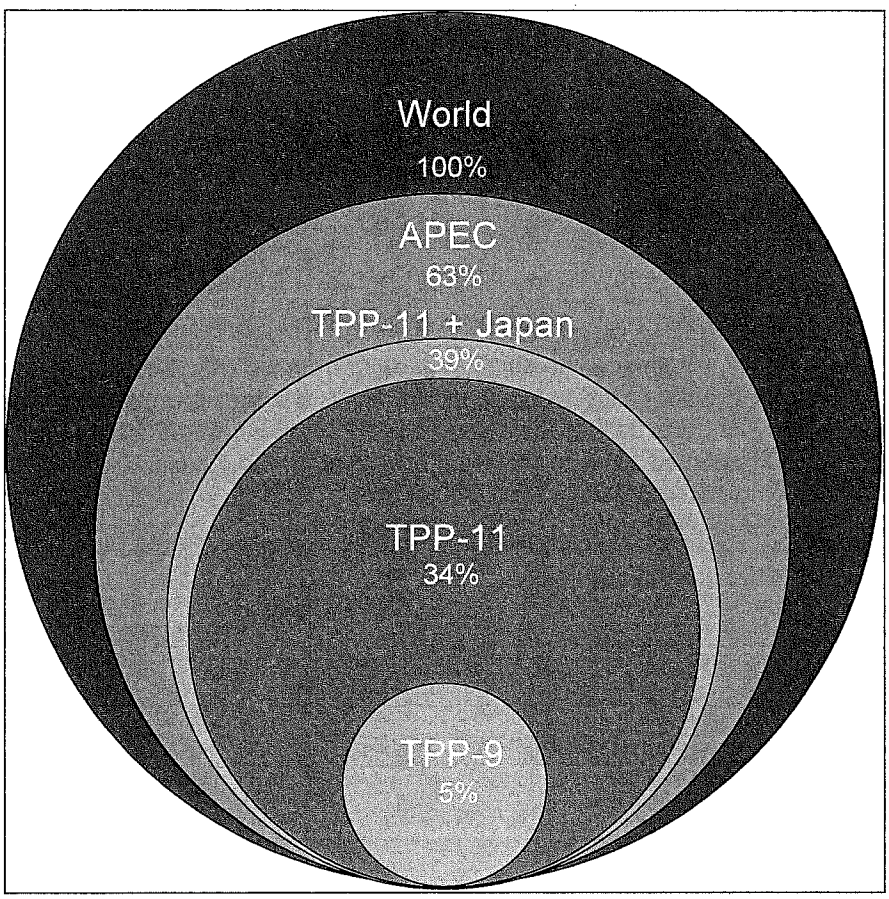
Enhanced TPP

Japan would increase the economic importance of the TPP from the U.S. perspective. It would increase the amount of U.S merchandise trade that the TPP (the original 9 countries plus Canada and Mexico) would cover, from 34% to 39% based on 2011 data and would also increase trade in services and foreign investment activity within the TPP. (See **Figure 1**.) Japan would increase the share of the world economy accounted for by TPP countries (including Canada and Mexico), from around about 30% to about 38%.[18]

[18] CRS calculations based on data in nominal dollars contained in the CIA *World Factbook* at http://www.cia.gov and in CRS Report R42344, *Trans-Pacific Partnership (TPP) Countries: Comparative Trade and Economic Analysis*, by Brock R. Williams.

Figure 1. U.S. Merchandise Trade with Various Countries and Trading Blocs

(shares of total, 2011)



Source: Analysis by CRS. See CRS Report R42344, *Trans-Pacific Partnership (TPP) Countries: Comparative Trade and Economic Analysis*, by Brock R. Williams, Data from U.S. ITC.

Japan's participation might strengthen the U.S. position on many issues within the TPP. The United States and Japan share some common objectives, including strong intellectual property rights protection; protection of foreign investment; clear rules of origin to facilitate trade; and market access for services.

Foreign Policy Interests

In addition to trade and investment interests, Japan's participation in the TPP could affect U.S. political and foreign policy interests. The U.S. entry into the TPP negotiations is part of the Obama Administration's foreign policy and military "rebalancing" to the Asia-Pacific—often referred to as the "pivot" to the Pacific—announced in 2011.[19] The pivot refers to a series of diplomatic, military, and economic measures that the United States has taken or plans to initiate to influence the evolving rules and norms of the Asia-Pacific region. Many policymakers and

[19] For more analysis of the "pivot," see CRS Report R42448, *Pivot to the Pacific? The Obama Administration's "Rebalancing" Toward Asia*, coordinated by Mark E. Manyin.

analysts believe that China's pursuit of its own bilateral and multilateral economic arrangements has produced a competition of sorts over the shape of Asia's future economic architecture, in which the United States and several other countries in the Pacific are pushing for a deeper set of regional economic rules and expectations than Chinese leaders prefer.[20] The potential inclusion of Japan, as the second largest economy—and richest economy on a per capita basis—in East Asia could transform this struggle between alternative visions of regional trade rules. Additionally, U.S. and Japanese participation in the same free trade agreement could arguably be viewed as a means to reaffirm their alliance. The long-running bilateral relationship at times over the years has been overshadowed by U.S. and Japanese interests and concerns elsewhere in Asia, e.g., China and the Korean Peninsula, and in other parts of the world.

Japan's Objectives

Underlying the arguments for Japan to join the TPP talks is a growing feeling among many Japanese that, after two decades of relatively sluggish growth, Japan's economic and political influence is waning in comparison with China and with middle powers such as South Korea. The rapid aging and gradual shrinking of Japan's population has added to a sense among many in Japan that the country needs to develop new sources of growth to maintain, if not increase, the country's living standards. Japanese proponents of TPP have called for joining the talks for a number of overlapping reasons, some defensive in nature, others more proactive:

- **A desire to promote Japanese growth and prevent the hollowing out of Japan**—i.e., the relocation of Japanese companies to other countries—by expanding Japanese exports, especially to the fast-growing Asia-Pacific region. The decade-long stalemate in the WTO's "Doha Round" of trade talks, plus the explosion in bilateral and multilateral FTAs over the past decade, has led Japan to cautiously pursue its own FTAs.[21] As noted earlier, Japan is an important link in the Asia's global supply chains, and the TPP could facilitate operations within the supply chain. Conversely, greater trans-Pacific economic integration could potentially erode Japan's place in these manufacturing and export networks.[22] In his March 15, 2013 press conference announcing his decision to seek entry into the TPP negotiations, Prime Minister Abe spoke of the multiple commercial benefits Japan would derive from joining, and how doing so would help "leave to our children and our children's children a strong Japan...."[23]
- **A feeling that Japan is being left behind in negotiating FTAs.** Although Japan has signed 13 FTAs—what it calls Economic Partnership Agreements (EPAs)—it has none with a major economic power, with the possible exception of the 2011 Japan-India EPA, and many of them exclude agricultural trade. (See **Table 3.**) In contrast, South Korea, the country many Japanese now compare themselves to, has signed FTAs with the United States, the European Union (EU), and in 2012 opened

[20] August 2012 conversation with Takeshi Terada, Professor, Doshisha University.

[21] For historical background on Japan's FTA strategy, see archived CRS Report RL33044, *Japan's Free Trade Agreement Program*, by Raymond J. Ahearn.

[22] For more information on supply chains, CRS Report R40167, *Globalized Supply Chains and U.S. Policy*, by Dick K. Nanto.

[23] Japanese Prime Minister's Office, "Press Conference by Prime Minister Shinzo Abe," Friday, March 15, 2013 (provisional translation).

negotiations with China. If Japan is left behind in the FTA race, the feeling runs, its companies will be left at a competitive disadvantage.[24] Japan has belatedly tried to make up for the gap in 2013 by launching FTA negotiations with the EU and with China and South Korea on a trilateral FTA.

- **A desire to help shape the rules of economic activity in the Asia-Pacific and beyond.** In his announcement of Japan's bid to participate, Prime Minister Abe said that the TPP would likely serve as "a basis for rule-making" in other multilateral trade negotiations.[25] If Japan waited any longer to join the talks, in his view, it would be too late to help write the TPP's rules. "Now is our last chance," Abe said, "Losing this opportunity would simply leave Japan out from the rule-making in the world. Future historians will no doubt see that "the TPP was the opening of the Asia-Pacific Century."[26]

Table 3. Japan's Free Trade Agreements

In Force	Negotiating	Under Discussion
Japan—ASEAN[a]	Japan—Australia	
Japan—Brunei	ASEAN+3	Japan—Canada
Japan—Cambodia	ASEAN+6	
Japan—Chile	Japan—European Union	Japan—Mongolia
Japan—India	Japan—China—South Korea	Japan—South Korea
Japan—Indonesia		TPP
Japan—Malaysia		
Japan—Mexico		
Japan—Peru		
Japan—Philippines		
Japan—Singapore		
Japan—Switzerland		
Japan—Thailand		
Japan—Vietnam		

Source: Japanese Ministry of Foreign Affairs, http://www.mofa.go.jp/policy/economy/fta/index.html.

[24] For instance, in his opening statement at a November 2011 press conference to discuss Japan's decision to explore joining the TPP talks, Prime Minister Noda said, "as a trading nation, in order to pass down the affluence we have cultivated to our future generations and to develop our society into one with vigor, we must incorporate the economic growth of the Asia-Pacific region." Japanese Prime Minister's Office, "Press Conference by Prime Minister Yoshihiko Noda," Friday, November 11, 2011. In his March 2013 press conference, Prime Minister Abe said "If Japan alone should become inward-looking, we would have no chance of growth."

[25] Abe specifically mentioned the 16-nation Regional Comprehensive Economic Partnership (RCEP), a 16-nation economic grouping among nearly all East Asian countries plus Australia, India, and New Zealand. Thus, in Abe's vision, TPP and RCEP appear to complement rather than compete with one another.

[26] "Press Conference by Prime Minister Shinzo Abe," Friday, March 15, 2013.

a. ASEAN stands for the Association of Southeast Asian Nations, which consists of Brunei Darussalem, Burma (Myanmar), Cambodia, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand, and Vietnam.

- **A belief that entering the TPP will help promote economic reforms inside Japan.** Over the years, many experts and government officials have argued that Japan needs structural reform to spur its economy. A number of Japanese commentators and officials believe that one way to overcome resistance to reform from vested interests is through negotiating a comprehensive, high-standard FTA such as the TPP, which will help reform-minded groups and individuals by giving them political cover. Also, negotiating the TPP could potentially enable Japan to gain benefits by trading structural reforms for concessions from negotiating partners.
- **A hope that entering the TPP will help Japan's strategic situation in Asia.** Joining the TPP would complement Japan's moves in recent years to augment the U.S.-Japan alliance by strengthening Tokyo's relationships with middle powers in and around the Asian region. Behind this push is a concern that China's rise is diminishing Japan's influence and jeopardizing its security and economic interests. Since leading his party to power in late 2012, Prime Minister Abe has made one of his top priorities restoring Japanese standing, through revitalizing its economy and strengthening relations with the United States.[27]

Japanese Politics and the TPP

The question of whether Japan should join the TPP negotiations has often been front-page news in Japan and has generated enormous political controversy since serious discussion of the possibility began in 2009 and 2010. Both Prime Minister Abe's ruling Liberal Democratic Party (LDP) and the largest opposition party, the Democratic Party of Japan (DPJ) are split over the TPP issue. Until Abe's March 2013 announcement, the frequent turnover among Japanese prime ministers—Abe is the seventh premier in as many years—failed to produce the leadership that might unify the pro-TPP camps across the two parties. These political weaknesses exacerbated the traditional institutional limitations of the prime minister's powers, making it easier for motivated interests to effectively veto government action and stymie the efforts of Abe's two predecessors from unambiguously trying to enter the talks. For the moment, Abe appears to have surmounted these obstacles, in part by using his high popularity ratings as leverage against opponents in his LDP and by centralizing decision-making on TPP issues in the prime minister's office. The latter move could blunt opposition to the TPP within the LDP. Abe came to power in December 2012 after leading the LDP to victory in national elections, ending the DPJ's roughly three-year reign.

Japan's powerful agricultural institutions, most notably the nationwide agricultural cooperative organization (JA), have been the most vocal opponents of joining the TPP, as has been true of virtually all trade liberalization agreements that Japan has pursued for the past 40-50 years. JA has called for over 800 farm items to be exempt from tariff elimination.[28] Japan's farm sector has taken advantage of the fact that Japan's rural areas are over-represented in the Diet. As a result,

[27] See, for instance, Japanese Prime Minister's Office, "Press Conference by Prime Minister Shinzo Abe," December 26, 2012; and Shinzo Abe, "Japan is Back," Speech at the Center for Strategic and International Studies, February 22, 2013.

[28] "Abe Surprises on TPP," *The Oriental Economist*, Volume 81, No.3, March 2013.

farm lobbies have significant sway in both the ruling LDP and opposition DPJ and have supported an array of policies that benefit the agricultural sector. For example, many farm products remain protected behind high tariff barriers such as rice (778%) and wheat (252%). (For others, see **Table 4**.) Additionally, a range of other policies ensure that Japanese farming remains small scale, performed increasingly by aging and part-time farmers, and generally unproductive compared to farms in most other countries. The Japanese government provides around ¥1 trillion (about $12 billion) annually in direct income to farming households.[29] The Abe government and the LDP reportedly are considering a new subsidy package that could be offered to Japan's farm sector to compensate for losses that would be expected if a TPP agreement is reached.[30]

Table 4. Comparative Japanese and U.S. Tariff Rates on Select Agricultural Products

(Average applied ad valorem MFN rates)

Category	Japan	United States
Animal Products	18.9	2.3
Dairy Products	93.3	20.3
Fruits & Vegetables	10.6	4.9
Coffee & Tea	15.3	3.2
Cereals & Preparations	42.0	3.5
Oilseeds, Fats & Oils	9.0	4.6
Sugars and Confectionary	27.2	10.3
Beverages & Tobacco	14.6	15.6

Source: WTO Tariff Profiles.

JA has allied with a variety of other powerful interest groups to mount an aggressive campaign against entering the TPP. The most significant of these other groups may be the Japan Medical Association, which argues that TPP will erode if not eliminate Japan's universal healthcare insurance system because it will be forced to pay higher prices for medicines and medical equipment. Many experts argue that until Abe's March 2013 announcement, Japan's traditional agriculture interests, medical lobby, and other TPP opponents successfully controlled the debate about TPP inside Japan. They have gained the support of scores of lawmakers, including over 200 LDP members (over half the LDP's parliamentary caucus) that prior to Abe's decision joined a group calling for Japan not to join the TPP. Nonetheless, in mid-March, after considerable internal debate the LDP formally announced it supported Abe's decision.[31] Around the same time, an LDP panel on the TPP designated five product lines – rice, sugarcane/sugar products, wheat, dairy products, and beef – as "important items" that must be protected.[32] In 2012, prior to the elections that swept Abe into power, the Abe-led LDP had said it opposed entering the negotiations unless the final agreement allowed for some exemptions, a position that many interpreted as designed to appeal to anti-TPP voters. At the time, the LDP also objected to some

[29] Aurelia George Mulgan, "Japan's New Agricultural Policy Plan Neglects Trade Liberalisation," East Asia Forum blog, November 2, 2011, http://www.eastasiaforum.org.

[30] "Analysis: New Farm Subsidy May Turn Into Another Pork Barrel," *Nikkei Report*, March 26, 2013.

[31] Liberal Democratic Party, "LDP's Decision to Participate in the TPP," March 13, 2013.

[32] "LDP Designates Rice, Sugar, Others as 'Important Items'," U.S. Embassy Tokyo, Japan Morning Highlights, March 13, 2013.

investor-state dispute settlement requirements that might be agreed to in the TPP, and argued that government procurement and financial services must have their basis in Japan's "special characteristics."[33] It is unclear to what extent these views have or will become Japanese government positions. The reservations about TPP among many LDP members indicate that, if Japan enters the talks, the Abe government may face difficulties gaining domestic support for making painful concessions, particularly if Abe's public approval ratings decline.

The Views of U.S. Stakeholders

In a December 7, 2011 *Federal Register* notice, the Office of the USTR solicited the views of private sector stakeholders on whether Japan should be included in the TPP. USTR received over 100 responses. Around 40% of the responses were from agricultural firms, another 25% came from manufacturing firms, 15% from services providers and the remainder from various non-government organizations (NGOs) and business associations. Some of the responses came from Japanese companies or associations representing Japanese companies.

In a few cases, the respondents expressed outright opposition to Japan's participation. One of the most notable members of this group is the American Automotive Policy Council (AAPC).[34] The AAPC represents the three Detroit-based auto manufacturers—Chrysler, Ford and General Motors. In its statement, the AAPC said:

> The AAPC opposes Japan joining the Trans-Pacific Partnership negotiations at this time.... Japan's trade barriers in the auto sector cannot be addressed easily or quickly, and will needlessly slow down the negotiations. To date Japan has not indicated a willingness to change its decades-long practice of maintaining a closed automotive market. Given the systemic trade imbalance and lack of willingness to reform, a U.S. free trade agreement with Japan would only lock-in the already one-way trade relationship that Japan's closed auto market has created, and significantly delay, if not prevent proceeding with a high quality TPP trade agreement with other more compatible trade partners in the important and rapidly growing Pan-Pacific region.

The AFL-CIO also opposes Japan's participation in the TPP, having stated:

> Given the numerous unknowns about the yet unfinished Trans-Pacific FTA, it is difficult to provide significant technical advice or even formulate well-grounded opinion with respect to the possible impacts on working families of Japan's accession to the Trans-Pacific FTA.
>
> As such, the AFL-CIO has serious concerns regarding the premature expansion of the Trans-Pacific FTA negotiations to include Japan or any other nation before US negotiators first demonstrate an ability to successfully negotiate an agreement that will produce genuine benefits for American workers and increase domestic production.
>
> [Japan's] markets are notoriously closed to foreign goods, and this is not the result of high tariff barriers.... To gain significant and substantial market access to Japan, the United States

[33] Aurelia George Mulgan, "Can Trade Talks Drive Reform in Japan?" *Current History*, Volume: 111, Issue: 746, September 2012, p. 242.

[34] AAPC, The American Automotive Policy Council's (AAPC) Views Regarding Japan's Expression of Interest in the Tans-Pacific Partnership (TPP) Trade Negotiations, January 13, 2012.

> Trade Representative (USTR) would have to adopt a new and revolutionary approach.... If USTR is not willing to 'think outside the box' and abandon its currently slavish approach to free trade, it is difficult to see how Japan's accession to the Trans-Pacific FTA can benefit American working families.[35]

In some cases, respondents expressed strong support for Japan's inclusion in the TPP. For example, Caterpillar, Inc. argues that the TPP would be the vehicle for addressing Japan's remaining non-tariff barriers.[36] The U.S. Chamber of Commerce and the U.S.-Japan Business Council, in separate submissions, also expressed support for Japan's participation in the TPP negotiations. However, each group asserted that Japan would have to address issues that have plagued relations with member companies, including regulatory barriers, favored treatment of insurance and express delivery subsidiaries of Japan Post, and government procurement, among others.[37]

Some Members of Congress have weighed in on the issue. For example, in a November 8, 2011, bipartisan letter to USTR Ron Kirk, the Chairmen and Ranking Members of the House Ways and Means Committee and the Senate Finance Committee stated that Japan's participation "would represent an opportunity for much needed change in Japan's approach to international trade." They assert that, while Japan is a long-time U.S. ally and friend in Asia,

> paramount considerations in evaluating a request relating to a trade agreement must be whether Japan is willing and able to meet the high standard commitments inherent in U.S. free trade agreements and whether inclusion would truly open this historically closed market to the benefit of our companies, workers, and farmers.

These comments and others from stakeholders suggest that the debate within the United States and negotiations with Japan on the TPP will be difficult and complex. The legacies of a sometimes contentious bilateral economic relationship have carried over into the TPP negotiations.

Outlook, Possible Outcomes, and Consequences

Japan's negotiations with the United States, as well as its negotiations with Australia and New Zealand, continue with no publically announced deadline or timeframe. The Obama Administration has stated that it wants to take as much time as necessary but would not let these negotiations interfere with the pace of the negotiations among the current TPP countries.

If Japan enters the TPP, it could represent a major change in the shape and dynamic of the U.S.-Japan economic relationship. Over the years, trade policymakers, business representatives, and regional specialists in both countries have floated the concept of a U.S.-Japan FTA. Until the TPP talks began in earnest, the idea had not gained traction because the hurdles—Japanese agricultural policy, problems in auto trade, government regulations and practices—have been too high to

[35] AFL-CIO, Comments in Response to "Request for Comments on Japan's Expression of Interest in the Proposed Trans-Pacific Partnership Trade Agreement."

[36] Caterpillar's Views Regarding Expanding Trans-Pacific Partnership Negotiations to Include Japan, Mexico, and Canada, January 11, 2012, Submission to the Office of the USTR.

[37] U.S. Chamber of Commerce January 13, 2012, letter to USTR and U.S.-Japan Business Council, Public Comment, *Japan's Expression of Interest in the Proposed Trans-Pacific Partnership Negotiations.*

overcome. These same hurdles would need to be overcome if Japan and the United States are able to work successfully in the TPP.

The outlook for Japan's entry into the TPP negotiations remains unclear at this time and depends on a number of factors. Perhaps the most critical factor is whether Japanese political leaders can reach a political consensus on whether to proceed with the negotiations and then whether Japan can reach agreement with the TPP partners on conditions of its entry. The timing of Japan's decision on whether to proceed has likely been delayed by domestic politics. Recently, in return for the LDP and the New Komeito Party agreeing to a vote on the consumption tax, Prime Minister Noda promised to dissolve the Lower House "at an early date." As a result, new elections for the lower house would be called, possibly resulting in changes in control of the legislature. Therefore the decision on TPP will likely not before this December at the earliest but most likely later. Japan expert Ed Lincoln has suggested the decision will likely be pushed even farther out.[38]

The outcome of this issue could have implications for the U.S.-Japan bilateral trade relationship, the overall alliance, and the TPP. The TPP issue presents opportunities and challenges for the United States and Japan. On the one hand, if successful, it could reinvigorate an economic relationship that has remained steady but stagnant, by forcing the two countries to address long-standing, difficult issues, and allowing them to raise their relationship to a higher level. On the other hand, failure to do so could indicate that the underlying problems are too fundamental to overcome and could set back the relationship. It could signify the failure of the United States and/or Japan to deal with domestic opposition to a more open trade relationship.

The implications for the overall U.S.-Japanese alliance are less certain. While the TPP would likely be viewed as strengthening the alliance and failure of the negotiations could be considered a setback, the alliance is also built on common national security concerns, such as North Korea's nuclear program and the economic and military advancement of China, which could well trump trade problems.

Furthermore, Japan's possible entry into the TPP is largely viewed, on the one hand, as an important step in forming a wider Asia-Pacific regional trade arrangement. On the other hand, the absence of Japan could undermine the credibility of the TPP as a viable regional trade arrangement and a setback for Asia-Pacific economic integration.

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[38] *World Trade Online,* August 9, 2012.

THE AUSTRALIAN

Japan wins spot in mega trade pact

AAP APRIL 20, 2013 9:53PM

JAPAN has won its bid to enter talks on a massive Pacific trade pact that includes Australia.

The Trans-Pacific Partnership (TPP) would account for more than 40 per cent of the global economy.

Japan had to win over Canada to be included in the US-driven partnership, which also includes Brunei, Chile, Canada, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam.

Canada had been the sole nation of the 11 in the proposed agreement that still opposed Tokyo's participation.

"These consultations have been informed by a robust and ongoing engagement with Canadian stakeholders, and it's that engagement that helped inform this process," Canadian Trade Minister Ed Fast said.

"We look forward to continuing to work together (with Japan) to deepen our trade and investment relationship in a manner that will generate significant benefits for hard-working people in both our countries."

Canada's approval came after bilateral talks on the sidelines of an Asia-Pacific Economic Cooperation trade ministers' meeting in Surabaya.

Washington earlier this month gave Japan the thumbs-up for talks on the free-trade agreement despite opposition from Japanese farmers and some US labour groups and manufacturers.

President Barack Obama has championed the TPP as a way to boost the US economy through trade and to build a US-driven order in a fast-growing region where China - which is not part of the talks - is gaining clout.

To allay concerns of higher competition in the US automotive industry, Japan, the world's third-largest economy, agreed that US tariffs on its cars would be phased out at the latest possible time allowed by a future accord.

Japan's Ministry of Economy APEC office director Ken Sasaji said Japan's participation in the talks was a major step toward the TPP's aim to create a free-trade zone among nations on the Pacific rim.

"As APEC leaders agreed, our final destination is FTAAP - a free-trade agreement in the Asia-Pacific," Sasaji told reporters.

"Now Japan is promoting various efforts to promote economic integration and economic partnerships, especially the trans-Pacific partnership, which is one of the most important efforts."

COMMITTEE ON FINANCE
NEWS RELEASE
Max Baucus (D-Mont.)
http://finance.senate.gov

FOR IMMEDIATE RELEASE
April 24, 2013

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BAUCUS SEES TRANS-PACIFIC PARTNERSHIP TRADE AGREEMENT AS MAJOR SPARK TO U.S. ECONOMY

Finance Chairman Sets June Target to Introduce Fast Track Authority and Job Training Bill

WASHINGTON – At a Senate Finance Committee hearing today, Chairman Max Baucus (D-Mont.) said Congress must capitalize on the Trans-Pacific Partnership (TPP) trade agreement to benefit from the fast pace of economic growth in many Asian economies, boost U.S. exports and create jobs in Montana and across the country. Senator Baucus also said he is working to renew Trade Promotion Authority and the critical job training program Trade Adjustment Assistance and set a target to introduce a bipartisan bill by June.

"The TPP presents tremendous opportunities to expand U.S. exports and support hundreds of thousands of good-paying jobs here in America. The Asia-Pacific economies are some of the fastest growing in the world, and Asia is importing more and more goods from around the world. The United States needs to share in that growth, and the TPP offers the way to do so," Senator Baucus said. **"I am also looking forward to working to renew Trade Promotion Authority and Trade Adjustment Assistance this year. Fast track authority will help us conclude the TPP negotiations, and that will bring concrete benefits for American ranchers, farmers, businesses and workers."**

In 2011, the GDP of nearly all of the Asia-Pacific economies grew faster than the U.S. growth rate of 1.8 percent. More than half of them enjoyed growth above the world average of 3.8 percent. And Asia's share of world imports grew from 18.5 percent in 1983 to 30.9 percent in 2011. Senator Baucus said the TPP is the best way for the U.S. to share in that growth.

Senator Baucus said Japan's inclusion in the TPP talks represents a significant step towards a more unified Pacific region and an opportunity to build on recent progress breaking down Japan's barriers to trade. Earlier this year, Japan lowered its age-based restrictions on U.S. beef exports and began accepting them in much larger quantities. Japan is also the top market for U.S. pork products, importing more than the second- and third-ranking markets combined.

Senator Baucus also said the TPP agreement must address unscientific barriers to U.S. agriculture products, issues with state-owned enterprises and intellectual property protection and enforcement.

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Safeguards for Tobacco Control: Options for the TPPA

For full analysis, see American Journal of Law and Medicine, 2013 Symposium Issue, by Robert Stumberg
April 13, 2013 – v5c

TPPA threats to tobacco control

The tobacco industry uses an international campaign of litigation and lobbying to chill, divert or delay tobacco-control policies. Existing flexibilities in trade agreements might enable countries to defend their measures, but the multi-year, multi-million dollar cost of doing so is daunting. The tobacco industry seeks to reinforce its strategy in trade negotiations to expand market access, strengthen trade rules, and expand investor rights. The industry stands to benefit from at least six chapters of the proposed Trans-Pacific Partnership Agreement (TPPA). Based on publicly available drafts, these chapters add WTO-plus rules that could be used in later rounds of litigation or to bolster industry threats in lobbying:

(1) *Investment* chapter – expands investor-state arbitration. Philip Morris International uses investment agreements to challenge tobacco-control measures; PMI argues that the measures frustrate their expectations and ability to market tobacco products.

(2) *Intellectual property chapter* – adds a new right to use a trade name that indicates a location even if the product does not originate from it (e.g., Parmigiano or Marlboro). This proposal excludes wine and spirits, but it still applies to tobacco.

(3) *Cross-border services chapter* – expands the service sectors to which trade rules apply (e.g., tobacco distribution, packaging, and advertising); it potentially limits domestic regulation of such services. It could be used to challenge restrictions on advertising, promotion, or sales as "zero quotas."

(4) *Regulatory coherence chapter* – promotes industry stakeholder participation in decision-making; promotes regulatory impact assessments, which the tobacco industry has used to generate evidence to support its litigation.

(5) *Technical barriers to trade chapter* – potentially limits how governments cooperate to set standards or guidelines for tobacco control.

(6) *Tariff schedules* – expand market access in countries with high tobacco tariffs (notably Vietnam). Studies show that after high tariffs are reduced, prices go down, marketing increases, competition increases, and smoking rates go up in the range of 10%, often double that increase among women and girls, who are specifically targeted.

Intersecting frameworks: trade promotion and tobacco control

The Framework Convention on Tobacco Control requires 176 parties to fill the regulatory framework by exercising their regulatory powers. The WTO agreements require 157 members to refrain from exercising regulatory powers that restrict trade.

The trade and tobacco frameworks have overlapping coverage. The following chart maps where six chapters of the TPPA intersect with types of tobacco-control measures. At most of these intersections, the tobacco industry litigates or lobbies in its campaign to shrink the policy space available for regulation. In the TPPA negotiations, the industry expects to benefit from WTO-plus elements such as expanded coverage (e.g., regulation of services), stronger trade rules (e.g., use of trademarks), and investor protection (e.g., expanded opportunities to litigate).

Intersecting Frameworks

Tobacco Control: Selected FCTC measures	Trade Promotion: Selected TPPA chapters					
	Goods, tariff reduction	Goods, technical barriers	Intellect. property	Cross-border services	Regulatory coherence	Investment
6. Price & tax measures 2b. Restrict duty-free sales	✓	✓			✓	✓
Product contents 9. Regulate (or ban) 10. Disclose	✓	✓			✓	✓
11. Packaging & labeling 1a. Misleading 1b. Warnings 2. Constituents & emissions		✓	✓	✓	✓	✓
13. Advertising 1. Comprehensive ban 2. Restrictions 3. Minimum 4. Eliminate cross-border 5. Eliminate sponsorship		✓	✓	✓	✓	✓
5. General 3. Protect from commercial interests					✓	✓

Limits of the GATT/GATS health exception

If a country is challenged under the TPPA, it might be able to defend a tobacco-control measure under a health exception, which typically incorporates the GATT/GATS exception (WTO exception) by reference. Six elements of an exception create a complex formula for defending tobacco measures:

(1) *Scope* – Based on the model of U.S. free trade agreements, the baseline health exception applies to selected chapters of the agreement but not to specific rules being used to litigate against tobacco-control measures (including the investment chapter, among others).

(2) *Protection* – Tobacco investors use MFN to incorporate rules from outside the primary agreement that provide more favorable treatment. The draft TPPA investment chapter excludes procedural treatment from MFN, but MFN would still apply to substantive investor rights.

(3) *Deference* – The WTO agreements have no terms of deference to non-WTO treaties.

(4) *Nexus* – The necessity test creates uncertainty with stages of analysis that enable litigation to challenge the contribution of a measure, weigh that contribution against trade restrictiveness, and identify less-restrictive alternatives. Some scholars predict that investment arbitrators would apply the necessity test with less deference than trade panels.

(5) *Objective* – Some measures serve multiple purposes, including non-health purposes like revenue or business licensing; their connection to protecting health may be indirect.

(6) *Additional restrictions* – Even a "necessary" measure can be challenged as having a discriminatory effect in the market as applied. This works against incremental change or measures that freeze the market at its current stage of development.

Win or lose, the threat of costly litigation has long been part of the tobacco industry's strategy to chill, divert or delay implementation of tobacco-control measures. Each of the exception's six elements provides an opportunity to litigate, and together they create uncertainty of outcomes. The most certain litigation threat is not that tobacco companies or their allies will win; it is the likely litigation costs of one to two million USD per year for several years – more than the tobacco control budget for most developing countries.

U.S. proposal for a TPPA tobacco exception

Anticipating potential litigation, the United States has vetted a narrowly crafted TPPA exception for regulation of tobacco products. But this does not protect legislation or measures adopted by tax, licensing or customs authorities. In place of the necessity test, it requires scientific evidence, a burden of proof that the GATT/GATS exception does not require. The U.S. proposal would not have protected against the clove cigarette dispute that the United States lost, the WTO claims against Australia, or the investment claims against Australia or Uruguay.

The U.S. proposal is in the form of a summary that has not been tabled. What follows is the original summary with each key term noted to show, first, the shortcomings of that term, and second, stronger alternatives for that term. The alternatives are also compared in the chart below, so the notes are keyed to columns of that chart.

Original summary of the U.S. proposal

"[1] Language in the general exceptions chapter that [2a] allows health authorities [2b] to adopt [2c] regulations [2d] on specific tobacco products/classes [3a] that impose origin-neutral, [3b] science-based restrictions [4] [5] in order to [6] safeguard public health."

Column 1: Scope

1. U.S. proposal – "*Language in the general exceptions chapter*"

   1. *Shortcoming* – It is not clear whether the U.S. proposal applies to all chapters or whether it applies to selected chapters or rules, excluding those that contain rules that are being used to challenge tobacco control-measures.

   1. *Alternatives* – Make clear that the tobacco exception applies generally: "*Nothing in this agreement* [prevents] or [applies]."

Column 2: Protection

2a. US proposal – "*allows health authorities in TPP governments*"

   2a. *Shortcoming* – By covering only health authorities the U.S. proposal leaves out non-health authorities that are often involved in tobacco control, e.g., licensing, taxation, and customs authorities.

   2a. *Alternatives* – Stronger protection would provide that nothing "*prevents a party*." Note that the U.S. government takes the position that the "nothing prevents" language does not apply to the investment rule that requires compensation for expropriation. An exception that does not apply to expropriation would be significantly compromised. A stronger alternative that works on expropriation would be: Nothing in this Agreement *"applies"* to measures [covered by the exception]. Alternatively, an interpretive clause could be added: For greater certainty, this exception applies to any duty to compensate for direct or indirect expropriation.

2b. U.S. proposal – "*to adopt*"

2b. *Shortcoming* – The GATT/GATS exception covers measures that a party adopts or enforces. To cover only measures that a country *adopts* appears to leave out existing measures that a country enforces.

2b. *Alternatives* – Use the GATT/GATS language: "*adopting or enforcing*."

2c. U.S. proposal – "*regulations*"

2c. *Shortcoming* – By covering only regulations, the U.S. proposal appears to not cover legislation, which is how most governments establish their tobacco-control measures.

2c. *Alternatives* – Use the GATT/GATS exception, which applies broadly to "*measures*."

2d. U.S. proposal – "*on specific tobacco products/classes*"

2d. *Shortcoming* – Covering only regulations on tobacco products appears to not cover measures that apply to tobacco-related services (e.g., distribution, packaging, advertising) or investments (e.g., trademarks).

2d. *Alternatives* – Use "measures." The scope of measures could be limited to "*tobacco-control measures*," but the clearest way to limit the class of measures is in the objective (see column 6 below).

Column 3: Additional restrictions

3a. US proposal – "*that impose origin-neutral,*"

3a. *Shortcoming* – "Origin-neutral" is a synonym of national treatment; a measure can be a de facto violation of either.

3a. *Alternatives* – Use "*facially origin-neutral*." A stronger alternative is to delete "origin-neutral" as an additional restriction.

3b. U.S. proposal – "*science-based restrictions*"

3b. *Shortcoming* – Proving that restrictions are "science-based" is a heavier burden than the GATT/GATS health exception, which requires only a qualitative, logical rationale. The tobacco industry has a long history of generating scientific evidence to counter a defending government's science. For example, in the *Cloves Cigarettes* case, some science was not enough.

3b. *Alternatives* – A stronger alternative is to delete "science-based" as an additional restriction.

Column 4: Deference

4. U.S. proposal – *none*

4. *Shortcoming* – Without terms of deference, the threat of extended litigation to defend a measure based on this exception is more likely.

4. *Alternatives* – Terms of deference would be: "*that a party considers appropriate*."

Column 5: Nexus

5. U.S. proposal – *"in order to"*

5. *Comment* – This is an appropriate nexus from a health perspective; it requires a rational connection between a measure and its health objective.

5. *Alternatives* – An alternative nexus would be: "*that contribute or aim to*." This would cover measures that are either (a) designed to achieve health objectives, or (b) make a contribution to achieving health objectives, even if they serve multiple purposes.

Column 6: Objective

6. U.S. proposal – *"safeguard public health"*

6. *Comment* – This is a broad health objective, which is good. A reason to consider alternatives is this: If the prior elements of the U.S. proposal are strengthened, negotiators may want to narrow the objective of safeguarding public health in order to avoid "slippery slope" opposition from other sectors such as alcohol and processed food products.

6. *Alternatives* – If the strongest objective, protecting public health, is too broad to address "slippery slope" concerns, an alternative is "*reduce use of tobacco products or its harms*."

Examples of how alternatives can be combined

The alternatives can be mixed and matched in various combinations. For example:

"Nothing in this Agreement prevents a party from adopting or enforcing …
… measures that it considers appropriate for science-based protection of public health."
… measures that contribute or aim to reduce use of tobacco products or its harms."
… measures that it considers appropriate to reduce use of tobacco products or its harms."

"Nothing in this Agreement applies to measures that contribute to or aim to reduce tobacco use or its harms."

Additional interpretive clauses:

For greater certainty,
… this exception applies in addition to other exceptions; it has no effect on operation of those exceptions.
… this exception applies to any duty to compensate for direct or indirect expropriation.
… if this exception applies to a measure, it is consistent with MFN treatment.

The clearest and strongest alternative – Use an exclusion

The more elegant alternative to a complex exception is to simply exclude tobacco-control measures. An exclusion provides better protection than a defense; it contains litigation at the initial stage of determining whether a treaty applies to a measure. If the political will is lacking for a full exclusion, there are several ways to draft a partial exclusion.

See the next page for a chart that summarizes the alternatives noted above.

Alternatives to the U.S. Proposal for a Tobacco Exception

1. Scope	2. Protection	3. Additional restrictions	4. Deference	5. Nexus	6. Objective
U.S. Proposal					
[1] Language in the general exceptions chapter: *Unclear whether it applies to all chapters and articles.*	[2a] allows health authorities in TPP governments [2b] to adopt [2c] regulations [2d] on specific tobacco products/ classes	that impose [3a] origin-neutral, [3b] science-based restrictions	[4] *none*	[5] in order to	[6] safeguard public health
First alternative for key terms ... *read columns as better to best protection*					
[1] *Add to the chapters covered by the exception:* For purposes of [*listed chapters plus*] ... investment, intellectual property, regulatory coherence, etc.	[2a] [nothing] prevents a party [2b] from adopting or enforcing [2c] measures [2d] *none*	[3a] [that are] facially origin neutral [3b] *none – see "contribute to" as a nexus*	[4] *none*	[5] to	[6] reduce use of tobacco products or its harms
Second alternative for key terms					
[1] Nothing in this Agreement	[2a] prevents a party [2b] from adopting or enforcing [2c] measures	[3a] *none* [3b] *none*	[4] *none*	[5] that contribute or aim to	[6] reduce use of tobacco products or its harms
Third alternative for key terms					
[1] Nothing in this Agreement	[2a] applies to [2c] measures	[3a] *none* [3b] *none*	[4] that a party [it] considers appropriate	[5] to	[6] protect public health

Examples of how alternatives can be combined

Nothing in this Agreement prevents a party from adopting or enforcing ...
... measures that contribute or aim to reduce use of tobacco products or harms.
... measures that it considers appropriate for science-based protection of public health.
... measures that it considers appropriate to reduce use of tobacco products or harms.
Nothing in this Agreement applies to measures that contribute to or aim to reduce tobacco use or its harms.

Interpretation clauses: For greater certainty, ...
... this exception applies in addition to other exceptions; it has no effect on operation of those exceptions.
... this exception applies to any duty to compensate for direct or indirect expropriation.
... if this exception applies to a measure, it is consistent with MFN treatment.

> Inside U.S. Trade - 04/12/2013

> With TPP Tobacco Proposal On Hold, Stakeholders Eye Impact On EU FTA

> Posted: April 11, 2013

>

> Although the United States continues to hold off on tabling a draft proposal in the Trans-Pacific Partnership (TPP) talks that would establish a special "safe harbor" for tobacco regulations, members of Congress and U.S. stakeholders are already beginning to think through what this potential new development in U.S. trade policy would mean for the forthcoming U.S.-European Union trade negotiations.

>

> Industry sources opposed to the draft proposal concede that, if the White House ultimately goes ahead with it in the context of TPP, that will set a precedent and would likely mean that the Office of the U.S. Trade Representative would then look to table the same proposal in the context of talks with Europe. "You can't do it in TPP and not do it in the EU FTA," one industry source lamented.

>

> This source said that, if the U.S. goes ahead with its tobacco proposal in TPP, business groups opposing it would likely demand that the U.S. completely reverse course in the EU FTA talks. However, this outcome would probably be unrealistic, this source conceded, and U.S. business groups will end up focusing on ensuring that the U.S. and EU do not agree to anything that would be even more far-reaching than the outcome on tobacco in the TPP context.

>

> Conversely, sources on both sides of the issue agreed that if the opposition to the U.S. proposal from the business community and members of Congress is so strong that the administration abandons it in the TPP context, it would appear to make little sense for the administration to reopen this issue in the talks with Europe. Either way, then, TPP could set an important precedent for what position the U.S. takes in the trans-Atlantic talks, sources agreed.

>

> Of course, it is entirely possible that the EU would reject the tobacco proposal even if the U.S. were to table it in the bilateral trade talks. Although the EU typically takes a more cautious approach than the U.S. when it comes to health matters -- for instance, the EU is much slower to approve genetically modified organisms (GMOs) for consumption -- some trade officials in Europe believe that the U.S. proposal is misguided and would likely oppose it, sources said.

>

> Overall, many trade lawyers have joined with U.S. tobacco companies and business groups in criticizing the U.S. proposal. They argue that World Trade Organization rules already provide sufficient leeway to governments to implement measures meant to promote public health, including in the area of tobacco control, and some fear that special rules for tobacco could lead to the misguided perception that general WTO rules are too weak.

>

> Several opponents to the U.S. tobacco proposal added that it would be ironic for the U.S. to demand a specific "safe harbor" for tobacco litigation while simultaneously urging the EU to speed up GMO approvals, for instance, in the context of the FTA talks. One industry source warned that if the U.S. demanded a tobacco exemption, the EU would surely demand a similar exemption for the beef hormones issue, or some other sensitive topic.

>

> But U.S. anti-smoking advocates are hoping that the European Commission as a whole will decide to push for special tobacco provisions in a U.S.-EU trade deal, regardless of which position the U.S. takes. They note that European countries are already strong proponents of tobacco control, and the European Commission last January published a draft revision to its Tobacco Products Directive (TPD) that would further restrict the way tobacco

products can be sold.
>
> In the TPP context, the U.S. is the most powerful negotiator and will likely have a large say over what special language, if any, is ultimately included in a TPP deal, one anti-smoking advocate noted. In the trans-Atlantic talks, by contrast, the two negotiating partners are more evenly paired, meaning that an EU decision to push tobacco control in the bilateral talks could carry real weight and may be difficult for the U.S. to dismiss, the advocate said.
>
> In an interview, Rep. Henry Waxman (D-CA) -- a major proponent of tobacco control and a supporter of the USTR draft TPP proposal -- underscored the fact that Europe is a proponent of tobacco control, and hinted that he would like to see the administration move ahead with its "safe harbor" proposal in both trade contexts.
>
> "As the administration lays the groundwork for negotiations of an EU-U.S. FTA, I will continue to advocate for protecting the authority to regulate tobacco products under the Tobacco Control Act," he said. At its core, the U.S. draft proposal is an effort to ensure it can regulate on tobacco pursuant to that act. The WTO's Appellate Body ruled that the legislation is discriminatory, and the U.S. has until July 24 to comply with the case findings.
>
> "The EU has taken strong action to regulate tobacco products, and there is great opportunity for collaboration in an EU FTA to protect public health measure in Europe and the United States," Waxman added. The California congressman is not only urging USTR to go forward with its proposal in TPP, but has even argued that it should strengthen the proposal by excluding tobacco products from tariff cuts (Inside U.S. Trade, June 29).
>
> A U.S. tobacco control advocate was similarly optimistic. "We are gearing up for the EU-U.S. agreement," he said. "The EU has a major change to their tobacco policies working its way through the system, so they should be sensitive to this issue." This advocate stressed that civil society groups are "still developing our strategy and building partnerships." This source also emphasized that strategy in the EU FTA context "will depend on the lessons of the TPP."
>
> Both anti-smoking advocates and business representatives said it remains unclear why USTR publicly described its draft TPP proposal last May but has continually held off on tabling it. However, many speculated that the administration must have been surprised by the level of opposition, and subsequently decided to hold off on doing anything with the proposal until the end of the negotiations in order to avoid confronting opponents unnecessarily over the issue.
>
> One industry source said it is still a bit unclear whether and how the TPP negotiations will come together, meaning it would make little sense for USTR to insist on its tobacco proposal at this point. Sources on all sides of the debate said the administration is not actively engaging with the private sector on its proposal at this time. Anti-smoking advocates, and even some industry sources, believe the administration will still ultimately table its proposal in the TPP talks.
>
> Still, anti-smoking advocates appear to be getting a bit nervous. In a March 28 letter to Deputy National Security Adviser Michael Froman, five major health groups urged the administration to formally table the proposal at the next round of negotiations, which is taking place in mid-May in Peru.
>
> "We urge the United States to offer the tobacco proposal during the upcoming round of negotiations in Peru," they wrote. "Since the goal is to conclude the TPP agreement later this year, there is increasing urgency to put forth the tobacco language." The groups expressed their disappointment that, 10 months after USTR posted the

outlines of the proposal on its website, negotiators have still not formally tabled it.
>
> That letter also notes that Secretary of State John Kerry, who previously served as chairman of the Senate Foreign Relations Committee, has urged USTR to move ahead with the TPP tobacco proposal. Kerry did so in a separate letter dated June 7, 2012, that was sent to then-USTR Ron Kirk. In that letter, Kerry not only supported the proposal but argued that USTR should completely exclude tobacco products from the confines of a TPP deal.
>
> The new letter sent last month by anti-smoking groups was signed by the American Academy of Pediatrics; Cancer Action Network; American Heart Association; American Lung Association; and the Campaign for Tobacco-Free Kids.
>
> In the interview, Waxman said he continues to urge USTR "to table it at the earliest possible opportunity." Last year, many observers said the proposal had been given the "green light" for inclusion in the TPP talks by the White House despite facing some skepticism from officials in USTR. The proposal was championed by the Department of Health and Human Services (HHS), they said, which favored special treatment for tobacco in a final TPP deal.
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> Inside U.S. Trade - 04/12/2013, Vol. 31, No. 15

> **Inside U.S. Trade - 04/12/2013**
> **Larsen: USTR Still Mulling Two Possible Approaches For Next TPA Bill**
> **Posted: April 11, 2013**
>
> After meeting this week with Acting U.S. Trade Representative Demetrios Marantis, Rep. Rick Larsen (D-WA) told Inside U.S. Trade that USTR appears to still be working out which approach it prefers when it comes to the renewal of Trade Promotion Authority (TPA). Republicans in Congress, as well as some Democrats, are eager to start the conversation on TPA in order to help facilitate passage of new trade deals and set the direction of U.S. trade policy.
>
> "I get the impression that USTR is trying to engage Congress on what is the best approach," the congressman said. The two options that USTR is considering is whether to take a "TPA timeline" approach, under which Congress would provide the administration with TPA for a set period of time -- as has been done in the past -- or whether TPA should be tethered to individual trade agreements, Larsen said.
>
> "It sounds like there is still some deliberation on which approach would be better, and USTR is still very open to congressional input on that question," he said.
>
> Larsen said he had not made up his mind yet on which approach would be preferable. Providing TPA for a set number of years would "put pressure on the administration and negotiating partners to get something done" before the authority expires because only those agreements concluded while TPA was still in force would enjoy the guarantee of an up-or-down vote in the U.S. Congress, he explained.
>
> On the other hand, the congressman conceded that by tying TPA authority to individual agreements, the U.S. could avoid potentially awkward situations where Congress is faced with the prospect of passing a trade agreement that does not enjoy TPA protections. This problem is not insurmountable -- especially in the House, where the leadership can craft a closed rule to ward off amendments -- but it can add legislative complications in the Senate.
>
> Larsen said he was glad that Marantis was discussing the issue of TPA with members of Congress, but hinted that the conversation may stay at a fairly preliminary level until the next USTR is in place. "Right now, I'm glad Demetrios is on the Hill, but he is still acting USTR," Larsen pointed out.
>
> The congressman, as well as other members of the New Democrat

Coalition, met with Marantis on April 10 in order to discuss U.S. trade policy. That conversation covered topics like TPA, the Trans-Pacific Partnership (TPP) negotiations and the upcoming trade talks between the United States and European Union. However, Larsen said that the conversation was fairly general on many of these topics.
>
> When it comes to Japan -- which is vying to join the ongoing TPP talks -- Marantis provided few details on whether and how this will occur. "With regards to Japan, no, there is nothing specific on when and how, except that what the negotiating countries have made clear is that if and when Japan comes in, they need to be able to be able to come in on the same timeline as the negotiations are moving on," he said.
>
> According to Larsen, current TPP partners "want to conclude these negotiations, and delaying them for the sake of a new country probably is not a top priority," he said.
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> Inside U.S. Trade - 04/12/2013, Vol. 31, No. 15

U.S. struggles with pharmaceutical goals in Asia trade talks

By Doug Palmer
WASHINGTON | Thu Mar 28, 2013 5:31pm EDT

(Reuters) - The United States is striving to find an appropriate balance in Asia-Pacific free trade talks between providing strong patent and data protections for U.S. drug manufacturers and ensuring poor people have access to medicine, a U.S. trade negotiator said on Thursday.

"We're looking to promote innovation and R&D (research and development) that results in the development of new medicines. But we are also - and this is just as important - we are trying to promote access to medicines for all," Deputy Assistant U.S. Trade Representative Probir Mehta said.
The remarks at a discussion organized by the Washington International Trade Association show the conflicting pressure on President Barack Obama's administration in talks on the Trans-Pacific Partnership (TPP), a proposed free trade agreement between the United States and ten countries in the Asia-Pacific region that negotiators hope to conclude this year.

Mehta said the United States would not make a new proposal on pharmaceuticals when TPP negotiators meet in Peru <http://www.reuters.com/places/peru> in mid-May for their 17th round of talks but would continue to exchange information on each country's policies "with a view to finding possible common ground."

U.S. drug manufacturers want the strongest possible intellectual property rights (IPR) protections in the pact, but advocacy groups such as Oxfam and Doctors Without Borders are warning TPP countries such as Vietnam and Malaysia that such terms threaten to raise the price of medicines in the region by restricting production of generic drugs.
Former U.S. Trade Representative Ron Kirk summarized the situation at a meeting of the President's Export Council shortly before he left office this month.

"It is very difficult to convince (other TPP countries) of the need to embrace, accept, and implement robust IPR chapters when, many times, we haves NGOs (non-governmental organizations) from here in the United States that are sitting there and giving them contrary information," Kirk said.

The tension is illustrated in the area of "biologic medicines," where U.S. drug companies such as Pfizer and Eli Lilly (and many members of Congress want test data for new drugs protected for 12 years in the TPP pact to delay the development of generic versions.
Congress provided 12 years of data protection for biologics in Obama's healthcare reform legislation, the Affordable Care Act, in line with what many experts say is needed to recoup the average $1.2 billion cost of developing the drugs.

But in annual budgets, the White House has proposed lowering the period of data exclusivity to seven years to encourage faster development of generic versions of the drugs and to save billions in Medicare and Medicaid costs.

So far, U.S. negotiators have not asked for 12 years of data exclusivity for biologics in the TPP, prompting Senator Orrin Hatch, the top Republican on the Senate Finance Committee, to recently ask whether the Obama administration was trying to change U.S. law to the lower standard through the TPP talks.

On Thursday, Mehta said "biologic medicines are clearly the future of the biopharmaceutical industry and certainly a very important area of innovation in the United States. But at this point, we are still reflecting on input and discussing this issue with our trading partners."

Although that stance might seem encouraging for groups that favor early availability of generic medicines, Stephanie Burgos, a senior policy adviser at Oxfam America, said she fears the Obama administration is simply waiting until the end of the negotiation to press its demands, forcing poorer TPP countries such as Vietnam and Malaysia to decide whether to accept tough intellectual property provisions or walk away.

"Instead of a compromise, it's like 'let's put this on hold until everything else is agreed' in the hope that countries that are objecting to the provisions won't have the wherewithal to continue objecting," Burgos said.

Jay Taylor, vice president for international affairs at Pharmaceutical Research and Manufacturers of Americas, said generic versions of most drugs are already available in TPP countries and shouldn't be affected by the pact.

"The TPP, if done correctly, should reduce tariffs and extra additive costs to medicines that ultimately hurt patients," Taylor said.

By lifting incomes in the region, it also should make medicines relatively more affordable, he said. (Reporting by Doug Palmer; Editing by Jim Loney)

THE HILL

THE HILL'S Congress Blog
Where lawmakers come to blog

Free trade versus food democracy

By Jim Harkness, president, Institute for Agriculture and Trade Policy, Minneapolis, Minn. - 04/16/13 01:20 PM ET

There has been a quiet revolution going around the world, as communities and nations retake control of their food systems. In the U.S., more people are taking a look at processed foods at the supermarket and opting instead for healthier choices, grown locally with fewer pesticides. People in Cambodia have taken a hard look at what's happening to their climate, soil and seeds, and figured out a new, low-cost way to produce rice, increasing production and putting farmers in charge. Brazilians are favoring local farmers growing sustainable foods for school lunch programs, lowering hunger rates dramatically as a result.

This trend is larger than individual choice: people are using their rights as citizens to make sure governments, from local to national, support these innovations. Unfortunately, U.S. trade policy seems wedded to a discredited notion of how we should get our food and who should benefit.

These local shifts involve choices, and in many cases choices that favor local producers over transnational corporations, local markets over imports; it seems that the U.S. Trade Representative (USTR) has a problem with that. In its latest report, the agency highlights what it calls the growing problems of "localization barriers to trade," and vows renewed vigilance against these barriers to the free flow of goods and services. A free flow to where? And for whose benefit?

In the U.S., local food is sometimes dismissed as an elite niche market, but in the rest of the world it has another meaning entirely. For decades, Western aid and trade officials have told poor countries to rely on international markets to feed their people; governments were forced to cut support for "inefficient" things like local food production and emergency grain reserves; domestic farming was undermined as cheap imports flooded in. When the price of internationally traded food spiked in 2007-08, and again in 2011, the poorest couldn't afford staples like wheat and rice, and global hunger soared. The developing countries that fared best were those that built domestic production and insulated themselves from volatile global markets. So while the USTR attack on all things local may be great for the U.S. food giants, it pushes an economic model that has been discredited by actual events.

Talks for a Trans-Pacific Partnership (TPP) that would unite markets of 11 countries have been going on for several years. Japan just announced it will enter the talks, despite the vigorous opposition of local farmers concerned about what such an agreement could mean for cherished local rice varieties and rural livelihoods. U.S. dairy farmers, already weakened by rising feed prices, worry that opening the U.S. market to imports from New Zealand will devastate local farms and cooperatives in favor of processed milk solids imports.

Now, President Obama has announced that he will launch new talks for a Transatlantic trade deal uniting the troubled economies of the EU and the United States. As we've seen before, instead of creating new opportunities for growth, this further "competition" will only serve to drive standards down to the lowest common denominator to the benefit of multinational corporations.

For years, the U.S. government has acted on behalf of agribusiness and large pharmaceutical companies to challenge EU bans on GMO foods and limits on the use of antibiotics and dubious drugs like ractopamine and bovine growth hormone in meat and dairy production. Those limits are the result of hard-fought battles by European farmers, scientists and consumers to slow the advance of questionable technologies and instead embrace the precautionary principle, which compels governments to make sure food additives are safe before putting them in our crops and on our plates. Instead, the U.S. government continues with recklessly lax regulation of such emerging technologies as nanomaterial coatings on fruits and vegetables, and synthetically engineered food flavorings.

Lowered standards like these could wipe out local efforts to rein in corporate power and rebuild food systems along more democratic lines, setting a poor precedent — and that's the point. As Vice President Biden said of these trade deals earlier this month, "What we're talking about is shaping a new standard that then becomes the metric by which all future trade agreements are measured."

Let's not start down that path. Instead of doubling down on bad ideas of the past, we must insist on a 21st-century trade system designed to improve food security and affirm democratic control of our food system.

Harkness is the president of the Institute for Agriculture and Trade Policy in Minneapolis, Minn.

Source:
http://thehill.com/blogs/congress-blog/foreign-policy/294179-free-trade-versus-food-democracy

Energy

India Takes Aim at U.S. State, Local Incentives for Renewable Energy Sector

By Daniel Pruzin

GENEVA–India April 17 took aim at credits, rebates and other incentive programs for the renewable energy sector provided by state and local authorities in the United States, which New Delhi suggests may be in violation of global trade rules.

In a communication forwarded to the World Trade Organization, India charged that some of the incentive programs in question make the availability of incentives contingent upon the use of domestic or state-specific products.

This "raises concerns about their compatibility with the obligation of the United States" under Article 2 of the WTO's Agreement on Trade-Related Investment Measures (TRIMs) and Article III:4 of the General Agreement on Tariffs and Trade, India said. "There are issues of consistency with relevant provisions of (WTO's) Agreement on Subsidies and Countervailing Measures as well."

Article 2 prohibits investment measures that are in violation of the national treatment principle established under Article III of GATT. Article III:4 in particular requires WTO members to provide imported goods with the same treatment afforded domestically produced goods with respect to all laws, regulations and requirements affecting their internal sale.

The Indian communication follows the Feb. 6 announcement by the United States that it was initiating WTO dispute settlement proceedings to address what it charges are illegal domestic content requirements in India's national solar energy program.

Five State, Local Programs Cited

India in particular cited five programs at the state and local level which raised concerns: the state of Michigan's 2008 Clean, Renewable, and Efficient Energy Act (Public Act 295); the Los Angeles Department of Water and Power's Solar Photovoltaic Incentive Program; the state of California's Self Generation Incentive Program (SGIP); and the Commercial Solar Photovoltaic Performance-Based Incentive Program as well as the Residential Solar PV Rebate Program offered by Austin Energy, a publicly-owned power company and a department of the City of Austin, Texas.

According to India, the Michigan program grants renewable energy credits to electricity providers for each megawatt hour of electricity generated from a renewable energy system constructed using equipment made in the state, or for each megawatt hour of electricity from a renewable energy system constructed using a workforce composed of residents from the state.

Under the Los Angeles program, payment credits are provided for photovoltaic and solar power equipment where at least 50 percent of the components are manufactured or assembled within the city limits, or where at least 50 percent of the wholesale value of the product is derived from the use of local labor or locally manufactured components.

California's SPIG program, which offers incentive payments to producers of wind turbine, fuel cell, and other environmentally friendly energy sources, provides an additional 20 percent incentive payment for the installation of equipment or technologies from a California supplier, India noted, while the two programs operated by Austin Energy offer higher rebates and higher payments for solar power generated from equipment which is at least 60 percent manufactured or assembled in Austin Energy's service area.

India asked the United States to provide details on the current status for each of the targeted programs in terms of their duration. It also asked the United States to provide details on any other state, regional or local level renewable energy programs where incentives or benefits are granted contingent upon compliance with domestic content requirements.

U.S. Has Similar Complaint Against India

The U.S. complaint against India focuses on domestic content requirements under the Jawaharlal Nehru National Solar Mission (JNNSM).
According to the Office of the U.S. Trade Representative, India initially required that developers of solar photovoltaic (PV) projects employing crystalline silicon technology use solar modules manufactured in India. India later expanded the domestic sourcing requirement to cover crystalline silicon solar cells as well.

India has also drafted new provisions that might expand the scope of the domestic content requirements to include solar thin film technologies, which comprise the majority of U.S. solar exports to India, USTR charged. India also offers solar energy developers participating in the JNNSM a guarantee that the government will purchase a certain amount of solar power at a highly subsidized tariff rate, provided that they use domestically manufactured solar equipment instead of imports.

The United States may request the establishment of a WTO dispute panel to rule on its complaint if WTO-required consultations between the two sides fail to produce a settlement.

Tar sands oil pipeline bill advances in Vermont Senate, in spite of warning from petroleum industry

Posted By Andrew Stein On March 24, 2013 @ 4:10 pm In Energy & Environment | 6 Comments

[1]

Despite legal pressures from the petroleum industry, the Vermont Senate advanced a bill on Friday designed to enhance state oversight of oil transmission pipelines.

Senators on the floor overwhelmingly supported S.58, which was freighted by concerns over Canadian tar sands oil being potentially pumped through the northeast region of Vermont. The 40-mile pipeline in question runs through the Northeast Kingdom, and has been in use for lighter crude since the 1940s. Critics say tar sands oil is more corrosive, has a higher risk of leaking from old pipelines and is harder to clean up in the case of a spill.

The voice vote moves the bill to a third and final reading of the legislation in the Senate this week.

According to Rep. David Deen, D-Westminster, if the Senate does not approve the bill, the House will not take it up. Deen, who chairs the House Fish and Wildlife Committee, introduced parallel legislation to S.58 in the House, [2] and his committee heard weeks of testimony on the issue. He told VTDigger that his committee recently dropped the bill to focus on a shoreline protection bill.

If S.58 were signed into law, it would add review by Act 250 environmental commissions in case of any "cognizable physical change to the pipeline or associated facilities, unless the change is solely for the purpose of repair." While natural gas pipelines fall under the direct purview of the quasi-judicial Public Service Board, an oil pipeline would only trigger review if it met the development review criteria of Act 250.

Act 250 is the state's governing land-use law, which regulates large-scale commercial developments. Regional Act 250 commissions determine whether proposed developments should receive permits.

Although the Senate voted in favor of the bill on Friday, the body sent the bill to the Judiciary Committee just a day before to address some legal concerns raised by lobbyists. After testimony from legal experts, the committee changed the bill's language.

A lobbyist, legal concerns and a warning letter

The decision to send the bill to Judiciary followed a letter from Downs Rachlin Martin lobbyist Joseph Choquette, who represents the American Petroleum Institute. He sent senators a letter on behalf of the Portland Pipe Line Corp., raising legal questions about S.58.

The Portland Pipe Line Corp. owns the Portland-Montreal pipeline, which connects Montreal oil refineries to Portland, Maine. The pipeline, which cuts through a northern slice of Vermont, is the only current entity that would be subject to S.58, and Portland Pipe Line CEO Larry Wilson told legislators in February that he opposes any added regulations on the line. [3]

Choquette's letter defended the current Act 250 process. He argued that there's no need to go down a road that could lead to legal issues with potential federal pre-emption. He said Act 250 already applies.

"We understand that any cognizable physical change to this pipeline would require a permit under existing law if such change may have a significant adverse impact on the environment," Choquette wrote. "To that end, there is a process already under way with full participation by environmental advocacy groups."

Choquette called on the Senate to send the bill to the Judiciary Committee for review, and he cautioned that the bill might violate the Vermont and U.S. constitutions.

"Treating this pipeline facility and company differently than all other regulated projects and entities that operate in Vermont would arguably run afoul of federal pre-emption principles that explicitly bar states from regulating oil pipeline safety; potentially constitute an impermissible attempt to nullify the President's exercise of his foreign affairs power under the U.S. Constitution as reflected in the Presidential Permits issued to Portland Pipe Line and potentially impose an unconstitutional burden on foreign or interstate commerce," he wrote.

Before the Senate took up the bill on Thursday, Choquette sent the letter to Sens. Dick Sears, D-Bennington, and Kevin Mullin, R-Rutland.

Sears, who chairs the Judiciary Committee, told VTDigger that Choquette's suggestion to bring the bill into his committee wasn't motivated by the letter so much as by the recognition that the bill affected one company.

"I don't think we should not do something because there's a threat of a lawsuit, but I think we should make ourselves fully aware of what we're up against," he said. "If the committee of jurisdiction thinks it's good public policy to pass a bill, I don't want to be in a position of killing it. But I do want to be in a position of making it the least risk-adverse as we can."

The committee that moved the bill to the floor is the Senate Natural Resources and Energy Committee.

Attorneys, competing views and a change of language

Friday morning, Sears and his committee met with legislative counsel and attorneys from Downs Rachlin Martin (DRM).

Peter Van Oot, a veteran environmental attorney with DRM, previously chaired the very Act 250 commission that would be charged with overseeing changes to the pipeline. He has also represented Portland Pipe Line for more than a decade.

He told the committee that the Choquette letter was not a threat of litigation from his client.

"They are trying to protect their business interests ... but I want to make it very clear that they have not asked us to threaten litigation, and we have not threatened litigation," he told the committee – a comment which was greeted with gesticulated signs of incredulity from the panel's members.

Van Oot did, however, raise concerns about potential targeting of Portland Pipe Line, if the bill were passed.

"This would dramatically change the rules and it would dramatically change the rules for one and only one facility and for one and only one entity, at least currently," he said. "When you look at that context, that suggests to me that this entity is being singled out and discriminated in that anyone else would play by very different rules under Act 250."

Robert Luce, another DRM attorney who testified, won a major case in the U.S. court of appeals that found railroads in Vermont were federally exempt from Act 250.

The bill, he said, "would create a very different standard for a particular industry, which distinguishes it from all other industries. ... The question that comes up from a constitutional perspective ... is why are you singling this particular industry out for this treatment."

Luce said that the bill would conflict with the White House and could violate the dormant commerce clause under the U.S. Constitution.

"Requiring that (regulation) would delay, restrict or prohibit the use of the pipeline for certain business purposes, and doing that directly interferes with presidential powers," he said. "This pipeline is operating under a presidential permit issued by the president or the State Department."

Legislative counsel, on the other hand, advised the committee that the presidential permits only apply to portions of the pipeline by the borders, not the entire pipeline.

There is also language in the bill that stipulates regulation of safety issues falls under the strict purview of the federal government. It is a provision meant to avoid a federal lawsuit, like the one the state currently finds itself embroiled in with Entergy Corp. over regulating the Vermont Yankee nuclear plant. [4]

The Legislature's legal team told the committee that changing the bill's language from requiring Act 250 review for "a change to the pipeline" to "a cognizable physical change to the pipeline" was more in line with existing case law and thus "more defensible."

The language also echoes the wording used in Choquette's letter.

The committee supported the language and so did the Senate in its second reading, but there was no discussion about whether the new language would trigger Act 250 review if Portland Pipe Line Corp. pumped tar sands oil through Vermont – which is the very notion that prompted the bill's creation.

Portland Pipe Line's Larry Wilson previously told legislators that he's "aggressively" seeking new opportunities for his company's line. Such opportunities include contracts with oil companies that want to distribute petroleum products from Alberta's tar sands region.

The Senate's decision comes two weeks after the Canadian government [5] voiced concern that Vermont towns were approving resolutions opposing the movement of tar sands oil through the state.

The bill is "basically unnecessary"

Jim Murphy, senior counsel for the National Wildlife Federation, and Sandra Levine, senior attorney for the Conservation Law Foundation, say that while they appreciate legislators' efforts, the state already has Act 250 jurisdiction over any such changes to the pipeline.

Joined by a coalition of environmental groups and Northeast Kingdom residents, the two attorneys asked the Northeastern Act 250 commission in January to verify that the state's

governing land-use law has authority over potential changes to the Portland-Montreal Pipeline. [6] The request is still pending.

"We've testified in the Senate about this, that it's basically unnecessary," Levine said. "If you're buying yourself a lawsuit, which clearly the pipeline company seems to be threatening, I think one should be thinking about whether it makes sense or not."

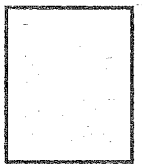
At the same time, she said, the Legislature can't back down from large corporations.

"Clearly the Legislature needs to be more careful, considering the litigation that came out of the Vermont Yankee vote," she added. "But the Legislature has a lot of authority, and it shouldn't let threats from corporations necessarily guide its actions."

Murphy said he has concerns about the new language in the bill, and he said that the previous language would not pre-empt federal authority.

"If you actually look at ... a presidential permit ... there is no basis, I believe, for determining that it would pre-empt the clear ability of states to regulate siting, routing and land-use issues, which is what Act 250 does," Murphy said.

DRM Letter to Senators on S.58



DRM Letter to Senators on Pipeline Bill

1 document

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6 Comments To "Tar sands oil pipeline bill advances in Vermont Senate, in spite of warning from petroleum industry"

#1 Comment By John Greenberg On March 25, 2013 @ 9:58 am

The article makes several references to the Vermont Yankee preemption lawsuit.

I therefore think it is only fair to note that nothing in that suit pertained to the PRODUCTS the Vermont legislature created: namely, Acts 74 and 150. No one suggested in that case that there was anything in the texts of the laws themselves which unconstitutionally entered the field preempted by the federal government.

Instead, Entergy focused on the legislative discussions which preceded the bills, and Judge Murtha found that legislators were "motivated" by safety considerations.

If Murtha's decision stands, then legislators would be ill-advised to pass ANY law at this point, if similar comments can be found anywhere in the legislative record. However free of preempted language the text of the law as passed might be, that fact could easily be ignored. It certainly was in the VY case. On the other hand, if there are more than one or 2 legislators who uttered the word "safety" in front of a microphone, the actual word of the law adopted will make little difference to judges who follow Murtha's decision. The Murtha precedent ALREADY pertains if there's any such language in the record.

Indeed, that's precisely why Murtha's decision is so disastrous: it would make it virtually impossible for a citizen legislature to do its business.

#2 Comment By Peter Romans On March 25, 2013 @ 7:52 pm

THE TYEE
B.C.'S HOME FOR NEWS, CULTURE AND SOLUTIONS

Testing the Right to Frack

NAFTA investor lawsuit against shale gas moratorium adds reason to fear FIPA.

View full article and comments:

The controversial Canada-China Foreign Investment Promotion and Protection Agreement, or FIPA, is still not ratified. It's hard to know exactly why that is given the Conservative government's enthusiasm for these corporate rights treaties. But the surprising strength and size of the public backlash to the China FIPA surely played a role.

One big reason people are so worried about this specific treaty (versus Harper's FIPAs with Tanzania, Cameroon, Zambia, etc) is how it will empower corporations from the world's largest consumer of energy and natural resources to sue Canada for hundreds of millions of dollars for delays in getting oil, gas and minerals out of the ground. Delays like a moratorium or ban on hydraulic fracturing, for example, or stricter environmental rules that make projects more expensive, will be vulnerable to investor-state lawsuits that can cost hundreds of millions if not billions of dollars at the end of the day.

This becomes a bigger problem for Canada as the China National Offshore Oil Corporation (CNOOC) . The formerly Canadian energy company has fracking operations in northern British Columbia and a desire to expand them. But public is leading to calls for action against the environmentally risky drilling technique. It's not a matter of if but when CNOOC would file a FIPA challenge against any crackdown on fracking. The absurd scenario is playing out right now in Quebec.

Demanding $250 million from Canadians

Last year, a U.S.-owned energy firm Lone Pine Resources sued Canada using investment rules in the North American Free Trade Agreement (NAFTA). The firm is challenging Quebec's 2011 moratorium on fracking in the St. Lawrence Valley, which was extended indefinitely by the new Parti Quebecois government. Lone Pine wants $250 million in compensation for the "arbitrary, capricious, and illegal revocation of [its] valuable right to mine for oil and gas."

Fracking uses massive amounts of water, thousands of litres of chemicals, and thousands of pounds of sand. This toxic stew is forced into the ground at high pressure in order to fracture the rock, allowing gas to flow up the well. Fracking fluid can contaminate drinking water with substances that cause cancer and organ damage, and affect neurological, reproductive and endocrine systems. Safely disposing of fracking wastewater is incredibly difficult. The process has been linked to earthquakes.

Despite these risks, Lone Pine's NAFTA claim says the Quebec government acted "with no cognizable public purpose," even though there is broad public support for a precautionary moratorium while the environmental impacts of fracking are studied. Milos Barutciski, a lawyer with Bennett Jones LLP, which is representing Lone Pine in the arbitration, told The Globe and the moratorium "was done for purely political reasons -- exactly what the NAFTA rights are supposed to be protecting investors against."

How level?

The investment chapter in NAFTA, like the FIPA with China, is often described as a way to level the playing field between national and foreign firms. But scratch the surface and you find that

the non-discrimination rules are the least important part. The treaties actually give foreign firms more rights and legal protection than local companies.

As a Canadian firm, Nexen would have to challenge a hypothetical freeze on fracking in B.C. before a provincial or federal court. New company owners CNOOC can bypass the courts to challenge B.C. or Canadian policies in front of largely unaccountable, paid arbitrators deciding the matter behind closed doors at the World Bank or elsewhere. Arbitrators have leaned heavily in favour of companies over governments in disputes related to energy and mining projects. Even when cases don't reach a final decision, there can be high costs to governments for getting in the way of mega-projects.

On March 8, the Canadian government announced it had settled outside of arbitration in another NAFTA investment claim from St. Marys Cement. The formerly Canadian (now Brazilian) cement and aggregate company had challenged a decision to rezone a large section of farmland in the province of Ontario so that a highly controversial quarry could not be built. The rezoning decision was celebrated by the nearby community but St. Marys claimed it violated NAFTA's minimum standards of treatment guarantee, and the treaty's prohibition on so-called indirect, or regulatory, expropriation.

The firm retracted its claim but only after the Ontario government agreed to pay $15 million of its stated $21-million investment in the quarry to date. In the middle of a recession, Ontario taxpayers basically paid St Mary's to not dig a quarry. That looks more like extortion than respecting minimum standards of treatment. The club these treaties give to investors to bully governments over conservation and environmental measures why Canada's mining sector [illegible] of the recent FIPAs with African countries where they are currently invested or interested in expanding.

The club swings both ways. Of the [illegible] against Canada, which total more than $5 billion in corporate claims, all involve reported breaches minimum standards of treatment, and most involve claims of indirect expropriation without compensation. It is a sad record that shows just how broadly investors will interpret their rights in treaties like the FIPA. Even where Canada wins a case, we have still paid sometimes millions of dollars defending it.

In the Lone Pine case, as with [illegible], the company says that Quebec failed to provide a "stable business and legal environment." But there is nothing in NAFTA or the FIPA with China on minimum performance requirements for corporations – no way to hold investors accountable for environmental, human rights and other violations. In fact performance requirements are banned outright, as Newfoundland and Labrador learned after Exxon Mobil and Murphy Oil successfully sued Canada under NAFTA to get out of a profit-sharing plan for offshore oil development.

Resistance to FIPA with China

For these reasons, and in particular the way investment treaties give foreign firms greater rights than national firms, the Australian government has rejected the practice of including investor-state dispute settlement in its trade agreements. Like Canada, Australia loves its mining companies. But it doesn't feel the need to socialize the risk they take when they invest at home or abroad. In Australia's 2011 trade policy, the government says Aussie companies should find other ways, outside of investment treaties, to secure their investments.

In B.C., resistance to the FIPA with China is very strong. The Hupacasath First Nation has filed for an injunction against the treaty, to stop the Harper government from ratifying until it has consulted with First Nations as the Constitution requires. The impact of the FIPA on Indigenous and Treaty rights could be pronounced, especially if it creates added pressure to approve unpopular tar sands, fracking, mining or pipeline projects containing Chinese investment. The Hupacasath will go to court for the first time in early April and are looking for support at

It was clear before the Lone Pine lawsuit against Quebec's fracking ban that the investment protections in NAFTA and Canada's many FIPAs were excessive. But the case brings new

urgency to the need to drastically reform or abolish the investor-state dispute settlement process. This is even more important as leaks from the ongoing Canada-European Union free trade negotiations show the Harper government entertaining [illegible] rules for European firms in Canada than the FIPA granted Chinese firms.

The chill effect from investor-state arbitration -- the worry in government that a policy will attract a lawsuit -- can be enough to deter strong public health and environmental protections. We have to be able to say "no" to fracking and other destructive mega-projects without paying hundreds of millions to oil, gas and mineral companies. If Harper ratifies the FIPA with China, or signs an even worse investment treaty with Europe, it will be much more difficult to do that.

Then again, with this government, that might be the treaty's biggest selling point.

Stuart Trew is the Council of Canadians' trade campaigner.

MAINE INTERNATIONAL TRADE CENTER

Global Resources. Local Expertise.

2013 Maine FDI List

Name	City	County	Parent Company	Headquarters	Products/Service
C&L Aviation Services	Bangor	Penobscot	C&L Aerospace	Australia	FAA certified repair station
Bachmann Industries Inc.	Auburn	Androscoggin	RHI Engineering	Austria	Civil engineering
Hannaford Brothers	Scarborough	Cumberland	Delhaize	Belgium	Food Retail
Abilis NE	Portland	Cumberland	Abilis Solutions	Canada	IT/Financial services
Albarrie Environmental Services	Lewiston	Androscoggin	Albarrie Canada Limited	Canada	Dust collection services & supplies
American Steel and Aluminum Corporation	South Portland	Cumberland	Novamerican Steel Inc.	Canada	aluminum and metal products
Bangor Hydro Electric Co.	Bangor	Penobscot	Emera	Canada	Utility (power distribution)
Boralex	Fort Fairfield	Aroostook	Boralex	Canada	Biomass power generation
Cascades Auburn Fiber, Inc.	Auburn	Androscoggin	Cascades	Canada	Pulp
Cavendish Agri Services Ltd.	Wales	Androscoggin	Cavendish Agri Services Ltd.	Canada	Chemical manufacturers and distributors
Cavendish Farms	Presque Isle	Aroostook	Cavendish Farms	Canada	Frozen potato products
Chadwick-BaRoss Inc.	Westbrook	Cumberland	Strongco Corp.	Canada	Heavy equipment distributor
Cherryfield Foods Inc.	Cherryfield	Washington	Oxford Frozen Foods	Canada	Retail food products
Cooke Aquaculture	Machiasport	Washington	Cooke Aquaculture	Canada	Aquaculture
Douglas Brothers Stainless Steel	Portland	Cumberland	Robert Mitchell, Inc.	Canada	Fabricated stainless steel piping
Stantec	Portland	Cumberland	Stantec, Inc.	Canada	Consulting services civil engineering
Federal Marine Terminals	Eastport	Washington	FedNav	Canada	Marine freight handling
Great Lakes Hydro America, LLC	Millinocket	Penobscot	Brookfield	Canada	Hydroelectric power generation
Heritage Memorials Ltd.	Sanford	York	Heritage Memorials Ltd.	Canada	Monuments and markers
Highland Lumber Company	Dixfield	Oxford	J.D. Irving Ltd.	Canada	Timber
Irving Forest Products	Fort Kent	Aroostook	J.D. Irving Ltd.	Canada	Pulp, tissue, paper
Irving Lumber Company	Strong	Franklin	J.D. Irving, Limited	Canada	Timber
Irving Oil Corporation	Statewide		Irving Oil Limited	Canada	Fuel, oil, gas, heating contractors
Irving Woodlands LLC	Ashland	Aroostook	J.D. Irving Ltd.	Canada	Sawmill
Fraser Sawmills (aka Ashland Lumbermill)	Ashland	Aroostook	Fraser Papers	Canada	Wholesale lumber
Katahdin Forest Management, LLC	Millinocket	Penobscot	Brookfield	Canada	Pulp, paper
Katahdin Timberlands, LLC	Millinocket	Penobscot	Brookfield	Canada	Timber
McCain Fertilizers Ltd.	Presque Isle	Aroostook	McCain Foods	Canada	Fertilizers
McCain Foods USA Inc.	Easton	Aroostook	McCain Foods	Canada	Potato products, french fries

2013 Maine FDI List

Name	City	County	Parent Company	Headquarters	Products/Service
Moose River Lumber Company	Jackman	Somerset	Sly-Crete Inc.	Canada	Lumber
Nautel	Bangor	Penobscot	Nautel	Canada	Transmitters
Orion Rope Works	Winslow	Kennebec	Canada Cordage Inc.	Canada	Rope
Padinox Inc., DBA Chaudier	Freeport	Cumberland	Padinox Inc.	Canada	Stainless steel cookware, utensils
Pattison Sign Group (NE)	Limestone	Aroostook	The Jim Pattison Group	Canada	Signage
Pepin Lumber Company	Coburn Gore	Franklin	Maurice Pepin	Canada	Lumber
Portbec D&G Forest Products	Bangor	Penobscot	Portbec Forest Products Ltd.	Canada	Forest products
St. Croix Courier	Calais	Washington	St. Croix Publishing	Canada	Newspapers
Stratton Lumber Inc.	Stratton	Franklin	Fontaine Inc.	Canada	Lumber
TD Bank	Statewide		Toronto Dominion	Canada	Financial services
T4G Limited Saco	Saco	Cumberland	T4G Limited	Canada	IT project services
Thomas Equipment Inc. USA	Mars Hill	Aroostook	Thomas Equipment Inc.	Canada	Skid steer loaders, mini excavators, potato handling equipment
Timber Resource Group	Farmington	Franklin	Fontaine Inc.	Canada	Logging services
Twin Rivers Paper Company	Madawaska	Aroostook	Twin Rivers Paper Company	Canada	Timber
Huhtamaki Food Service	Waterville	Kennebec	Huhtamaki Inc.	Finland	Food service, consumer packaging, tableware products
UPM-Madison	Madison	Somerset	UPM	Finland	Paper
Metso Paper USA Inc.	Biddeford	York	Metso Corporation	Finland	Paper
Greentech	Yarmouth	Cumberland	Greentech	France	Biotech, research, seaweed
Lufthansa Technik	Auburn	Androscoggin	Lufthansa Technik	Germany	FAA certified repair station
CYRO	Sanford	York	Evonik Industries AG	Germany	Industrial plastic sheeting
Kässbohrer All Terrain Vehicles, Inc.	Lewiston	Androscoggin	Käsbohrer Geländefahrzeug AG	Germany	Suppliers snow grooming vehicles
Lohmann Animal Health	Winslow	Kennebec	PHW Group	Germany	Poultry biologics
Tuchenhagen North America LLC	Portland	Cumberland	GEA Group	Germany	Centrifugal pumps
T-Mobile USA	Waterville	Kennebec	Deutsche Telekom	Germany	Mobile Phone Service Provider (call
Weber Machine USA	Bangor	Penobscot	Weber	Germany	Contractor's equipment
New Generation Network	Portland	Cumberland	New Generation Network	Germany	IT services
Bachmann Industries Inc.	Auburn	Androscoggin	Clyde Bergemann Power Group	Germany	Industrial Bypass and Exhaust Systems

MAINE INTERNATIONAL TRADE CENTER
Global Resources. Local Expertise.

2013 Maine FDI List

Name	City	County	Parent Company	Headquarters	Products/Service
Airco Industrial Gases	Kittery	York	The Linde Group	Germany	Industrial gases
Creative Mold Company	Auburn	Androscoggin	DESMA	Germany	Molds
Woodland Pulp, LLC	Baileyville	Washington	International Grand Investment Corp	Hong Kong	Wood pulp
Pike Industries	Lewiston	Androscoggin	CRH	Ireland	Construction
System Logistics	Lewiston	Androscoggin	System Logistics; div. of System Group S.p.A.	Italy	Material handling systems
Maine Manufacturing, LLC	Sanford	York	GVS	Italy	Filtration devices
Albatrans, Inc.	Portland	Cumberland	Albatrans SpA	Italy	Freight forwarders
Somic America	Brewer	Penobscot	Somic Ishikawa	Japan	Automotive components
Plasmine Technology Inc.	Portland	Cumberland	Harima Chemicals Inc.	Japan	Chemicals dealers (rosin)
World Harbors	Auburn	Androscoggin	Mizkan Group	Japan	Sauces, marinades, drink mixes
AVX Tantalum Corporation	Biddeford	York	Kyocera Corporation	Japan	Electronic capacitors
Ducktrap River Fish Farm	Belfast	Waldo	Fjord Seafood ASA	Norway	Smoked seafood
Jotul North America	Portland	Cumberland	Jotul ASA	Norway	Cast iron stoves
MariCal	Portland	Cumberland	Teknoinvest Management AS	Norway	Aquaculture
Rubb Inc.	Sanford	York	Rubb Motor A/S	Norway	Tension membrane structures
Vingtech	Biddeford	York	Simrad Optronics ASA	Norway	Mechanical & electro optical engineering
Laserwords	Lewiston	Androscoggin	SPi Global	Philippines	Publishing
SAPPI Fine Paper North America	Westbrook	Cumberland	SAPPI Limited	South Africa	Paper
Central Maine Power Co.	Augusta	Kennebec	Iberdrola	Spain	Utility (Power Distribution)
Dragon Products Company Inc.	Thomaston	Knox	Portland Valderrivas (and Cementos Lemona)	Spain	Cement manufacturing
Sprague Energy	South Portland	Cumberland	Axel Johnson Inc./Axel Johnson AB	Sweden	Materials handling services (oil, petroleum etc.)
Rynel	Wiscasset	Lincoln	Molnlycke Health Care AB	Sweden	Medical foam/wound care components
Clariant Corporation	Lewiston	Androscoggin	Clariant	Switzerland	Speciality chemicals
Eldur Corporation	Bangor	Penobscot	Eldur AG	Switzerland	Leadwire manufacturers
Lanco Assembly Systems	Westbrook	Cumberland	Lanco AG	Switzerland	Turnkey automated assembly & test systems

2013 Maine FDI List

Name	City	County	Parent Company	Headquarters	Products/Service
Lindt Chocolate Store	South Portland	Cumberland	Chocoladefabriken Lindt & Spruengli International AG	Switzerland	**Chocolate**
Lonza Rockland	Rockland	Knox	Lonza	Switzerland	**Agar - molecular biology industry**
Poland Spring Water Corporation	Poland Spring	Androscoggin	Nestle	Switzerland	**Bottled Spring water**
Remstar International Inc.	Westbrook	Cumberland	Kardex-Remstar International Group	Switzerland	**Automated storage and retrieval systems**
Schlumpf Inc.	Windham	Cumberland	Schulmpf AG	Switzerland	**Unwinding and winding machinery components**
Tate & Lyle	Houlton	Aroostook	Tate & Lyle	United Kingdom	**Potato starch**
Hunting Dearborn, Inc.	Fryeburg	Oxford	Hunting PLC	United Kingdom	**Deep hole drilling**
Citizens Bank	Portland	Cumberland	Royal Bank of Scotland	United Kingdom	**Financial services**
H I L Technology	Portland	Cumberland	Hydro International	United Kingdom	**Waste and storm water treatment technology**
WahlcoMetroflex	Lewiston	Androscoggin	Senior PLC	United Kingdom	**Expansion joints/industrial metal fabricator**
Quantrix	Portland	Cumberland	IDBS	United Kingdom	**Database/info systems; business analysis**
AMEC	Portland	Cumberland	AMEC	United Kingdom	**Engineering consultancy**
Bucksport Energy LLC	Bucksport	Hancock	Hydro-Quebec (Canada) & GDF Suez (Fr)		**Power generation (gas)**

CITIZEN TRADE POLICY COMMISSION
DRAFT AGENDA

Friday, May 24, 2013 at 9:30 A.M.
Room 214, Burton M. Cross State Office Building
Augusta, Maine

9:30 AM Meeting called to order

I. Welcome and introductions

II. Review of Legislative Bills of Interest (Lock Kiermaier, Staff) (9:30 AM)

III. Presentation from Daniel Deveau, Maine Canada Trade Ombudsman (10 AM)

IV. Presentation from Representative Sharon Treat regarding her written comments submitted to the USTR on the Trans-Atlantic Trade and Investment Partnership (TTIP) (10:30 AM)

V. Update on IGPAC/USTR activity (Representative Sharon Treat, CTPC Chair) (11:00 AM)

VI. Articles of interest (Lock Kiermaier, Staff) (11:30 AM)

VII. Proposed next meeting date and suggestions for agenda topics

Adjourn

Citizen Trade Policy Commission

Bills of Possible Interest

126th Maine State Legislature; 1st Regular Session

Updated 5/23/13

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
890	**An Act To Buy American-made Products**	Sen. Troy Jackson	Labor, Commerce, Research, and Econ. Dev	3/14/2013	5/16/2013	Divided Report	Not yet determined	This bill is a concept draft pursuant to Joint Rule 208. This bill proposes to provide a preference in state purchasing for American-made products.	As a concept bill there is not much to react to , plus the bill has been tabled.
491	**An Act Regarding Timber Harvesting on Land Managed by the Division of Parks and Public Lands**	Sen. Troy Jackson	Labor, Commerce, Research, and Econ. Dev	3/14/2013	5/16/2013	tabled in Senate	No Fiscal Impact	This bill prohibits the Department of Agriculture, Conservation and Forestry, Division of Parks and Public Lands from contracting for timber harvesting on land under its management if the contractor uses persons employed under the federal labor certification process for employment of foreign workers in logging for that purpose.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
1315	**An Act To Ensure the Safety of Compounded Drugs**	Rep. Sharon Treat	Labor, Commerce, Research, and Econ. Dev	4/22/2013	4/30/2013	OTP-AMD	Not yet determined	This bill strengthens Maine's laws on compounding pharmacies. See detailed summary on CTPC WORD document	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
171	**An Act To Facilitate the Licensing of International Mail Order Prescription Pharmacies by the Maine Board of Pharmacy**	Sen. Troy Jackson	Labor, Commerce, Research, and Econ. Dev	2/19/2013	5/17/2013	Divided Report	No Fiscal Impact	The purpose of this bill is to facilitate the licensing of international mail order prescription pharmacies by the Maine Board of Pharmacy. See detailed summary on CTPC WORD document	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
449	**An Act To Ensure Consumer Choice in the Purchase of Prescription Drugs**	Sen. Doug Thomas	Labor, Commerce, Research, and Econ. Dev	3/13/2013	5/17/2013	Carry Over Request	Not yet determined	This bill clarifies and affirms the ability of Maine consumers to purchase mail order prescription drugs from licensed pharmacies that are located in certain nations specified under federal law.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
813	**An Act To Promote the Sale of Maine Milk**	Rep. Joseph Brooks	State & Local Gov	3/27/2013	4/8/2013	Senate; Dead	Not yet determined	This bill requires a state-owned or state-operated facility that sells or contracts with a person to sell beverages directly to the public, including a facility on the Maine Turnpike, to have available for sale milk processed at a milk plant in the State. This bill exempts facilities in an institutional setting in which sales of beverages to the public are incidental, including a state-owned postsecondary institution or correctional facility.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
1326	**An Act To Prevent Youth Tobacco Use**	Rep. Megan Rochelo	Taxation	5/6/2013	5/14/2013	ONTP	Not yet determined	This bill requires that all tobacco products be taxed at rates equivalent to the current tax on cigarettes. The bill provides an appropriations and allocations section to fund anticipated increased demand on the tobacco hotline for those people who are seeking to quit tobacco use.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1338	**An Act To Prohibit State and Local Governments from Contracting with Corporations That Engage in Business in Known Terrorist States**	Rep. Teresea Hayes	State & Local Gov	4/22/2013	5/6/2013	Divided Report	Not yet determined	This bill requires that, beginning January 1, 2014, the State, the University of Maine System, the Maine Community College System, the Maine Maritime Academy and municipalities exclude any business entity or individual from doing business with the State, the University of Maine System, the Maine Community College System, the Maine Maritime Academy or a municipality if that business entity or individual does business with any company, or any subsidiary, affiliate or parent of any company, that does business with a country designated by federal law as a state sponsor of terrorism. It also requires that counties and school boards adopt policies by January 1, 2014 that require counties and school boards to exclude any business entity or individual from doing business with a county or school board if that business entity or individual does business with any company, or any subsidiary, affiliate or parent of any company, that does business with a country designated as a state sponsor of terrorism.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1381	**An Act To Promote Rural Job Creation and Workforce Development**	Sen. Troy Jackson	Labor, Commerce, Research, and Econ. Dev	4/22/2013	5/3/2013	Senate; Dead	Not yet determined	This bill gives a preference in state contracting to bidders who primarily employ residents of the State and to bidders who coordinate with regional workforce development programs and who fill at least 20% of positions on the project with low-income or long-term unemployed people. The bill requires that successful bidders on public building or public works contracts with the State, counties, cities and towns and every charitable or educational institution that is supported in whole or in part by aid granted by the State or by a municipality commit to coordinate with regional workforce development programs and make best efforts to hire low-income and long-term unemployed people. The bill also requires state public works programs to give hiring preference to residents of the county where the work is being performed.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1254	**An Act To Increase Consumption of Maine Foods in All State Institutions**	Rep. Craig Hickman	State & Local Gov	4/22/2013	5/1/2013	Divided Report	Not yet determined	Current law requires state and school purchasers to buy meat, fish, dairy products, excluding milk and eggs, and species of fruits and fresh vegetables directly from Maine food producers or from food brokers. This bill establishes a minimum percentage of Maine foodstuffs that must be purchased, requiring at least 15% for the 10 years beginning January 1, 2014, at least 25% for the next 10 years and at least 35% beginning in 2034.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties
1103	**An Act To Encourage Development in the Logging Industry**	Sen. Troy Jackson	State & Local Gov	4/8/2013	4/12/2013	Divided Report	Not yet determined	This bill would withhold a tax incentive, eliminate General Fund money for forest fire protection, and would proscribe a tax penalty for individuals who, either directly or through a contracting entity, hire foreign H-2A visa workers for timber harvesting operations or fail to give required notice concerning their use of H-2A foreign workers for timber harvesting on their land.	The purpose of this bill could concievably be overriden by prospective sections of the TPPA or other existing or prosepective international trade treaties

LD #	Bill Title	Bill Sponsor	Committee of Reference	Date of Public Hearing	Date of Work Session	Current status	Fiscal Impact?	Summary	CTPC Staff Comment
1151	**An Act Regarding the Administration and Financial Transparency of the Citizen Trade Policy Commission**	Rep. Joyce Maker	Labor, Commerce, Research, and Econ. Dev	4/8/2013	4/12/2013	Enacted; on the Appropriations Table	Appropriations to a new Citizen Trade Policy Commission program in the Legislature and offsetting deappropriations	This bill modifies the law governing the Citizen Trade Policy Commission to provide that: 1. To the extent funding permits, the Legislature, through the commission, must contract for year-round staff support for the commission. To the extent the commission lacks adequate staff support, the commission may request staff support from the Legislative Council, except that Legislative Council staff support is not authorized when the Legislature is in regular or special session; and 2. All funds appropriated, allocated or otherwise provided to the commission must be separately accounted for and used solely for the purposes of the commission and are nonlapsing. At the beginning of each fiscal year, and at any other time at the request of the cochairs of the commission, the Executive Director of the Legislative Council must provide to the commission an accounting of all funds available to the commission, including funds for staff support. The bill is designated an emergency to ensure that the limited funding available to the commission does not lapse at the end of the current fiscal year.	

Canada and the U.S. share.

A long tradition of cooperation in defending our continent and fighting for freedom.
The world's largest trading relationship.
A common border that stretches across 8,893 kilometers (5,526 miles) of land and three oceans.
Stewardship of a rich and diverse environment, including 20 percent of the world's supply of fresh water in the Great Lakes
Canada is the leading market for goods for 35 U.S. states. The U.S. exports more goods and services to Canada than to any individual country – more than to Japan and Mexico combined.
The Canada-U.S. relationship also includes one of the world's largest bilateral investment relationships. The United States is Canada's largest foreign investor and the most popular destination for Canadian investment.

Partners for Energy Security

Canadians and Americans share the closest energy relationship in the world. Canada is the leading and most secure, reliable, and competitive energy supplier to the United States, including crude oil and refined petroleum products, natural gas, electricity, coal and uranium. Canada also imports a significant amount of energy from the US, particularly electricity and natural gas.

In 2011, Canada's energy exports were valued at US$120 billion (CAN$119 billion), with virtually all (90%) of it going to the US. In addition, Canada:

Exported 2.7 million barrels per day of crude oil and refined products to the U.S., representing 24% of total U.S. petroleum imports;
Supplied approximately 20% of the uranium used in U.S. nuclear power plants;
Provided 90% of all U.S. natural gas imports, representing 13% of U.S. consumption; and
Imported US$56 billion (CAN$55 billion) of energy products, of which US$18.2 billion (CAN$18 billion) (33%) was from the US. Canadian natural gas imports, which now stand at almost 3 billion cubic feet per day, have tripled approximately since 2006. With the exception of very small amounts of natural gas imports, Canada purchases most of its natural gas from the US.

Like natural gas, there is significant two-way trade in electricity between Canada and the US. The Canada and US electricity grid is deeply integrated with more than 30 major transmission interties connecting all Canadian provinces to neighbouring US states, except Nova Scotia, PEI, and Newfoundland.

Oil

Canada: the largest oil supplier to the United States

Canada is the world's 6th largest oil producer. In 2011, Canada's total oil production was 3 million barrels a day; output is expected to rise further with increased development of oil sands.

Canada's oil reserves represent a safe, secure and long-term energy supply for North America.

Canada has the world's third-largest proven reserves (after Saudi Arabia and Venezuela) at 172.8 billion barrels, 168.7 billion of which are in the oil sands. As technology evolves, oil sands reserves could grow even larger, up to an estimated 315 billion barrels. Beyond the oil sands, petroleum development is also taking place in several other parts of Canada, including the north and the Atlantic offshore region.

Canadian oil is a major contributor to U.S. energy security by helping to eliminate dependence on foreign oil. A 2011 study commissioned by the U.S. Department of Energy shows that higher oil imports from Canada, almost all of which would come from the oil sands, could help to eliminate U.S. dependence on imports from foreign suppliers such as Venezuela and the Middle East by 2030.

Canada's stable economic and political environment attracts businesses from around the world. The oil sands represent significant business opportunities for Canadians and Americans. U.S. firms are significant investors, producers and developers of new technology in Canada's oil sector. In the oil sands alone, close to 1,000 U.S. companies of all sizes, from almost every state, and from all sectors of the economy, including engineering, high-tech, and financial services, directly supply goods and services to companies producing oil in Canada.

In fact, between 2010 and 2035, oil sands development is anticipated to support, on average, an estimated 93,000 jobs per year in the U.S. With increased pipeline capacity, this could grow to, on average, 160,000 jobs per year. Oil sands development is also anticipated to contribute, on average, US$8.5 billion (CAN$8.4 billion) per year to the U.S. gross domestic product over the same time period, and US$14.6 billion (CAN$14.4 billion) with increased pipeline capacity.

Finally, Canada's regulatory framework is among the most stringent in the world. Projects are subject to rigorous environmental and regulatory review, and the federal and provincial governments require extensive environmental monitoring and reporting throughout the life of each project.

Natural Gas

Canada: the largest natural gas supplier to the United States

Canada is the third-largest natural gas producer in the world, producing 5.4 trillion cubic feet per year, and the world's third-largest exporter of natural gas.

In 2011, Canada provided 90% of all U.S. natural gas imports, representing 13% of U.S. consumption. Canadian exports of natural gas go primarily to the U.S. Northeast, Midwest, Rocky Mountains, California and Pacific Northwest.

Canadian Natural Gas Facts - 2011

14.0 billion cubic feet/day — total production
8.7 billion cubic feet/day — total exports
70.0 trillion cubic feet — total proved reserves

Canada is continually investing in natural gas exploration and infrastructure.

Current estimates suggest Canada's marketable natural gas resource ranges between 733 and 1304 trillion cubic feet, representing well over one hundred years of domestic production at current rates.

Shale gas innovative technology is expanding Canadian production. Liquefied natural gas export terminals are being developed to reach overseas markets. Canadian interest in shale gas production is growing quickly, particularly in the Horn River and Montney Basins in northeast British Columbia.

Free trade and open markets, as well as a stable policy and regulatory environment, encourage natural gas investments and strengthen North American energy security.

Electricity

Canada: the largest electricity supplier to the United States

Canada is one of the world's largest producers of hydroelectricity. As the largest source of renewable power in North America, hydroelectricity accounts for about 60% of Canada's total electricity generation, representing over three times the global average.

In fact, over 3/4 of Canada's electricity comes from sources that do not emit greenhouse gases. Clean Canadian electricity represents a reliable source of power and is a key element in ensuring long-term North American energy security and maintaining our collective efforts to reduce greenhouse gas emissions.

The portion of Canada's electricity generated by coal—which totaled 12.6% in 2010—has been decreasing over the last few years. Emissions from the electricity generating sector will continue to fall over the coming years as new emission regulations for power generating facilities will require power plants to meet more stringent emissions standards.

Maine and Canada

29,200 Maine jobs depend on trade with Canada
6,300 Mainers are employed by Canadian-owned businesses
Maine sells more goods to Canada than to any other country in the world
Total Canada–Maine goods trade: $3.3 billion

Maine–Canada facts

Foreign export markets

Largest export market: Canada
% foreign-bound goods sold to Canada: 32%

Merchandise trade

Maine exports to Canada: $1.1 billion
Maine imports from Canada: $2.1 billion
Bilateral trade: $3.3 billion

Jobs*

jobs that depend on trade with Canada: 29,200
employed by Canadian-owned businesses: 6,300

** Job numbers from trade (2010 data) and Canadian-owned businesses (2009 data) are from a 2012 study commissioned by the Government of Canada*

Tourism

Maine visits by Canadians: 1,143,600, *$356 million spent*
Maine visits to Canada: 841,700, *$106 million spent*

Top exports

Fish & crustaceans: $245 million
Paper & paperboard: $190 million
Wood & semi-finished wood products: $156 million
Wood pulp: $45 million
Softwood lumber: $37 million
Prepared vegetables: $37 million
Fuel oil: $33 million
Fruits & nuts: $32 million
Meat, fish & seafood preparations: $30 million
Plastics & plastic articles: $24 million
Automobiles: $19 million

Optical, medical & precision instruments: $15 million
Motor vehicle parts: $14 million

Top imports

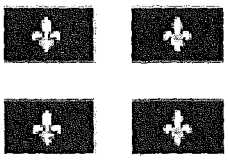
Wood pulp: $343 million
Fuel oil: $300 million
Fish & crustaceans: $152 million
Natural gas & other gases: $133 million
Paper & paperboard: $131 million
Electricity: $130 million
Inorganic chemicals: $104 million
Plastics & plastic articles: $59 million
Softwood lumber: $44 million
Prepared vegetables: $40 million
Wood & semi-finished wood products: $37 million
Salt, sulfur, earth & stone, lime & cement: $27 million
Iron & steel tubes, pipes & sheets: $23 million

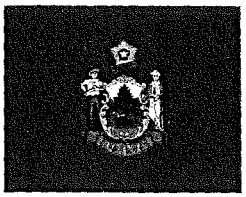
Maine exports $1.1 billion in goods to Canada

Forest products (38%)
Agriculture (34%)
Equipment & machinery (8%)
Transportation (7%)
Energy (3%)
Minerals & metals (3%)
Other (7%)

Maine imports $2.1 billion in goods from Canada

Energy (27%)
Forest products (26%)
Agriculture (15%)
Chemicals (6%)
Minerals & metals (4%)
Equipment & machinery (4%)
Other (17%)





COOPERATION AGREEMENT

BETWEEN

THE *GOUVERNEMENT DU QUÉBEC*

AND

THE GOVERNMENT OF THE STATE OF MAINE

THE *GOUVERNEMENT DU QUÉBEC*,

represented herein by its Premier, Ms Pauline Marois

AND

THE GOVERNMENT OF THE STATE OF MAINE,

represented herein by its Governor, Mr. Paul LePage

Hereinafter referred to as the Parties,

WHEREAS Québec and the State of Maine have a common border, are historically linked and share common interests;

WHEREAS Québec and the State of Maine maintain close economic and cultural relations;

WHEREAS Québec and the State of Maine also maintain cooperative relations through organizations such as the Conference of New England Governors and Eastern Canadian Premiers, the Council of State Governments and the Eastern Border Transportation Coalition;

WHEREAS THE PARTIES WISH to strengthen their ties and increase their cooperation in the areas of regional economic development, energy, natural resources, transportation, public safety, culture and the Francophonie;

WHEREAS THE PARTIES ALSO WISH to encourage and foster relations between their business communities;

AGREE TO THE FOLLOWING:

SECTION 1

The Parties shall encourage and support cooperation in the areas of regional economic development, energy, natural resources, transportation, public safety, culture and the Francophonie within their respective powers.

SECTION 2

The Parties shall also encourage businesses and economic development organizations to participate in international economic events that are held in Québec and Maine.

They shall promote meetings and networking between their respective businesses.

SECTION 3

ENERGY AND NATURAL RESOURCES

The Parties agree to encourage the exchange of information and expertise as well as stronger cooperative relations between stakeholders from different spheres in the areas of clean and environmentally friendly energy technologies, particularly hydroelectricity, wind energy, bioenergy, and the development of smart grids and innovative energy efficiency programs. They also agree to continue their dialogue in an effort to find common solutions to the joint challenges that are affecting energy and other areas, the supply of clean and renewable electricity, competitiveness and the stability of energy prices for consumers.

The Parties emphasize the strategic character of the cross-border infrastructures that are used to transport oil and gas.

The Parties agree to continue their regular dialogue on the forestry sector. They agree to work actively together to promote the use of timber in construction.

SECTION 4

TRANSPORTATION

The Parties recognize the significance of close cooperation between the *Ministère des Transports du Québec* and the Maine Department of Transportation in supporting the greater economic and sustainable development of the region and its competitiveness. As part of their respective objectives, the Parties agree to encourage cooperation between the widest possible range of public and private stakeholders with a view to improving the movement of goods and people and increasing the efficiency, safety and security of transportation systems on both sides of the border.

The Parties agree to work together on issues of common interest, such as the improvement of road infrastructures surrounding border crossing facilities, intelligent transportation systems, road safety, including interactions between road network users and large wildlife, legislation and research, communications in emergency situations that affect transportation, and all other issues that the Parties deem appropriate.

The Parties shall promote meetings and networking between their respective businesses.

improvement of energy efficiency, the reduction of greenhouse gases and adaptation to the impacts of climate change.

SECTION 5

SECURITY

The Parties agree to encourage their respective law enforcement organizations to cooperate with each other.

They agree to continue to share information in accordance with the Agreement between the *Gouvernement du Québec* and the Government of the state of Maine with respect to the exchange of law enforcement information, which was signed on February 12, 2004.

They also agree to provide mutual assistance to the extent possible in managing any emergency or disaster when the affected jurisdiction requests assistance, whether said request arises from a natural disaster, a hazard, a technological disaster or civil emergency aspects of resource shortages, as stipulated in the International Emergency Management Assistance Memorandum of Understanding, done at Halifax, on July 18th, 2000.

SECTION 6

CULTURE

The Parties agree to work together to encourage exchanges related to culture.

SECTION 7

THE FRANCOPHONIE

The Parties agree to work together to strengthen their ties and exchanges in relation to the Francophonie and share their expertise and know-how in French in a number of areas.

In addition, they intend to cooperate closely to carry out the World Acadian Congress, which will take place August 8 to 24, 2014, in Acadia of the Lands and Forests.

SECTION 8

IMPLEMENTATION OF THE AGREEMENT

The Parties shall create a Québec-Maine Joint Committee that is responsible for implementing this Agreement. The members of this committee shall be appointed

b) determine the approaches to be used to carry out the activities and projects selected under the Action Plan and determine the resources required by both Parties to ensure their efficient implementation;

c) monitor the activities undertaken under this agreement, evaluate the results and, as warranted, make the required adjustments;

d) examine all issues related to the implementation and interpretation of this agreement; and

e) identify sectoral agreements and joint documents whose signature is planned in the subsequent two years.

The Québec-Maine Joint Committee shall forward to the Premier of Québec and the Governor of Maine an annual report of its activities.

SECTION 9

FINAL PROVISIONS

The Parties may mutually agree to expand this Agreement to include new areas of cooperation or to increase or complete the current degrees of cooperation, where appropriate, by signing agreements, minutes of proceedings, official records or any other joint document concerning the specific sectors, activities or projects.

This agreement shall be in full force and effect on the day it is signed by the Parties and shall remain in full force and effect until terminated by notice given in writing by one or the other Party. This agreement shall terminate the 180th day following the said notice in writing.

This Agreement replaces the Memorandum of understanding on Economic Cooperation between the *Gouvernement du Québec* and the Government of the State of Maine, which was signed on June 8, 1995.

Done at _____ on this th day of 2013, in duplicate, in French and English, both texts being equally authentic.

FOR THE *GOUVERNEMENT DU QUÉBEC*

_____

FOR THE GOVERNMENT OF THE STATE OF MAINE

_____

Proclamation

WHEREAS, Maine potato farmers have had a significant harvest;

WHEREAS, the quality of Maine potatoes meet certain exacting criteria;

WHEREAS, the processing of these potatoes may need to be accomplished in Canada pursuant to an easement granted;

WHEREAS, commercial vehicles may not have the appropriate equipment available to move this product on an expedited basis;

WHEREAS, farmers in the region may be able to transport this product to market on an emergency basis to prevent spoilage; and

WHEREAS, these conditions require immediate action to ensure that crops are not lost due to failure to transport.

NOW, THEREFORE, I, Paul R. LePage, Governor of the State of Maine, by virtue of the authority vested in me by the Constitution and laws of Maine, find that these conditions constitute a limited civil emergency under 37-B M.R.S.A. § 742, and thereby necessitate the suspension of the enforcement of the provisions of Title 29-A, Chapter 5, and of Title 29-A, section 1252 against individuals transporting potatoes pursuant to the Canadian easement, save that the enforcement of Title 29-A, section 1251 shall not be suspended. Accordingly, I do hereby declare that a State of Emergency exists for these limited purposes within the State of Maine as of March 22, 2013 through April 20, 2013.

Paul R. LePage, Governor

AR5/AR5_documents/doc20-rev1.pdf). Authors were nominated starting in January 2010 and selected in May 2010. All IPCC reports go through two broad reviews: a "first-order draft" reviewed by experts, and a "second-order draft" reviewed by both experts and governments. The Second Order Draft of the Working Group II contribution to the 5th Assessment Report will be available for review beginning on 29 March 2013.

As part of the U.S. Government Review of the Second Order Draft of the Working Group II Contribution to the 5th Assessment Report, the U.S. Government is soliciting comments from experts in relevant fields of expertise (Again, the Table of Contents for the Working Group contribution can be viewed here: *http://www.ipcc-wg2.gov/AR5/AR5_documents/doc20-rev1.pdf*)

Experts may now register to review the draft report at: *http://review.globalchange.gov*; the report will be available for download once it is released, 29 March 2013. To be considered for inclusion in the U.S. Government submission, comments must be received by 01 May 2013.

The *United States Global Change Research Program* will coordinate collection and compilation of U.S. expert comments and the review of the report by a Review Committee of Federal scientists and program managers in order to develop a consolidated U.S. Government submission, which will be provided to the IPCC by 24 May 2013. Expert comments received within the comment period will be considered for inclusion in the U.S. Government submission. Instructions for registering as a reviewer, the process of the review itself and submission of comments—as well as the Second Order Draft of the report—are available at: *http://review.globalchange.gov.*

Experts may choose to provide comments directly through the IPCC's expert review process, which occurs in parallel with the U.S. government review. More information on the IPCC's comment process can be found at *http://www.ipcc.ch/activities/activities.shtml* and *http://www.ipcc.ch/pdf/ar5/review_of_wg_contributions.pdf.* To avoid duplication, those participating in the U.S. Government Review should not also participate in the Expert Review process which submits comments directly to the IPCC Secretariat. Comments to the U.S. government review should be submitted using the Web-based system at: *http://review.globalchange.gov.*

This certification will be published in the **Federal Register.**

Dated: March 27, 2013.

Trigg Talley,

Director, Office of Global Change, Department of State.

[FR Doc. 2013–07505 Filed 3–29–13; 8:45 am]

BILLING CODE 4710–09–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Request for comments and notice of a public hearing.

SUMMARY: On March 20, 2013, the United States Trade Representative (USTR) notified Congress of the Administration's intention to enter into negotiations for a Transatlantic Trade and Investment Partnership (TTIP) agreement with the European Union (EU) aimed at achieving a substantial increase in transatlantic trade and investment. Before initiating such negotiations, the Trade Act of 1974 requires that, with respect to any proposed trade agreement, any interested persons be afforded an opportunity to present his or her view regarding any matters related to the proposed trade agreement. Accordingly, USTR is seeking public comments on the proposed TTIP, including regarding U.S. interests and priorities, in order to develop U.S. negotiating positions. Comments may be provided in writing and orally at a public hearing.

DATES: Written comments are due by midnight, May 10, 2013. Persons wishing to testify orally at the hearing must provide written notification of their intention, as well as a summary of their testimony, by midnight, May 10, 2013. The hearing will be held on May 29 and 30 beginning at 9:30 a.m., at the main hearing room of the United States International Trade Commission, 500 E Street SW., Washington, DC 20436.

ADDRESSES: Public comments should be submitted electronically at *www.regulations.gov.* If you are unable to provide submissions at *www.regulations.gov,* please contact Yvonne Jamison, Trade Policy Staff Committee (TPSC), at (202) 395–3475, to arrange for an alternative method of transmission.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning written comments, please contact Yvonne Jamison at the above number. All other questions regarding the TTIP agreement should be directed to David Weiner, Deputy Assistant USTR for Europe, at (202) 395–9679.

SUPPLEMENTARY INFORMATION:

1. Background

The decision to launch negotiations for a TTIP agreement follows a year-long exploratory process conducted by the U.S.-EU High Level Working Group on Jobs and Growth (HLWG), established by President Obama and EU leaders during their November 2011 Summit Meeting, and led by U.S. Trade Representative Ron Kirk and EU Commissioner for Trade Karel De Gucht. USTR provided two opportunities for the public to comment as part of the HLWG mandate in 2012; comments received in response to these solicitations, and during a large number of advisory committee briefings and other meetings with stakeholders, played an important role in shaping the HLWG's recommendations. In its February 11, 2013 Final Report, the HLWG concluded that an agreement that addresses a broad range of bilateral trade and investment policies, as well as global issues of common interest, could generate substantial economic benefits on both sides of the Atlantic. (See *http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/final-report-us-eu-hlwg*).

USTR is observing the consultative and administrative procedures of the Bipartisan Trade Promotion Authority Act of 2002 (19 U.S.C. 3804) with respect to notifying and consulting with Congress regarding the TTIP negotiations. These procedures include providing Congress with 90 days advance written notice of the President's intent to enter into negotiations and consulting with appropriate Congressional committees regarding the negotiations. To that end, on March 20, 2013, after having consulted with relevant Congressional committees, the USTR notified Congress that the President intends to enter into negotiations of an agreement with the EU, with the objective of concluding a high-standard agreement that will benefit U.S. workers, manufacturers, service suppliers, farmers, ranchers, innovators, creators, small- and medium-sized businesses, and consumers.

In addition, under the Trade Act of 1974, as amended (19 U.S.C. 2151, 2153), in the case of an agreement such as the proposed TTIP agreement, the President must (i) afford interested persons an opportunity to present their views regarding any matter relevant to the proposed agreement, (ii) designate an agency or inter-agency committee to

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hold a public hearing regarding the proposed agreement, and (iii) seek the advice of the U.S. International Trade Commission (ITC) regarding the probable economic effect on U.S. industries and consumers of the modification of tariffs on imports pursuant to the proposed agreement. USTR intends to hold a public hearing on specific issues pertaining to the proposed negotiations on May 29 and 30, 2013. In addition, USTR has requested that the ITC provide advice to USTR on the probable economic effects of an agreement.

2. Public Comments

Written Comments: The TPSC Chair invites interested parties to submit written comments to assist USTR as it works with other U.S. government agencies and continues to consult with Congress to develop U.S. negotiating objectives and proposals for the proposed TTIP agreement. Comments may address the reduction or elimination of tariffs or non-tariff barriers on any articles provided for in the Harmonized Tariff Schedule of the United States (HTSUS) that are products of the EU, any concession that should be sought by the United States, or any other matter relevant to the proposed agreement. The TPSC Chair invites comments on all of these matters and, in particular, seeks comments regarding:

(a) General and product-specific negotiating objectives for the proposed agreement;

(b) economic costs and benefits to U.S. producers and consumers of removal of tariffs and removal or reduction in non-tariff barriers on articles traded with the EU;

(c) treatment of specific goods (described by HTSUS numbers) under the proposed agreement, including comments on—

(1) product-specific import or export interests or barriers,

(2) experience with particular measures that should be addressed in the negotiations, and

(3) approach to tariff negotiations, including recommended staging and ways to address export priorities and import sensitivities in the context of the proposed agreement;

(d) adequacy of existing customs measures to ensure that duty rates under an agreement with the EU apply only to goods eligible to receive such treatment, and appropriate rules of origin for goods entering the United States under the proposed agreement;

(e) existing sanitary and phytosanitary measures and technical barriers to trade that should be addressed in the negotiations;

(f) opportunities for greater transatlantic regulatory compatibility, including concrete ideas on how greater compatibility could be achieved in a particular economic sector, without diminishing the ability of the United States to continue to meet legitimate regulatory objectives, for example with respect to health, safety and the environment, and which sectors should be the focus of such efforts;

(g) opportunities to reduce unnecessary costs and administrative delays stemming from regulatory differences, including how that could be achieved in a particular economic sector;

(h) opportunities to enhance customs cooperation between the United States and the EU and its member states, ensure transparent, efficient, and predictable conduct of customs operations, and ensure that customs measures are not applied in a manner that creates unwarranted procedural obstacles to trade;

(i) existing barriers to trade in services between the United States and the EU that should be addressed in the negotiations;

(j) relevant electronic commerce and cross-border data flow issues that should be addressed in the negotiations;

(k) relevant investment issues that should be addressed in the negotiations;

(l) relevant competition-related matters that should be addressed in the negotiations;

(m) relevant government procurement issues, including coverage of any government agencies or state-owned enterprises engaged in procurements of interest, that should be addressed in the negotiations;

(n) relevant environmental issues that should be addressed in the negotiations;

(o) relevant labor issues that should be addressed in the negotiations;

(p) relevant transparency and anticorruption issues that should be addressed in the negotiations; and

(q) relevant trade-related intellectual property rights issues that should be raised with the EU.

In addition to the matters described above, the TPSC invites comments on new principles or disciplines addressing emerging challenges in international trade that should be pursued in the negotiations and that would benefit U.S.-EU trade as well as strengthen the multilateral rules-based trading system and support other trade-related priorities, including, for example, with respect to state-owned enterprises, "localization" barriers to trade, and other developments on which the United States and the EU may share similar concerns.

At a later date, USTR, through the TPSC, will publish notice of reviews regarding (a) the possible environmental effects of the proposed agreement and the scope of the U.S. environmental review of the proposed agreement, and (b) the impact of the proposed agreement on U.S. employment and labor markets.

Oral Testimony: A hearing will be held on May 29 and May 30 in the Main Hearing Room at the U.S. International Trade Commission, 500 E St. SW., Washington, DC 20436. Persons wishing to testify at the hearing must provide written notification of their intention by May 10, 2013. The intent to testify notification must be made in the "Type Comment" field under docket number USTR–2013–0019 on the regulations.gov Web site and should include the name, address and telephone number of the person presenting the testimony. A summary of the testimony must accompany the notification. Remarks at the hearing should be limited to no more than five minutes to allow for possible questions from the TPSC.

3. Requirements for Submissions

Persons submitting comments must do so in English and must identify (on the first page of the submission) the "Transatlantic Trade and Investment Partnership." In order to be assured of consideration, comments should be submitted by May 10, 2013.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *www.regulations.gov* Web site. To submit comments via *www.regulations.gov*, enter docket number USTR–2013–0019 on the home page and click "search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled "Comment Now!" (For further information on using the *www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on "How to Use This Site" on the left side of the home page).

The *www.regulations.gov* Web site allows users to provide comments by filling in a "Type Comment" field, or by attaching a document using an "Upload File" field. USTR prefers that comments be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type Comment" field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those

two, please indicate the name of the application in the "Type Comment" field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC". Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

As noted, USTR strongly urges submitters to file comments through *www.regulations.gov,* if at all possible. Any alternative arrangements must be made with Ms. Jamison in advance of transmitting a comment. Ms. Jamison should be contacted at (202) 395–3475. General information concerning USTR is available at *www.ustr.gov.*

4. Public Inspection of Submissions

Comments will be placed in the docket and open to public inspection, except business confidential information. Comments may be viewed on the *http:www.regulations.gov* Web site by entering the relevant docket number in the search field on the home page.

Douglas Bell,

Chair, Trade Policy Staff Committee.

[FR Doc. 2013–07430 Filed 3–29–13; 8:45 am]

BILLING CODE 3290–F3–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0087]

Limited Service Exclusion for Household Goods Motor Carriers and Related Registration Requirements for Brokers

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; request for public comment.

SUMMARY: FMCSA provides notice and requests comments on the Agency's process for determining the appropriate use of the Limited Service Exclusion (LSE), a statutory exception to the definition of Household Goods (HHG) motor carrier provided at 49 U.S.C. 13102(12)(C). In addition, this notice explains the registration requirements of brokers that arrange for the transportation of shipments that are eligible for the LSE.

DATES: You must submit comments on or before May 1, 2013.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2013–0087 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility, (M–30), U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., West Building Ground Floor, Room 12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. All submissions must include the Agency name and docket number for this notice. See the "Public Participation" heading below for instructions on submitting comments and additional information.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Rodgers, Commercial Enforcement and Investigations Division, U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Telephone (202)366–3031 or *CIE_mailbox@dot.gov.* Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal and/or copyrighted information you provide.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2013–0087), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and insert "FMCSA–2013–0087" in the "Search" box, and then click the "Search" button to the right of the white box. Click on the top "Comment Now" box which appears next to the notice. Fill in your contact information, as desired and your comment, uploading documents if appropriate. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this enforcement policy based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov* and insert "FMCSA–2013–0087" in the "Search" box and and then click on "Search." Click on the "Open Docket Folder" link and all the information for the notice, and the list of comments will appear with a link to each one. Click on the comment you would like to read. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of

STATE OF MAINE
HOUSE OF REPRESENTATIVES
126th LEGISLATURE

May 10, 2010

Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Comments on the Trans-Atlantic Trade and Investment Partnership (TTIP):
Concerns of State and Local Governments
Provided by Maine Representative Sharon Anglin Treat
Federal Register Docket Number USTR–2013–0019
https://federalregister.gov/a/2013-07430

Thank you for the opportunity to provide written comments on the proposed Transatlantic Trade and Investment Partnership (TTIP). I am a legislator serving my 11th term in the Maine Legislature, currently in the Maine House of Representatives, having also served in the Maine Senate. I co-chair the Maine Citizen Trade Policy Commission, and am House Chair of the Legislature's Joint Standing Committee on Insurance & Financial Services Committee. I am also a cleared advisor representing Maine on the Intergovernmental Policy Advisory Committee to the U.S. Trade Representative.

While these written comments are provided in my individual capacity, the positions taken herein reflect policy that has been previously adopted by the Maine Citizen Trade Advisory Council (CTPC) and communicated to the USTR as well as our Congressional delegation. These comments on the TTIP draw extensively from the position papers and letters of the CTPC, as well as Joint Resolutions adopted by the Maine Legislature, which are posted on our website, addressing issues including procurement, tobacco regulation, pharmaceutical reimbursement and pricing, investment policies and dispute resolution, as well as insurance, consumer and environmental regulation, and trade promotion authority.

I intend to present oral testimony at the hearing scheduled for May 29-30, and at that time may be presenting on behalf of the Maine Citizen Trade Policy Commission, following consultation with the full Commission at its regularly scheduled meeting later this month.

Background. The Citizen Trade Policy Commission (CTPC) provides an ongoing state-level mechanism to assess the impact of international trade policies and agreements on Maine's state and local laws, business environment and working conditions. It was established in 2003 by PL

2003, Chapter 699. The 22 member Commission includes six legislators, an Attorney General designee, five non-voting agency officials representing the Department of Labor, the Department of Health and Human Services, the Department of Environmental Protection, The Maine International Trade Center, the Department of Agriculture, Food and Rural Resources, and 10 public members representing business, labor, health, farming, government and environmental interests.

The CTPC's statutory mandate was amended by PL 2007, Chapter 266 to require that the Commission hold regular meetings, gather information from the public through hearings, submit an annual report on its activities, and conduct a biennial assessment on the impacts of international trade agreements on Maine. All of the CTPC's annual assessments, reports, letters, press releases and meeting agendas, as well as related legislation, are posted on its website, and may be accessed here: http://www.maine.gov/legis/opla/citpolassessments.htm.

Comments on specific issues or potential chapters of the TTIP:

PROCUREMENT

The Maine CTPC has consistently endorsed the position that coverage of U.S. states as sub-central entities should be ***explicitly excluded*** from any procurement provisions in trade agreements. The CTPC was established by statute as a direct consequence of legislation addressing state procurement of "sweat free" products and concern about labor standards in our trading partners. Maine has comprehensive rules governing its own procurement policies, including recycled content standards for various products to promote reuse and recycling, and the state has adopted a Purchasing Code of Conduct requiring certification of "sweat free" labor practices for suppliers of apparel, textiles and footwear, pursuant to 5 MRSA Section 1825-O.

In order to assure that these Maine-specific rules are in fact complied with, the State has also enacted a law governing the authority and procedure that must be followed in order to bind the State of Maine to any procurement rules adopted in any trade agreement. Since 2009, the Governor may not unilaterally bind the state to any trade agreement, but must consult with the CTPC and the Maine International Trade Center, and the Legislature must pass a law authorizing the Governor to enter into the trade agreement, see Public Law, Chapter 385 H.P. 876 - L.D. 1257, "An Act To Require Legislative Consultation and Approval Prior to Committing the State to Binding International Trade Agreements" which reads as follows:

> "Sec. 1. 10 MRSA §13 is enacted to read:
> § 13. Legislative approval of trade agreements
> 1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.
> A. "Commission" means the Citizen Trade Policy Commission established in Title 5, section 12004- I, subsection 79-A.
> B. "Trade agreement" means an agreement reached between the United States Government and any other country, countries or other international political entity or entities that proposes to regulate trade, procurement, services or investment among the parties to the agreement. "Trade agreement" includes, but is not limited to, any agreements under the auspices of the World Trade Organization, all regional free trade agreements, including the North American Free Trade Agreement and the Central America Free Trade Agreement and all bilateral agreements entered into by the United States, as well as requests for binding agreement received from the United States Trade Representative.

2. State official prohibited from binding the State. If the United States Government provides the State with the opportunity to consent to or reject binding the State to a trade agreement, or a provision within a trade agreement, then an official of the State, including but not limited to the Governor, may not bind the State or give consent to the United States Government to bind the State in those circumstances, except as provided in this section.

3. Receipt of request for trade agreement. When a communication from the United States Trade Representative concerning a trade agreement provision is received by the State, the Governor shall submit a copy of the communication and the proposed trade agreement, or relevant provisions of the trade agreement, to the chairs of the commission, the President of the Senate, the Speaker of the House of Representatives, the Maine International Trade Center and the joint standing committees of the Legislature having jurisdiction over state and local government matters and business, research and economic development matters.

4. Review by commission. The commission, in consultation with the Maine International Trade Center, shall review and analyze the trade agreement and issue a report on the potential impact on the State of agreeing to be bound by the trade agreement, including any necessary implementing legislation, to the Legislature and the Governor.

5. Legislative approval of trade agreement required. Unless the Legislature by proper enactment of a law authorizes the Governor or another official of the State to enter into the specific proposed trade agreement, the State may not be bound by that trade agreement."

By letter to USTR dated August 1, 2012, the Maine CTPC has also stated support for permitting "Buy America" provisions in state and federal laws and regulations (see letter posted here: http://www.maine.gov/legis/opla/CTPCprocurementtradeletter.pdf). The letter states in pertinent part that the CTPC and State of Maine favor a policy that leaves to the U.S. states the decision whether and to what extent to be subject to the procurement provisions of trade agreements. Maine also commissioned a study of potential procurement impacts on the State from trade agreements broadly and the TPP specifically (see pages 27-34 of the CTPC's 2012 Trade Assessment, posted at: http://www.maine.gov/legis/opla/CTPC2012finalassessment.pdf).

Procurement provisions in any trade agreement, including the proposed TTIP, must not bind states without their explicit approval (opt-in) so that state "Buy American," "sweat free" and other procurement rules continue to be enforceable.

INVESTMENT

An investment chapter in the TTIP would provide both substantive investor protections and a process for investor-state dispute settlement. EU countries have entered into about 1,200 investment treaties, and the United States about 60 (counting treaties and investment chapters of FTAs). Most of these are with developing countries; they give a legal advantage to the EU or U.S. investor to challenge laws in a developing country. That one-sided advantage disappears in an investment agreement between the EU and the United States. In virtually all sectors, corporations are invested in subsidiaries on both sides of the Atlantic (valued at $US 3.7 trillion). Thus, if TTIP includes an investment chapter, corporations would have standing to challenge whichever side of the Atlantic is more progressive (less favorable to investors).

The goal set by the TTIP High-Level Working Group is to harmonize differences between U.S. and EU investor protections in favor of the most investor-friendly side of the Atlantic. This

would have the effect of canceling a decade of incremental reform in U.S. trade and investment agreements, for which the Maine CTPC has been a consistent advocate. These reforms include:

- ***Expropriation*** – an annex to clarify that except in rare circumstances, regulations that serve a public welfare objective do not constitute an indirect expropriation.
- ***Fair and equitable treatment*** – a clarification that FET is limited to the standard of treatment that is required by Customary International Law (CIL), which means that governments must only compensate investors when there is a state practice of doing so out of a sense of legal obligation.

Even with these reforms, the investor rights are unnecessarily vague. Yet the EU's investment treaties are worse; they give more power to arbitrators to ignore state practice and compensate investors based on doctrines developed by arbitrators. By favoring the most investor-friendly version, the goals of TTIP flatly ignore the limited progress that the United States has made to clarify the scope of foreign investor rights.

Investment rules and the investor-state dispute resolution system have been justified on the grounds that they protect foreign investors from the discriminatory or capricious actions of the host government, or protect investors from poorly performing or inefficient domestic courts. Independent, capable, and fair judicial systems are well-established in the both the U.S. and the EU. There is simply no reasonable justification for including an investment chapter in the TTIP.

Considering that the rule of law and judicial systems are well-developed on both sides of TTIP negotiations, there is no place for an investment chapter in the TTIP.

SERVICES AND REGULATORY COHERENCE

On a number of occasions, the Maine CTPC has commended USTR for paying close attention to WTO negotiations on services and for opposing proposals from other countries that would limit the regulatory authority of state and local governments. This is especially important with respect to essential services that are regulated by states and provided by local governments (e.g., insurance, health care facilities, licensing of professionals, waste management, distribution of energy, etc.). In the Trans-Pacific negotiations, some of the WTO proposals have resurfaced in a new chapter on "regulatory coherence." For example, the chapter promotes use of regulatory impact assessments that apply cost-benefit analysis in ways that are not consistent with state-level regulation of public utilities and other service providers.

The chapters on services and regulatory coherence are highly sensitive in light of our federal system and principles of dual sovereignty. U.S. negotiators risk ruining years of good will if they proceed to negotiate these chapters in the TTIP with the lack of transparency demonstrated in the Trans-Pacific process.

INSURANCE

Particularly with respect to regulation of services relating to insurance, the State of Maine has taken a strong position that trade and investment agreements must not limit state authority. Insurance regulation is primarily, and almost exclusively, a state-level activity. Maine has a strong interest in preserving its role as the primary regulator of the insurance industry providing services in the states, and in maintaining authority to set reserve standards to assure solvency of the industry and consumer protections, to perform market conduct exams, to require disclosure

of insurance policy terms, to seek redress through enforcement actions, and to exclude insurance policies and insurers from the market that do not meet these state standards.

The Maine Citizen Trade Policy Commission opposed the creation of a federal insurance office with powers to declare state insurance laws preempted by trade agreements, both pending and ratified (see letter of April 16, 2010 to Senator Christopher Dodd, posted here: http://www.maine.gov/legis/opla/citpoltradedocs.htm). Maine's Insurance Superintendent testified before Congress on these issues, and our Attorney General wrote to oppose the provisions. States throughout the country opposed these federal trade preemption provisions through the testimony of the National Association of Insurance Commissioners. That proposal was defeated, and the Federal Insurance Office that was established in the Dodd-Frank Act is purely advisory. TTIP should not include any provisions that subvert this state-federal regulatory balance.

The USTR should not include in any trade agreement, including the proposed TTIP, any provisions that limit or remove from U.S. state regulation insurance and other financial products and services currently regulated by the states.

TOBACCO CONTROL

Maine has some of the strongest tobacco control laws in the country, including tobacco taxes intended to reduce tobacco use and encourage and assist cessation. Maine was one of the 46 states and 5 territories that sued the tobacco industry and entered into a global settlement with the defendants. That settlement not only provides ongoing funding to the state's tobacco cessation and prevention efforts, it also established the regulatory framework codified in federal law. Since 1997 to 2005, rates for adults who smoke decreased from 30% to 21%, and the rate among high school students plunged nearly 60%. Maine has received national recognition for its impressive outcomes in tobacco prevention in schools, workplaces, communities and retail stores.

The continued success of these efforts is incredibly important to Maine policymakers, the medical and public health community and the parents of our youth. It is vital that tobacco be treated as a special case by our trade rules, and that the proposed TTIP include tobacco exception language that is clear, broad in scope, and effective. It must not preclude new policies in response to changes in our understanding of not only the science of addiction and health impacts, but also of marketing and psychology. It must be able to respond to the ever-evolving strategies and products of the tobacco industry as that global industry adapts to changing regulations and understanding.

For these reasons, and the actions of Philip Morris International (PMI) challenging tobacco regulations adopted in Uruguay and Australia using investor-state arbitration provisions, the Maine Citizen Trade Policy Commission wrote to the U.S. Trade Representative in a letter dated November 19, 2010 calling "for tobacco be carved out of TPP and any future trade agreement."

Unless there is a clear carve-out, a TTIP investment chapter would give PMI standing to challenge tobacco-control measures in the EU, as it would give British American Tobacco (BAT) standing to challenge measures in the United States.

One goal of TTIP is to eliminate tariffs, including tariffs on tobacco products. U.S. tariffs on cigarettes are 41.7 cents/kg + 0.9% (bound and applied rates); EU tariffs are 10% ad valorem (bound and applied rates). (WTO, Tariff Analysis Online)

U.S. trade negotiators have a history of negotiating tariff reductions in order to promote market access on behalf of tobacco companies. For many years, the U.S. Congress has adopted the Durbin and Doggett Amendments to appropriations acts; they prohibit federal agencies from promoting "the sale or export of tobacco or tobacco products" or seeking "the reduction or removal by any foreign country of restrictions on the marketing of tobacco or tobacco products, except for restrictions which are not applied equally to all tobacco or tobacco products of the same type." President Clinton issued Executive Order 13193 in 2001 to make clear that the prohibition applies to all executive agencies and "the implementation of international trade policy."

It is hard to avoid the conclusion that the purpose of eliminating tobacco tariffs is to promote tobacco trade or to provide tobacco companies with a windfall. For U.S. negotiators to do so in the TTIP would violate the Doggett Amendment and the Clinton Executive Order. Eliminating tariffs will also reduce the cost of tobacco products generally and undermine the efforts of Maine and other states to reduce tobacco use through steep taxes, a policy with proven effectiveness, particularly in reducing youth smoking.

USTR has vetted (but not yet proposed) an exception in the Trans-Pacific negotiations for regulations that restrict tobacco trade. The exception would apply only to regulations issued by health authorities, not to legislation; it would not apply to regulations adopted by tax, custom, or licensing authorities such as those at the state level. In short, the U.S. proposal is so narrow it would protect only the U.S. Food and Drug Administration, but not the states; and it would require a scientific burden of proof that exceeds the burden in the WTO health exception under GATT and GATS.

The Maine Citizen Trade Policy Commission has taken the position that it is more effective to simply exclude tobacco-control measures from all future trade agreements, including the TTIP. Whereas an exception requires extensive litigation to work as a defense, an exclusion (also called a carve-out) limits litigation to the preliminary question of whether a measure is covered.

ENVIRONMENTAL PROTECTIONS

To the extent the TTIP seeks to harmonize regulations, it is essential that regulations are harmonized upward. Further, governments – including U.S. state governments that in our federalist system share environmental regulatory authority with the federal government – must have the flexibility to develop more ambitious environmental policies in the future.

Of great concern with respect to the TTIP is the fact that the inclusion of so-called "national treatment for trade in gas" would remove the ability of the U.S. Department of Energy to review, condition, or deny exports of US liquid natural gas (LNG) to EU countries. Automatic exports of U.S. LNG to the EU, a significant importer of natural gas, would likely expand hydraulic fracturing (fracking), across the country and lead to higher domestic electricity prices, affecting consumers, U.S. manufacturing, and U.S. jobs.

The potential for "investor-state" provisions in the TTP raises particular concerns for the ability of states to protect the environment and natural resources. We know from the implementation of the North American Free Trade Agreement (NAFTA), and its investor-state dispute provisions, that corporate challenges under the investment chapter are frequently focused on environmental regulations and policies. Past and current WTO and NAFTA cases against Canadian provinces and U.S. states have included challenges to fracking moratoria, zoning and regulation of mining, renewable energy policy including local content requirements, regulating toxics in groundwater, and water pollution permitting – all subjects over which state governments have jurisdiction.

The current trade negotiation process is neither transparent nor inclusive, with negotiations taking place behind closed doors and confidential texts shared with very few state policymakers or advocates for public health and the environment. Currently, state and local officials have limited access to vital information about trade policy decisions, and no meaningful role in forming U.S. positions for trade negotiations - even though they are required to conform their democratically-enacted domestic policies to the constraints and priorities set in trade and investment pacts such as the TTIP.

The CTPC, a state government authority, has experienced over many years great difficulty even in scheduling timely briefings on USTR policies and activities, and there are limited opportunities for the Commission to influence the U.S. trade agenda and specific negotiations.

The TTIP should not override state authority to regulate environmental concerns when those state policies meet the legal standards in the U.S. Constitution.

ACCESS TO HEALTHCARE

State officials, including the Maine CTPC, have repeatedly warned the USTR over the past several years about the harm to U.S. health programs that will follow from the use of trade policy to restrict foreign and domestic medicine pricing programs. These concerns have been raised with respect to the Australia-US FTA, the Korea-US FTA and the Trans-Pacific Partnership Agreement.[1]

The Maine Citizen Trade Policy Commission recently commissioned a statutorily required biennial Assessment of the potential impact of trade policy on Maine's citizens, economy, laws and policies. The Assessment concluded that the impact of proposed provisions in the TPPA on pharmaceutical pricing in Maine, and on access to healthcare, could be significant. The analysis was based on the leaked June 2011 TPPA healthcare transparency text as well as intellectual property provisions under consideration in the TPPA negotiations.

On August 1, 2012, the Maine CTPC wrote to Ambassador Ron Kirk reiterating its concerns about the healthcare technologies text and referring to the Assessment. The letter is posted online here: http://www.maine.gov/legis/opla/CTPCpharmaceuticalstradeletter.pdf . The letter reasserts the Commission's support for the positions adopted in previous communications on this

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issue, in particular its February 12, 2010 letter to USTR. The Commission particularly noted the following:

- Its **support** for evidence-based reimbursement policies to restrain pharmaceutical prices;
- Its **endorsement** of the continued use of preferred drug lists to reduce pharmaceutical prices;
- Its **opposition** to *"any promotion of international restrictions on domestic pharmaceutical prices";* and
- Its **support** for *"the inclusion of a footnote in the TPPA and other trade agreements which "carves out" federal reimbursement programs such as Medicaid, 340 B and Medicare Part B".*

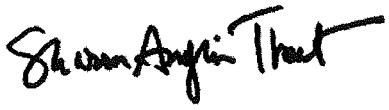
The Maine Citizen Trade Policy Commission has taken a strong position against inclusion of restrictive healthcare pricing and intellectual property provisions in any future trade agreement, including the TTIP. The Commission adopted the following strong statement on its position opposing the restrictive pricing language such as that proposed in leaked TPPA healthcare technologies text: ***"The CTPC voted unanimously to support provisions in the TPPA and other international trade agreements which emphasize, allow for and encourage the overall affordability of pharmaceuticals in each affected country."***

SUMMARY

The State of Maine has expressed many concerns about past U.S. trade and investment agreements, as well as the process used to negotiate and approve of these treaties. Through the Maine Citizen Trade Policy Commission, the state has conducted a thorough review of the impacts of these treaties on the state's sovereignty and its authority to protect the public health, safety and welfare.

As the USTR enters into negotiations for a Transatlantic Trade and Investment Partnership, it is imperative that the resultant treaty respects the sovereignty of U.S. states under the federalism provisions of the U.S. Constitution, and that negotiators consult in a meaningful way with state policymakers so that the TTIP does not undermine environmental and public health protections, access to healthcare, procurement standards, and regulation of services such as insurance, which have been reserved to the states. Thank you for your consideration.

Respectfully submitted,



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Article notes: 5/24/13 CTPC agenda

HHS Official Highlights Role in Formulating Tobacco, IPR Aspects of Trade Policy

- Contrary to past practice, the U.S. Department of Health and Human Services (HHS) is playing a much more significant role in the formulation of U.S. trade policy on health related issues for international trade treaties such as the TPPA;
- Previously, the HHS role was limited to consulting on the more technical aspect of health related trade issues ;
- Apparently, HHS has been influential in helping to develop the tobacco "carve out" proposal which may become part of the TPPA; the tobacco "carve out" proposal would allow nations to "adopt regulations that impose origin-neutral, science based restrictions on specific tobacco products or classes in order to safeguard public health"; and
- HHS also appears to be playing a significant role in a proposal for the TPPA which would increase access to pharmaceuticals by allowing pharmaceutical companies to be rewarded with stronger patent protections if they move quickly to gain marketing approval for distribution in other countries.

Cuba challenges Australian Tobacco Rules

- Under the WTO, Cuba is challenging Australian tobacco laws by alleging that these laws are creating "technical barriers" to trade and that these laws violate intellectual property rights;
- The Australian law in question is considered to be one of the most stringent tobacco labeling laws and currently prohibits " the use of logos, brand imagery, and promotional text.

Coup d'Etat to Trade Seen in Billionaire Toxic Lead Fight

- Using the investor-state arbitration process afforded by international trade agreements, Renco, a U.S. owned mining company, is seeking $800 million in damages from the nation of Peru for costs incurred by the company to comply with a mandated clean-up of toxic lead spills; and
- The nonprofit Global Trade Watch organization alleges that the investor-trade arbitration process is used frequently to as an effort to try "to limit the governance authority of nation states.

Medical, Health Leaders: TPP Must Reduce Epidemic of Tobacco Use

- Leading medical and health professionals in the U.S. have issued a statement entitled "Strategies for Creating a 21st Century Trade Agreement" which advocates for a the U.S. to champion an agenda for the TPPA which:
    - Safeguards public health;
    - Advances tobacco control measures at local, state and national levels; and
    - Prevents incursions by the tobacco industry against these measures.

No Decision Yet on Japan Participation at Next TPP Round, Official Says

- Although Japan has been formally accepted into the TPPA, it has not yet been resolved whether Japan will participate in the next round of TPPA negotiations which are scheduled to start on July 15th;and
- Technically, Japan is not allowed to participate in the negotiations until they are formally a part of the TPPA on July 23rd.

State Lawmakers Make Demands on LNG, Environment Investment in TPP

- More than 50 legislators (including Representative Sharon A. Treat) from 24 states have asked the USTR to include in the TPPA provisions which would allow the Department of Energy to retain control over liquefied natural gas (LNG) exports; and
- These same legislators are also asking the USTR to oppose inclusion of an investor-state dispute settlement mechanism in the TPPA.

U.S. Tables SPS Text; Other Countries Float Pharmaceutical IP Ideas

- The USTR has formally proposed inclusion of language in the TPPA which would establish a consultative mechanism for resolving sanitary and phytosanitary (SPS) disputes; many U.S. agricultural and food groups are opposed to this approach, favoring instead a provision which provide for fully enforceable SPS obligations; and
- Other TPPA member countries have developed proposals regarding the topic of pharmaceutical intellectual (IP) protections which would run counter to the current U.S. proposal to increase access to pharmaceuticals by allowing pharmaceutical companies to be rewarded with stronger patent protections if they move quickly to gain marketing approval for distribution in other countries.

2013 Report on Technical Barriers to Trade; USTR

- Foreign trade barriers exist in the form of product standards, technical regulations and testing, certification and other procedures used to determine whether particular products conform to certain standards;
- These factors commonly referred to as standards based trade measures can have both a positive and negative effect on the flow of international trade;
- In WTO parlance, these standards are referred to as "technical barriers to trade" (TBT);
- When TBTs are non-transparent, discriminatory or unwarranted, they can have the effect of significantly reducing trade for the U.S.; and
- The report goes on to indentify significantly deleterious TBTs and the various strategies that the USTR is employing to deal with them.

Live from the Trans Pacific Partnership: IP Chapter Shows No Sign of Resolution, End of Negotiation in 2013 Highly Unlikely

- Current TPPA negotiations are stalled around disagreements on intellectual property and pharmaceutical topics;
- Several of the TPPA nation participants have significant objections to the current copyright laws in the U.S which protect copyrights for a length of 70 years;
- The current disagreements have certainly rendered the anticipated finalization of the TPPA in October, 2013 as impossible to achieve and probably makes completion by the end of 2103 very unlikely as well.

HHS Official Highlights Role In Formulating Tobacco, IPR Aspects Of Trade Policy

Inside US Trade

Posted: April 22, 2013

A senior official in the Department of Health and Human Services (HHS) today (April 22) said that the department is playing a larger role than ever before in the development of U.S. trade policy, including on sensitive issues in the Trans-Pacific Partnership (TPP) negotiations like a draft proposal for a tobacco-specific "safe harbor" and the U.S. stance on issues related to intellectual property protections for pharmaceuticals.

In an interview with *Inside U.S. Trade*, HHS Assistant Secretary for Global Affairs Nils Daulaire said that, historically, the department's role in formulating trade policy has been more marginal. "HHS' seat at the table in the trade discussions has largely been occupied by the Food and Drug Administration, because the focus really has been on what does this mean for our regulatory regime when we have food and drugs imported into the U.S.," he said.

But Daulaire, who joined HHS in 2010, said he did not believe that this type of engagement on a "technical level" was sufficient, especially because trade issues often intersect with health concerns. For that reason, he said he has put more emphasis on substantive engagement "upstream," meaning while initial trade policies are still in the early phases of being formulated within the Obama administration.

"I came to the conclusion that unless we took a proactive role, and an upstream role, in discussions on trade issues with the USTR, we were going to be left in a position ... of either signing off on things or raising technical concerns," he said. Daulaire said that in the past, HHS had waited to be "the last on the clearance list" in the interagency process, and made clear in the interview that he wanted HHS to play a much larger role on health-related trade issues.

Daulaire heads up the department's Office of Global Affairs, which is part of the Office of the Secretary. His office is focused on global health policy and has a broader perspective than the FDA, which is also part of HHS.

In the interview, Daulaire acknowledged that the department does not have as much influence when it comes to trade-related matters as other parts of the administration for which trade is the central focus, such as the Office of the U.S. Trade Representative or the Commerce Department.

"We are the new kids on the block," he said. "I don't think there is any question that we are starting from a fairly low base and having to demonstrate both our value and our thoughtfulness in the process." At this point, "I would in no way consider us to be full equal players, but we are clearly actors in this dialogue," and that in and of itself is an important development, Daulaire said.

He made a similar point when participating in an April 5 panel on global health issues at the Center for Strategic and International Studies (CSIS). "We don't make the final decisions as to what USTR does; that is for the White House to decide," he said at that event. "But we want to

make sure, and I think it is really for the very first time, that this [health] perspective has been strongly introduced, and our secretary is deeply committed to this."

At that event, Daulaire also highlighted tobacco and issues related to pharmaceuticals as two issues on which HHS plays a role when helping to develop U.S. trade policy.

On tobacco, HHS has played a role in developing the "safe harbor" from tobacco-related litigation that the Obama administration has publicly described, but not yet tabled, in the TPP negotiations. Outside observers say HHS officials were the ones that initially suggested negotiating tobacco-specific provisions in TPP, while USTR was initially hesitant to endorse special provisions for tobacco.

"We consider this to be hugely important from the standpoint of global public health," Daulaire said, in reference to the draft proposal. Tobacco control "is unquestionably at the very top of our policy agenda in terms of domestic health, in terms of global health, and in terms of the interface with the trade environment," especially in light of estimates that one billion people could die of tobacco-related diseases in the twenty-first century, he said.

When asked directly if HHS was responsible for originally proposing tobacco-specific measures in TPP, the HHS official declined to answer. "All I can tell you is that there had not been this level of engagement and attention previously, and now there is, and we are very glad for all the engagement of many different parties," he said, adding that the fact that the U.S. draft proposal certainly reflects the increased engagement from HHS on trade policy.

The fact that the Obama administration has still has not tabled the proposal has some anti-smoking advocates nervous, although Daulaire appeared to downplay those fears. "We understand that this is moving forward," he said. "I can't go beyond what we can talk about publicly in terms of international trade negotiations, but let me just say that I do not feel discouraged."

The "safe harbor" proposal would clarify that, notwithstanding other rules contained in the final TPP deal, national health authorities may adopt regulations that impose origin-neutral, science-based restrictions on specific tobacco products or classes in order to safeguard public health. U.S. business and agricultural groups strongly oppose the proposal, saying there is no need to treat tobacco products differently from other products in trade deals.

Anti-smoking advocates, on the other hand, argue that the proposal does not go far enough, and that tobacco products should be completely "carved out" from the TPP talks. In their view, tobacco products should not even be subject to tariff cuts. However, the U.S. has thus far not adopted this complete carveout approach and is currently negotiating tariff phaseouts on tobacco products in TPP.

When asked about his views on a complete carveout, Daulaire signaled his possible support, although he stressed that he had not yet made up his mind on the issue.

"I think that is something that we are talking about at this point," he said. "I'm not a trade specialist, and the issue of carveouts is pretty complex," he explained. While his "knee-jerk" reaction would have been to support a complete carveout, his current response is "maybe,"

especially in light of his desire to learn more about the "nuance and the consequence" of including such a carveout in a trade deal, he said.

"As we move forward on this, we'll see where this goes, but it is certainly not something that I would unequivocally say is a bad idea," Daulaire explained. "The public health side is very clear and straightforward on this: tobacco is bad and anything we can do to reduce its use and its promotion is good for public health." At the same time, the administration as a whole must consider a range of issues when formulating policy, he said.

Daulaire declined to respond directly when asked whether special provisions for tobacco should be considered for other new trade agreements, including the planned U.S.-European Union trade talks, but he again signaled his possible support for the idea. "I don't see anything with TPP that makes it unique in terms of this," he said.

While each trade negotiation is different, he also noted that TPP is the first time that the U.S. has negotiated an agreement since passing a landmark 2009 tobacco bill.

That bill -- the Family Smoking Prevention and Tobacco Control Act -- was signed into law in June 2009 and gave the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products. The U.S. "safe harbor" draft proposal in TPP is essentially meant to ensure that FDA implementation of its new mandate under the 2009 law would be effectively shielded from legal challenge under a TPP agreement.

"This is also the first time that we've gone into a treaty negotiation since the FDA was given tobacco authority, so the ground has changed from earlier negotiations," Daulaire maintained. U.S. tobacco control advocates are already gearing up to engage with administration officials in the EU context, and are hoping that the administration will look to table special provisions on tobacco in that context as well (*Inside U.S. Trade*, April 12).

HHS is also playing a role in developing U.S. trade policy when it comes to access to medicines in the TPP, although here the department's role was initially more limited, according to Daulaire.

The Obama administration originally unveiled a proposal in this area based on an "access window" concept in the fall of 2011.The basic concept is that pharmaceutical companies would be rewarded with stronger patent protections under a TPP deal if they seek to gain marketing approval swiftly in other TPP countries. The proposal has faced skepticism from U.S. stakeholders and intense resistance from TPP partners (*Inside U.S. Trade*, March 15).

"We were not involved in the early stages of the policy that was put forward as the U.S. negotiating position," Daulaire explained, largely because "nobody thought to ask us." While FDA was asked to sign off on an initial version of that proposal, the concern of FDA is more limited to questions like "does this create problems in terms of the application of existing law and regulation," he explained.

The HHS official stressed that his office is focused on the broader interest of promoting global public health. "Our concern is a broader one ... and frankly, it was early in the administration, we hadn't gotten our ducks lined up yet, and it took us a while to recognize that this was an issue" and that HHS officials should substantively engage, he said.

In light of the resistance from other TPP partners to the original proposal, however, the administration is once again engaged in an interagency process to determine whether or not it should be modified, and HHS is involved in this new round of consultations, Daulaire said. "We have been welcomed to the table in terms of internal discussions within the administration to see whether a modified U.S. position would be warranted," he said.

While unable to speak to the precise nature of the deliberations within the administration, Daulaire said that HHS officials "are now very much engaged in this and in these conversations and are looking for ways to make sure that public health is well protected in this process." He said there is an "open consideration of what we can do to move things forward that is going to work both in terms of the negotiations and in terms of public health."

New York Times

May 6, 2013

Cuba Challenges Australian Tobacco Rules

By DAVID JOLLY

PARIS — Cuba is seeking to overturn Australia's tough tobacco-labeling rules at the World Trade Organization, the trade body said Monday, the first time that Havana has used the forum to directly confront another nation over its commercial laws.

Cuba, the world's dominant producer of fine cigars, has filed a "request for consultations" with Australia, Keith Rockwell, a spokesman for the W.T.O., said from Geneva, where the organization is based.

The two nations now have 60 days to reach an agreement, he said; if they fail to resolve their differences in that time, the next step would be for Cuba to begin a formal challenge with the establishment of a dispute resolution panel.

The request was filed on Friday but made public on Monday, Mr. Rockwell said.

Cuba is joining Ukraine, Honduras and the Dominican Republic in challenging Australia's tobacco-labeling laws at the W.T.O. All four nations argue that provisions of a 2011 Australian law, the Tobacco Plain Packaging Act, have created "technical barriers" to trade and violate intellectual property rights.

If Australia is ultimately found to have broken W.T.O. rules, it must either bring its laws into conformity or face retaliation in the form of increased duties on Australian goods.

As part of a national anti-smoking drive, Australia has passed some of the world's toughest laws on the labeling of cigars, cigarettes and other tobacco products, prohibiting "the use of logos, brand imagery, and promotional text" and strictly regulating the use of brand names. Tobacco products in Australia are sold in standard dark green boxes with gruesome images of people with diseases caused by smoking.

Australian and Cuban officials could not immediately be reached on Monday for comment.

Cuba, seeking to reinvigorate a stagnant economy, has in recent years allowed more free-market activity. It joined the World Trade Organization in 1995, soon after the group's founding, but has never before brought a formal challenge. It has been involved in cases brought by others, including a dispute between the spirits makers Pernod Ricard and Bacardi over U.S. rights to the Havana Club rum brand.

Cuba exported $215 million in cigars in 2011, the latest year for which figures are available, according to the National Statistics Agency. Cigar sales are handled by Habanos, a 50-50 joint venture between the Cuban state tobacco company and Altidis, a unit of Imperial Tobacco.

Habanos said exports of Cuban cigars rose in 2012 despite the economic slump in Spain and France, its top two markets, as sales to China, its No. 3 market, rose 6 percent. A U.S. embargo imposed in 1962 prohibits the import of Cuban cigars into the United States.

Emily Morris, an expert on the Cuban economy at University College London, said that overseas cigar sales make up only about 1.3 percent of Cuba's total exports and that Australia was just a small part of that. "They're keen on trademark protection for their premium cigars," Ms. Morris said. "A lot of the buying of cigars is based on the wonderful packaging."

Cuba's willingness to bring a W.T.O. case shows that "it has got a lot at stake in intellectual property now," she said, including in the pharmaceutical sector, where it earns more than $500 million a year.

The case puts Cuba in curious company in seeking to overturn a democratic country's health laws in the interest of its tobacco exports. The global tobacco industry spent millions of dollars in an unsuccessful campaign against the Australian law, and continues to resist efforts by others, including the European Union, to adopt similar laws.

Nevertheless, New Zealand officials have said they are planning to follow Australia's packaging example by sometime next year.

Victoria Burnett contributed reporting from Havana.

Bloomberg

Coup d'Etat to Trade Seen in Billionaire Toxic Lead Fight

(Corrects the timing of treaty terminations by South Africa in the 22nd paragraph and the law challenged by Australia in the 24th paragraph.)

Across the river from Belinda Elida Barja's two-room apartment, the lead and zinc smelters of Doe Run Peru spread smoke and dust in the mountain town of La Oroya.

Her 9-year-old son Kenyi has headaches, memory loss, stomach ailments and difficulty concentrating, Barja said. The lead in his blood measured 41 micrograms per deciliter in a 2007 test -- eight times the level the U.S. government considers a cause for action. Barja blames Doe Run Peru.

"They just think about making money," she said.

Most of La Oroya's children suffer elevated lead levels, according to the Peruvian government. Parents say some have symptoms -- consistent with lead poisoning -- that include anemia, convulsions, stunted growth, mental retardation and the ills Barja said her son suffers.

The question of responsibility is at the center of a high-stakes clash between Peru and U.S. billionaire Ira Rennert, who owned Doe Run Peru for more than a decade through Renco Group Inc. Far from defensive, Renco is demanding $800 million from Peru because it ordered a costly pollution clean-up that the company says forced Doe Run Peru into bankruptcy in 2010. Renco has said it's not responsible for the children's ailments.

Its demand was made under an arcane, often secretive investor-state arbitration system that is growing rapidly in size and scope, roiling global trade and angering countries from Australia to South Africa over the perceived trampling of their sovereign rights.

'Last Resort'

"It's like a quiet, slow-moving coup d'état," said Lori Wallach, director of the Global Trade Watch division of Public Citizen, a nonprofit that opposes many aspects of trade pacts. Investors and corporations are "using this regime to have another front at trying to limit the governance authority of nation states."

Arbitration clauses were originally included in treaties to deal with the nationalization or a company's

assets. Now arbitrators hear claims for lost business or costs stemming from public-health laws and environmental regulation and financial policies, with billions of dollars at stake.

In some instances, investors are even demanding that national laws or court judgments be overturned.

Once a "shield of last resort," arbitration has become a "sword of first resort," according to a paper by Howard Mann, a senior law adviser at the International Institute for Sustainable Development, a Winnipeg-based nonprofit. "They were never meant to be the first recourse of a foreign investor to create or settle a dispute," Mann said in an interview.

Shrimp Farm

A record 62 treaty-based arbitration cases were filed last year, bringing the total to 480 since 2000, according to the United Nations Commission on Trade and Development. Before then, there were fewer than three a year dating to 1987, when a Hong Kong company brought the first known case over Sri Lanka's destruction of a shrimp farm in a military operation against Tamil separatists.

Driving the growth are arbitration clauses enshrined in the "vast majority" of the world's 3,000-plus international investment agreements, according to the UN. Only 134 such pacts existed in 1980.

Many give the investor the right to choose from a set of procedural rules, usually from the World Bank or UN. Each side gets to pick one arbitrator apiece, usually lawyers, academics and former government officials, with the third selected by mutual agreement or an independent third party.

The scale has grown well beyond shrimp ponds. Last year's decisions included a $1.77 billion judgment against Ecuador in an Occidental Petroleum Corp. (OXY) case brought over a terminated oil concession. Ecuador is seeking an annulment of the decision through the World Bank's arbitration forum, and hasn't yet paid.

Battling Russia

In the largest unresolved case, former offshore shareholders of Yukos Oil Co. are seeking $114 billion from Russia over allegedly illegitimate criminal investigations, tax demands and arrests of Yukos officials, which culminated in the state acquiring most of the company's assets. It's one of 19 cases in which investors are demanding more than $1 billion, according to the UN.

The Russian government has argued that the dispute should be resolved in Russian courts, according to a summary of the country's position by the arbitrators.

The system provides protections for companies seeking to invest abroad where the legitimacy of local laws and domestic courts may be uncertain, according to the Obama administration and other supporters.

Investors prevailed in 70 percent of cases decided last year.

More Power

Renco, a New York-based metals, mining and industrial conglomerate that owned the La Oroya plant through a subsidiary, contends the pollution-curbing demands Peru made were onerous and unfair, and kept escalating. The government says it was only trying to hold Renco to the terms of the agreement under which it bought Doe Run Peru in 1997.

In addition to $800 million, closely-held Renco wants arbitrators to compel Peru to pay for any damages that may arise from a pending lawsuit filed in federal court in St. Louis, Missouri, on behalf of more than 700 La Oroya children.

"This clause gives more power to foreign investors than the people of Peru," said Conrado Olivera Alcocer, executive director of Joining Hands Network Peru, a group of charities that focuses on the environment and individual rights. A Peruvian has no right to file a claim in an international forum the way Doe Run does, Alcocer said.

While Peru says it still believes in investor-state arbitration, other nations aren't so sure. Since 2007, Bolivia, Venezuela and Ecuador have withdrawn from the World Bank's arbitration forum, which they said favored corporations over sovereign nations.

Apartheid Legacy

Within the last year, India froze negotiations on investment treaties and said it wouldn't agree to future pacts with arbitration clauses that can trump its courts. South Africa, which was challenged in an arbitration case over a law requiring mining companies to sell shares to citizens harmed under Apartheid, decided to terminate investment treaties after deciding the risks outweighed the benefits.

In 2011, Australia vowed that it would no longer include an arbitration clause in trade agreements, a potential complication in negotiations for the Trans Pacific Partnership, a proposed trade pact among 11 countries. The Australian position is at odds with the U.S. stance favoring the process.

Australia is facing an arbitration case filed by Philip Morris International challenging a law that requires cigarettes to be sold in plain packages. The U.S. cigarette maker is asking arbitrators to overturn the law, which was upheld by Australia's highest court, or award damages for lost business.

Italianate Xanadu

The man fighting Peru, Ira Rennert, is a Brooklyn native who used more than $1 billion in junk bonds to a business empire under Renco that includes a magnesium company, jewelry stores, auto-parts suppliers

and a defense contractor that introduced the world to the Hummer. Rennert, 78, is worth $5 billion, according to the Bloomberg Billionaires Index. He and Renco officials declined to comment for this story.

Rennert may be best known for his own Italianate version of Xanadu on the eastern tip of Long Island. Called Fair Field, the 43,000-square-foot mansion was built on 65 oceanfront acres, has 21 bedrooms, 14 full baths, three pools, two tennis courts and an assessed value of $248 million, tax records show.

The billionaire has often clashed with bondholders, regulators, business partners and neighbors, many of whom have spent years waging legal battles with him. In January, the Pension Benefit Guaranty Corp. sued Renco for allegedly trying to skirt $97.2 million in pension obligations at its bankrupt RG Steel LLC unit. Renco has denied the allegation.

Barren Crossroads

Renco's Salt Lake City-based subsidiary, U.S. Magnesium LLC, was sued by the Environmental Protection Agency in 2001 for alleged toxic waste violations; the case is in settlement talks, court filings say. Another Renco unit owns a lead smelter and refinery in Missouri that has been cited by regulators, and sued by neighbors who say they were harmed by emissions. The plant is scheduled to close at the end of the year.

The Renco company that operates the Missouri smelter said it is committed to meeting its environmental obligations, and declined to comment on the lawsuits.

La Oroya was an "uninhabited crossroads" in 1922 when an American company called Cerro de Pasco Copper Corp. built the smelter and refineries. They started producing copper, and now make lead, zinc, gold, silver and lesser known-metals like bismuth and antimony. Renco acquired the facility in 1997 for $248 million and named it Doe Run Peru. The seller was the Peruvian government, which had nationalized it 23 years earlier.

Miners' Hostels

A signpost in the oldest part of town declares it the capital of the metallurgical industry in Peru and South America. About 180 kilometers east of Lima, it's a four-hour drive of switchbacks, rockslides and steep drop-offs that top out at about 4,800 meters.

La Oroya is at 3,700 meters, a scruffy collection of bodegas, cafes and hostels, many filled with miners. Trucks rumble up and down the main road, and freight trains grind along nearby tracks. Doe Run Peru's piles of lead concentrate, roaring furnaces, brawny molds and waste treatment plants dominate the banks of the Mantaro River as it winds through La Oroya. One locked room holds $18 million in newly smelted silver bars.

Dust is overwhelming in some parts of the plant, especially near the furnaces, and most workers wear air-

filtering masks. Waste is carted by buckets to a black slag heap nearly as high as the surrounding mountains.

Directly across from it, a company sign on the riverbank says, "Doe Run Peru Does Not Contaminate the Mantaro River."

Dust Reduction

Under the terms of Renco's purchase, Doe Run Peru agreed to a 10-year pollution reduction plan that was estimated to cost $107 million, Renco said in its arbitration notice. The Peruvian government agreed to clean up soil around La Oroya that had been contaminated by decades of pollution under previous owners, including a state-owned company.

Neither side complied with the accord, each says.

Doe Run Peru has said it completed many projects, and plant employees showed off equipment that they said reduces dust and particle emissions, treats sewage and industrial wastewater and captures sulfur dioxide before it goes out the smokestack.

The company said it spent more than $300 million, about triple the original estimate. It acknowledges that it didn't complete a copper-plant upgrade that would have cost more than $100 million and was part of the clean-up plan, according to the arbitration notice.

In 2009, it received a 30-month extension, its second allowance of more time. The Peruvian government passed new regulations "so onerous" that Doe Run couldn't take advantage of the extension, the notice says.

Clean Hands

Unable to obtain financing, Renco closed the plant in 2009 and notified Peru the following year that it intended to file an arbitration case. Most of Doe Run Peru has reopened and is now being run by a management company hired by creditors.

Jose M. Reyes, Doe Run Peru's vice president of operations, said his former boss got a raw deal. A 43-year veteran of the plant, Reyes said the waste dumped into the Mantaro or going up the smokestack declined after Rennert bought the plant.

Reyes provided charts of company-funded research showing lead emissions declined 50 percent and pollution flows into the river were nearly eliminated between 1997 and 2008.

The state didn't fulfill its promise to clean up La Oroya's contaminated soil, he said. "There was unjust treatment on behalf of the Peruvian government."

Falling Ash

The government's soil cleanup is now under way, said Carlos Jose Valderrama, the Peruvian official responsible for investor-state arbitrations. It didn't make sense to undertake the project while the pollution continued during Renco's ownership of the plant, Valderrama said in an e-mail.

"The bottom line is that when Doe Run stopped operating and polluting, the contamination levels dropped," he said.

Valderrama said Peru supports the arbitration system, but disagrees with Renco's allegations. While it gave Doe Run extra time to finish the projects, the company failed to do so, Valderrama said.

"Peru has the necessary expectation that investors maintain clean hands, protect the environment and in short follow the rules," said Jonathan Hamilton, an attorney for Peru in the arbitration and partner at the law firm White & Case. "Renco and Doe Run did not follow the rules."

In La Oroya, some parents say they believe the plant's toxins stunted their children's' bodies and damaged their minds.

Before the plant closed in 2009, Barja said, white flecks of ash would settle in her son's hair. It looked like "dandruff falling from the sky," she said.

'Reckless' Decisions

Oshin Onofre, a 21-year-old in ripped jeans and a baby-blue sweater, said she started having convulsions and headaches 10 years ago. Although pills have controlled the convulsions, Onofre said she still struggles with memory loss, and had to drop out of nursing school last year. She lives with her mother.

Nashira Chavez is 9 but looks years younger. She weighs just 17 kilograms (38 pounds), according to her mother -- a little more than half the average weight of U.S. girls her age. When Nashira was two years old, a government test found 55 micrograms per deciliter of lead in her blood.

"The only possibility is the contamination because I feed them well," said her mother, Leli Ventura Yupanqui. "I have a 3-year-old granddaughter and she already weighs more than her."

Missouri Lawsuit

In the federal lawsuit in Missouri, attorneys for La Oroyan children -- including Kenyi, Oshin and Nashira -- say Renco is to blame for "negligently, carelessly and recklessly" making decisions that caused the release of toxic substances from the smelter. Renco has denied responsibility for the children's ailments.

Several studies have confirmed that La Oroya's children have high levels of lead. Lead poisoning is particularly dangerous for young children because it can interfere with mental and physical development, causing learning and behavioral problems, slowed growth and, in the worst cases, convulsions and death, according to the Mayo Clinic.

In 1999, the Peruvian Ministry of Health tested 346 children from different parts of La Oroya and found an average 33.6 micrograms of lead per deciliter. The highest levels were in Old La Oroya, the part of town nearest the smelter, where the average was 43.5 and the highest reading was 79.9.

Elevated Levels

Another study in 2005, by Saint Louis University with assistance from the CDC, found that more than 80 percent of children tested who were 6 and younger had blood lead levels of 20 micrograms or more per deciliter, and 8 percent of those had levels of 45 or higher. The average in Old La Oroya was 36.1 for children 6 and younger, the study said.

The Saint Louis University study also found elevated levels of arsenic, cadmium and antimony, metals that have been linked by the U.S. EPA to serious illnesses, in some cases cancer.

More recent blood tests, in 2011 at the La Oroya health clinic, found that lead had mostly declined to between 10 and 20 micrograms per deciliter, a drop that a local health official attributed to the plant's temporary closure in 2009 and better health habits by residents.

There has been no long-term study tracking the health impact of the plant's emissions on La Oroya residents.

Irreversible Effects

Prior research has documented irreversible effects of lead poisoning on children, according to Joseph Graziano, professor of environmental health sciences at Columbia University. Children with more than 80 micrograms per deciliter are at risk of seizures and possibly death, Graziano said.

Those whose blood lead levels reach the 30s and 40s "are likely to be experiencing deficits in intelligence, behavior disorders, some loss of motor function, anemia and impaired kidney function" -- and except for anemia, none of these effects are reversed by later reduction in blood-lead, he said.

On a recent afternoon, Giovanna Arroya arrived at the clinic around the corner from the La Oroya smelter with her son Paolo, a chubby 7-month-old in a tiger hat. Ushered into an examination room decorated with cut-out letters and hearts, Arroyo, 40, was peppered with questions as Paolo squirmed.

Does Paolo suck his thumb? Does he eat dirt? How long have they lived in Old La Oroya?

"He's very high risk," said Herbert Damian, the clinic doctor, noting Paolo was anemic, stuffed things in his mouth and lived near the plant. "You really need to take care of this."

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Medical, Public Health Leaders: TPP Must Reduce Epidemic of Tobacco Use

Leading medical and public health groups and individuals have issued Strategies for Creating a 21st Century Trade Agreement, on the eve of TPP negotiations in Peru, calling on the U.S. to advance specific proposals that will safeguard public health, advance tobacco control measures at local, state, and national levels, and prevent incursions by the tobacco industry against those measures.

Tobacco use is the leading preventable cause of death worldwide, causing six million deaths a year, and is a major contributor to the global pandemic of non-communicable diseases, including among childreen. Tobacco companies have recently accelerated their use of trade rules to attempt to delay and reverse tobacco control measures.

1. Trade agreements must guarantee nations' rights to protect public health from tobacco use.

1a. Incorporate reference to the Framework Convention on Tobacco Control (FCTC) in trade agreements.

1b. Incorporate in the text of each regional and bilateral trade agreement the WTO Doha Declaration on countries' rights to protect public health.

1c. Strengthen the primacy of public health principles.

2. The TPP must not undermine the right and ability of participating countries from exercising their domestic sovereignty in order to adopt or maintain measures to reduce tobacco use and to prevent the harm it causes to public health.

2a. Exclude tobacco control measures from existing and future trade agreements.

2b. Remove investor-state dispute settlement (ISDS) provisions.

3. We must set trade policy through a transparent process that involves the public.

3a. Trade agreements and trade rules which may affect public health should be discussed and debated publicly, and in Congress.

3b. Include effective public health representation in setting trade policies at the national, state, and local levels.

We further propose that advocacy for these goals can be strengthened by identifying and communicating with related constituencies concerned with trade.

Organizational Endorsements:

Action on Smoking and Health, Laurent Huber, MSFD, Director; Chris Bostic,MSFS, JD, Deputy Director for Policy

American Academy of Family Physicians, Julie K. Wood, MD, FAAFP, Vice President, Health of the Public and Interprofessional Activities

American Academy of Pediatrics, Jonathan D. Klein, MD, MPH, FAAP, Associate Executive Director and Director, **Julius B. Richmond Center of Excellence**

American College of Obstetricians and Gynecologists, Barbara Levy, MD, Vice President for Health Policy

American College of Physicians

American Heart Association, American Stroke Association, Terry Sue Mock, Senior Health Systems Policy Director

American Public Health Association, Georges C. Benjamin, MD, FACP, FACEP (E), Executive Director

Center for Policy Analysis on Trade and Health (CPATH): Joe Brenner, MA, Co-Director; Ellen R. Shaffer, PhD MPH, Co-Director; Sohil Sud, MD, MA, Senior Fellow, CPATH, Senior Pediatric Resident, UCSF

San Francisco Medical, Society, Steve Heilig, MPH

San Francisco Tobacco Free Coalition

Individual Endorsements: * Organizations listed for identification purposes only

Phillip Gardiner, Dr.PH, Program Officer, Policy and Regulatory Sciences, Tobacco Related Disease Research Program*

Stanton Glantz, PhD, Director, Center for Tobacco Control Research and Education, University of California, San Francisco*

Richard L. Barnes, JD, Health Sciences Clinical Professor; **Eric Crosbie**; **Mariaelena Gonzalez,** PhD; **Heikki Hiilamo**, PhD; **Lauren Lempert,** JD MPH

Holly Jarman, PhD, Research Assistant Professor, Center for Law, Ethics & Health / Department of Health Management & Policy, University of Michigan School of Public Health*

Wendy Max, PhD, Professor of Health Economics, Co-Director, Institute for Health & Aging, University of California, San Francisco*

Michael Ong, MD PhD, Associate Professor-in-Residence of Medicine, University of California, Los Angeles*

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Heather Wipfli, PhD, Associate Director, USC Institute for Global Health, Assistant Professor, Department of Preventive Medicine and School of International Relations*

Donald Zeigler, PhD, Adjunct Associate Clinical Professor, University of Illinois at Chicago School of Public Health. Retired Director of Prevention and Healthy Lifestyles, American Medical Association*

Inside U.S. Trade

Daily News

No Decision Yet On Japan Participation At Next TPP Round, Official Says

Posted: May 20, 2013

LIMA – In an interview here with *Inside U.S. Trade*, a U.S. trade official said there is still no decision on whether Japan will participate in the next round of Trans-Pacific Partnership (TPP) negotiations, which is widely expected to be held in late July in Malaysia. The official said TPP countries would likely discuss the issue here as well as in their capitals.

Earlier this month, a senior Japanese official said TPP members are planning to hold the next round July 15-25 and that Japan wanted to participate in at least the last few days. Tokyo cannot participate in the talks – or even review the official TPP texts – until July 23, when a 90-day consultative period in the U.S. expires and Japan official joins, he said (*Inside U.S. Trade*, May 3).

The fact that Japan, if it does participate in the July round, will not review the legal texts until July 23 means that it cannot substantively negotiate in Malaysia. Still, Japan wants to be seen at the table in July, partly for political reasons; for instance, one observer said Japanese officials are eager to demonstrate that they are helping to craft TPP rules as early on in the process as possible.

This observer speculated that TPP negotiators could agree to reserve the last day or two of the Malaysia round to walk Japanese officials through the various TPP chapters.

Once Japan joins, Assistant U.S. Trade Representative for Japan, Korea and APEC Affairs Wendy Cutler will be working on a lot of aspects of the plurilateral TPP negotiation that involve Japan as well as on the bilateral negotiations that will occur in parallel, the U.S. trade official said.

The U.S. has established two separate bilateral tracks with Japan on autos and non-tariff measures, and is also expected to negotiate bilaterally with Japan on goods market access.

The U.S. has also begun negotiating goods market access with Canada, although detailed bilateral discussions on goods are not slated to take place here, the official said. U.S. and Canadian officials exchanged market access offers in between the Peru and Singapore rounds and held an initial meeting in Washington intersessionally, according to the official.

Inside U.S. Trade

Daily News

State Lawmakers Make Demands On LNG, Environment, Investment In TPP

Posted: May 20, 2013

A group of more than 50 state legislators from 24 states today (May 20) sent a letter to Acting U.S. Trade Representative Demetrios Marantis urging him to negotiate provisions in the Trans-Pacific Partnership (TPP) that would allow the Department of Energy (DOE) to maintain control over liquefied natural gas (LNG) exports and would subject environmental obligations in TPP to binding dispute settlement procedures.

When it comes to LNG, current U.S. law requires DOE to accept applications to export natural gas unless such exports are determined not to be in the public interest, which is considered on a case-by-case basis. However, if the export destination is a country with which the United States has already implemented a free trade agreement, current U.S. law stipulates that exporting LNG is automatically deemed to be in the public interest, an exemption that environmental groups say is worrisome.

"We do not believe that the United States should forever cede its ability to manage natural gas resources – particularly when the potential impacts to communities and the environment are so high," the lawmakers wrote in their letter. If a final TPP agreement similarly exempts exports of LNG to TPP members from review, that could have major implications because Japan -- which will join TPP talks in July -- is a primary export destination for LNG.

In their letter, the state legislators demand that TPP be drafted in a way that allows DOE to continue to oversee LNG exports to TPP countries and press USTR for information on whether they intend to pursue this goal in the talks.

Maine Representative Sharon Treat, who helped organize the letter, told *Inside U.S. Trade* today that giving DOE the ability to retain this authority when it comes to TPP partners may very well require a change to U.S. law, something that could be controversial if done in the context of a trade deal. However, she stressed that this issue is important for state lawmakers that have to deal with the regulatory and environmental impact of natural gas extraction.

In a related development, DOE on Friday issued its second-ever approval of an application to export LNG to a non-FTA country from a state other than Alaska. It was the first such acceptance since DOE launched a months-long review of its process for determining when exports to non-FTA countries should be deemed in the public interest.

DOE's authorization makes clear that LNG exports to non-FTA countries will continue to be considered on a case-by-case basis, stating the department will "take a measured approach" in reviewing the other 19 pending applications. The approval is conditional, subject to environmental review, as well as final regulatory approval.

Concerning environmental protections, the state legislators listed a series of demands that largely supportthe current U.S. negotiating position. For instance, they called for a legally binding ban on trade of illegally harvested timber, an enforceable ban on trade in illegally taken wildlife, and binding provisions on sustainable fisheries management. The U.S. is facing resistance on these issues from other TPP partners that do not want them to be enforceable.

In the interview, Treat said she hoped that the letter could bolster the ability of U.S. negotiators to persuade their counterparts in other TPP countries that full enforceability for environmental provisions is an important issue for U.S. officials at both the federal and state levels. She also said it is important to show support for these issues so that USTR does not give in to demands by other TPP partners, especially as the U.S. is aspiring to conclude an agreement by the end of the year.

The state legislators also call on USTR to oppose inclusion of an investor-state dispute settlement mechanism in TPP. However, the U.S. is pushing hard to include such a mechanism in a final TPP agreement, although Australia continues to demand that it should not be subject to it.

Finally, the lawmakers urged USTR to draft TPP investment provisions in a way that does not undermine their ability "to enact and enforce fair, nondiscriminatory rules that protect communities, workers, and the environment." The letter was sent in the middle of the 17th round of TPP talks taking place in Lima, Peru.

Inside U.S. Trade

Daily News

U.S. Tables SPS Text; Other Countries Float Pharmaceutical IP Ideas

Posted: May 20, 2013

LIMA -- The United States has tabled legal text here that would establish a consultative mechanism for resolving sanitary and phytosanitary (SPS) disputes in a Trans-Pacific Partnership (TPP) agreement, while other TPP countries have informally floated new ideas for how to move forward in the controversial area of pharmaceutical intellectual property (IP) protections, according to a U.S. trade official.

In an interview midway through the Lima round, the official said the U.S. tabled its SPS disputes proposal last week and that the text follows the consultative mechanism approach laid out in the non-paper the U.S. floated at the March round of negotiations in Singapore. The SPS discussions took place here May 15-16

The official declined to characterize how other countries responded to the U.S. proposal, stressing that this was the first time they saw it and that they need time to review it.

But two informed sources said that one or several TPP countries during this round tabled a counterproposal that goes beyond the U.S. proposal by providing full dispute settlement procedures for SPS obligations. These sources pointed out that New Zealand, Peru and Chile are all likely in favor of full dispute settlement for SPS obligations because they are significant food exporters.

That would put them in line U.S. agriculture and food groups, which have quietly opposed the U.S. consultative mechanism approach while continuing to press the Obama administration to include fully enforceable SPS obligations in TPP.

On pharmaceutical IP, the U.S. trade official said that while there are no text-based negotiations taking place at this round, "various countries are coming to the table with various ideas of how to move the process forward."

According to informed sources, a group of TPP countries that includes Chile and New Zealand but not the U.S. has developed a discussion paper that lays out some common principles for protecting pharmaceutical IP, and one source said this paper was discussed here in Peru.

This source said the paper covers areas such as data exclusivity, patent linkage, and patent term extensions, using language from the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a starting point.

Another source said the countries involved in this effort see this discussion paper as a starting point for developing future legal text in case the U.S. further delays coming out with a revised proposal of its own on pharmaceutical IP.

The initial U.S. proposal, which focused on the idea of an "access window," met with criticism from other TPP countries as well as U.S. industry and civil society. The U.S. is currently exploring whether and how to revise it, but did not introduce any revised text here.

The U.S. trade official said the Obama administration has not yet completed this internal review process, which was the same message conveyed by U.S. chief negotiator Barbara Weisel during a briefing for stakeholders in Lima yesterday (May 19), according to informed sources.

The U.S. access window proposal would give brand-name drug companies access to stronger IP protections if they sought marketing approval for a drug in another TPP country within a certain period of time after first obtaining marketing approval in an initial TPP country. But the U.S. never defined the length of the access window.

On the controversial issue of textiles and apparel, the official said the U.S. has provided TPP countries with its short-supply list of items that would be subject to a more flexible rule of origin, ahead of group discussions on this topic that were slated to begin yesterday.

One informed source said the U.S. list contains 168 items, and the U.S. trade official said that was "more or less" an accurate number. Textile industry sources said the key question is to see how Vietnam responds to the U.S. proposal, although one source said Mexico has already conveyed concerns about the U.S. list.

This source said TPP countries will likely not be ready to take a formal position on the U.S. short supply proposals at this round, as they will need to vet them with capital-level officials and their domestic industries.

Yarns and fabrics on the short supply list would be exempted from the strict yarn-forward rule of origin the U.S. has tabled in the TPP, meaning they could be imported from non-TPP countries and still be used to make apparel that would eligible for tariff cuts under a final deal. Under yarn-forward, every component of an apparel item, starting with the yarn, has to be made in the TPP region in order to qualify for tariff benefits.

2013 REPORT ON TECHNICAL BARRIERS TO TRADE

UNITED STATES TRADE REPRESENTATIVE

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 17countries – 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).

Live from the Trans Pacific Partnership: IP Chapter Shows No Sign of Resolution, End of Negotiation in 2013 Highly Unlikely

http://infojustice.org/archives/29657 May 21, 2013

LIMA - There is a strong sense in the halls of the current TPP negotiation that the end is not in sight. And one of the primary reasons for the blocked progress is a lack of consensus on intellectual property and pharmaceuticals issues.

Officially, the Chief Negotiators have backed off the prior commitment to end the TPP negotiation by October, but are still clinging to a goal to end the negotiation by the "end of the year." But it is increasingly clear that even that goal is not achievable. The issues still under contention are massive.

The intellectual property chapter is rumored to be over 80 pages of text - including all the bracketed suggestions and alternatives. Some describe it as the longest text currently under negotiation.

Many of the issues are completely blocked. It does not apear that there has been any new negotiation text offered on the most controversial pharmaceutical provisions since the Melbourne round over a year ago. Nor does it appear that many countries have a mandate to negotiate (they only "consult" and "discuss") the pharmaceutical reimbursement chapter. Barbara Weisel described the pharmaceutical issues as being in a "period of reflection," and had no comment on when that period might end.

The internet issues are almost completely bracketed, with no consensus from the countries without FTAs with the United States that TRIPS plus issues on anti-circumvention liability and other hot button issues should be included at all, much less how they should be worded.

The recent spate of proposals for policy changes for US copyright law have caused a stir. The US is being asked by stakeholders how it can hold on to demands for parallel importation restrictions after the *Kirtsaeng* ruling, 70 year copyright terms after the Copyright Office proposed shifting them back to 50 years with formalities required for extensions, and strict restrictions on anti-circumvention liability exceptions when the Obama Administration and the Library of Congress have endorsed reforms that would violate the US proposal. In response to some of these questions, Barbara Weisel stated that USTR is "doing what we can to work with Congress" to make sure that the TPP will not restrict policy options.

And there is no plan to release any text to the public. This is stark contrast to the last to plurilateral agreements including countries in the region. The Free Trade Area for the Americas and the Anti-Counterfeiting Trade Agreement both released full texts of the negotiating document with brackets indicating text under consideration before the finalization of the texts. For ACTA, there were four publicly released texts between April 2010 and May 2011. For the TPP - none yet, despite the Chief Negotiators' pronouncement of end of year finalization plans.

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

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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 17countries – 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

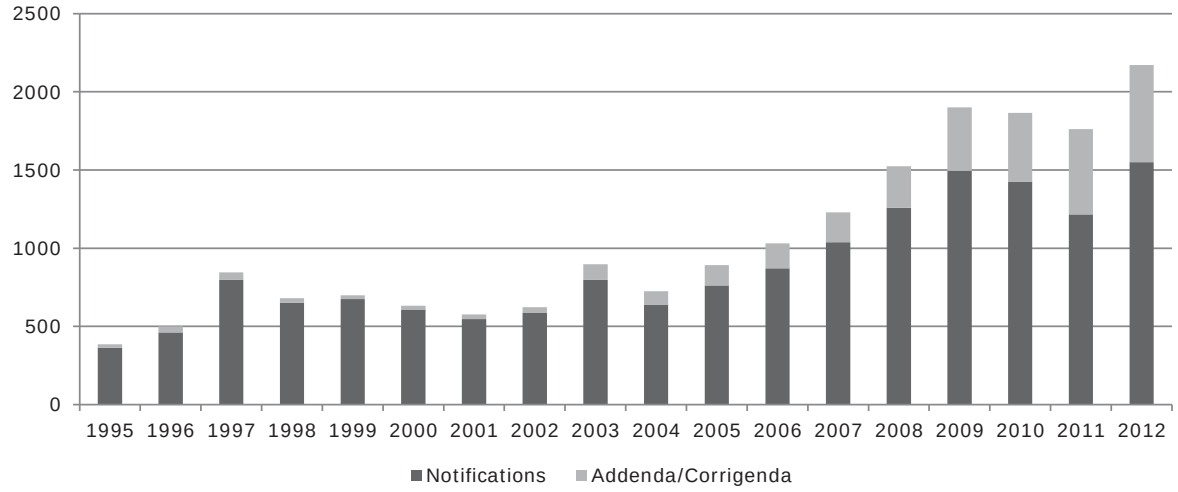
[5] Depending on the WTO Member's domestic processes, interested parties may participate directly in that Member's process for developing new standards-related measures, for example, by submitting written comments to the Member, or indirectly by working with their own governments to submit comments.

[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 1995***[10]



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

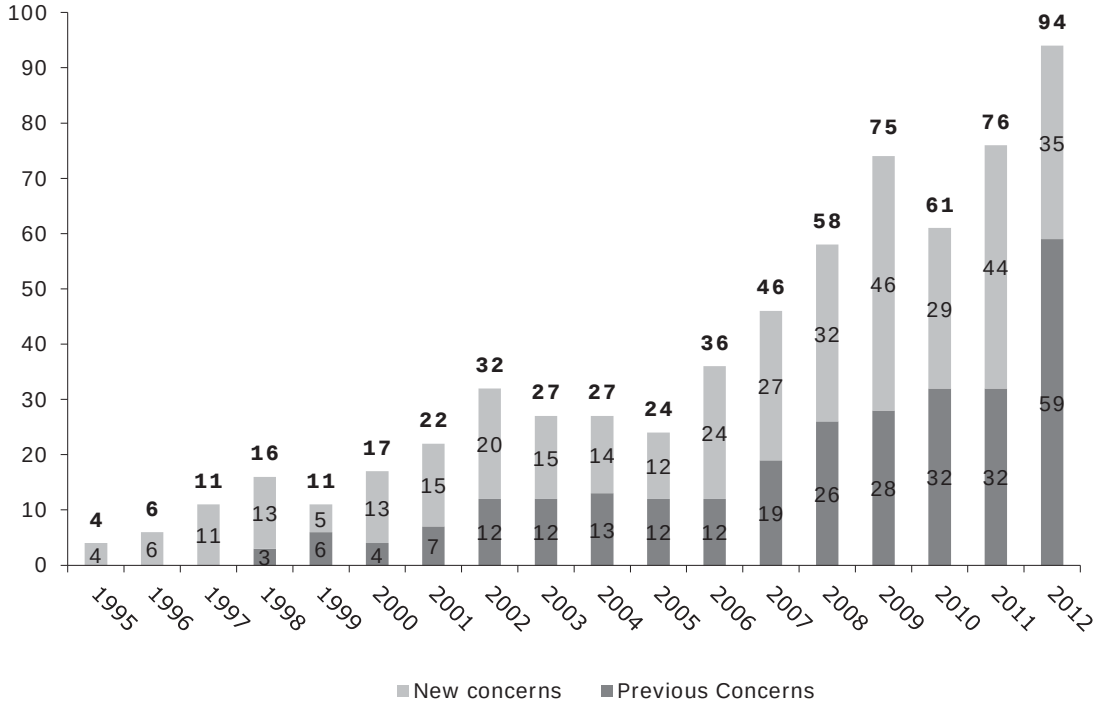
[11] See G/TBT/GEN/1/Rev.11 for a list of Members' submissions on the measures they have taken to implement and administer the TBT Agreement.

[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 year***[14]



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.

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[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 and 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.

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[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 use[21] voluntary consensus standards[22] 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 competition[24] 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*, 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 organizations[31] 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 CITEL (Inter-American Telecommunication Commission) MRA with respect to the United States. Under the CITEL MRA, two or more CITEL 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 CITEL. If Brazil implemented the CITEL 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 CITEL 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 (KMVSS) 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-KMVSS 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 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

CITIZEN TRADE POLICY COMMISSION
DRAFT AGENDA

Monday, July 1, 2013 at 9:30 A.M.
Room 214, Burton M. Cross State Office Building
Augusta, Maine

9:30 AM Meeting called to order

I. Welcome and introductions; newly appointed CTPC member, Pamela Taylor, Department of Labor

II. Review of 5/30/13 letter from U.S. Customs and Border Protection

III. Request from Representative Sharon A. Treat to be reimbursed for travel expenses to attend the Direct Stakeholder Engagement Event to be held on 7/10/13 in Washington DC and sponsored by the USTR in conjunction with the first round of the Transatlantic Trade and Investment Partnership (TTIP) (9:30 AM)

IV. Presentation from Kathie Leonard, President of Auburn Manufacturing and member of USTR (10 AM)

V. Update on IGPAC/USTR activity (Representative Sharon Treat, CTPC Chair) (11:00 AM)

VI. Articles of interest (Lock Kiermaier, Staff) (11:30 AM)

VII. Brief discussion on scheduling possible dates and locations for statutorily required 2 public hearings per year in different locations within the state.

VIII. Proposed next meeting date and suggestions for agenda topics

Adjourn

1300 Pennsylvania Avenue NW
Washington, DC 20229

RECEIVED JUN 14 2013

U.S. Customs and Border Protection

MAY 30 2013

Ms. Sharon Anglin Treat
Citizen Trade Policy Commission
State House Station #13
Augusta, ME 04333

Dear Ms. Treat:

Thank you for your recent letter to Secretary Napolitano concerning the Land Border User Fee Study in President Obama's fiscal year (FY) 2014 Budget to Congress. After consideration of the concerns you raise about the study, I would like to share more information regarding U.S. Customs and Border Protection's (CBP) reasoning and intentions.

First, it is important to note that CBP's Land Border User Fee Study, is only a study, and; not a proposed fee for FY 2014. As referenced in your letter, many northern border states and local communities have an integral travel and commerce cross-border relationship with Canada. The intention with any fee is to improve that throughput, not to dissuade it.

Consideration will be given to any potential economic benefits resulting from a fee. The additional revenue generated through reasonable land border fees would allow for more CBP officers at our ports and result in decreased wait times.

CBP's intent is to develop a full economic and cost benefit analysis, then conduct an assessment of logistics and steps involved in collection, and finally conduct a pilot that will test all steps involved in land border user fee collection without actual collections. CBP will follow the pilot by analyzing options for land border pedestrian and passenger vehicle fees.

CBP is committed to facilitating and securing lawful travel and trade through U.S. Ports of Entry. Recent years have seen historic travel volumes – with privately owned vehicle traffic up 4.7 percent since FY 2011 and projected to rise in future years. Truck volume has been increasing since the economic downturn, and is also up by 14 percent since FY 2009. Inbound trade volume overall has recovered with import values growing by 5 percent, reaching $2.3 trillion in FY 2012, and expected to exceed records in the air, land, and sea environments this year. We recognize the importance to our economy that a secure, streamlined border management process has on growing volumes of trade and travel.

There is currently a disparity in user fee collections between air, land, and sea ports of entry, because of the existing statutory framework and the long established collection mechanisms through air carriers and cruise lines. Currently, CBP incurs costs for inspecting pedestrians, bus passengers, vehicle passengers, and rail passengers, yet for the bulk of these activities, there are no fees in place to recover the costs. Therefore, the costs must be offset by taxpayer-funded

appropriations. In FY 2012, the portion of costs supported by appropriation totaled over $1.2 billion dollars.

In thousands	**FY 2010**	**FY 2011**	**FY 2012**
Total Land environment costs	$1,282,591	$1,253,938	$1,351,974
Land environment fee collections[1]	$67,226	$73,817	$78,550
Fee recovery level of all costs	5%	6%	6%
Land environment costs funded by appropriations (Total costs minus fee collections)	$1,215,366	$1,180,121	$1,273,423

Collections on the land border would likely be very different than current collection methods, and CBP will examine multiple methods and systems for actual collections and remittances. A few of the focus areas for the study may include (but will not be limited to) commercial bus and rail passengers, existing toll facilities, and penalties for Western Hemisphere Travel Initiative (WHTI) non-compliance.

In the course of the Land Border User Fee Study, CBP will explore the economic impact of increasing wait times at the border and lost opportunity costs versus a potential fee to determine which is potentially more harmful to cross-border travel and commerce. CBP recognizes the difference between daily land border commuters and international air and sea passengers, and will pursue a full understanding of any potential economic disincentive to cross-border trade and travel. CBP recognizes many northern border states and local communities have an integral travel and commerce cross-border relationship with Canada, and the intention with any fee, would be to improve throughput, not dissuade it.

Wait times, and their effect on the local and national economy, has been researched extensively. In February 2013, the National Center for Risk and Economic Analysis of Terrorism Events (CREATE) released a report regarding wait times titled, *The Impact on the U.S. Economy of Changes in Wait Times at Ports of Entry.* CREATE's analysis found that an increase or decrease in staffing at the Ports of Entry has a tremendous impact on wait times and the U.S. economy. The impacts begin with changes in tourism, business travel expenditures, and freight costs affecting not only local communities, but eventually the overall U.S. economy.

In summary, CREATE found that the impacts on the U.S. economy of adding 33 CBP officers are a $65.8 million increase in Gross Domestic Product (GDP), $21.2 million in opportunity cost savings, and employment gains of 1,094 annual jobs. The U.S. Travel Association found that every 33 overseas travelers creates one new American job, CREATE's findings equate to 33 American jobs per CBP officer added. In addition to economic benefits, greater law enforcement presence will result in increased security and enforcement effectiveness.

[1] CBP collects a small amount of fees through the CBP Trusted Traveler programs (NEXUS, FAST, SENTRI, Dedicated Commuter Lane (DCL)), I-94 entries, I-68 entries, I-190 entries, rail and truck (COBRA), and agriculture which are then applied to CBP's land environment costs.

As an example of the potential economic and enforcement benefits, CBP reported that for every 1,000 CBP officers hired, the following estimated outcomes could be expected:

- $2 billion increase in GDP
- $642 million in opportunity costs saved
- 33,148 annual jobs added
- 23,000 more enforcement actions
- $40 million drug seizure value increase
- $2.75 million currency seizure value increase
- $7.85 million trade penalty assessment increase
- $2.5 million Intellectual Property Rights seizures increase
- $42 million liquidated damage assessment increase

As we address expanded mission requirements, evolving threats, and increasing workload volumes, it is imperative that CBP explore alternative sources of funding in order to support national security and trade and travel facilitation missions that are vital to this nation. The study of a potential land border user fee[2] is just one of many options CBP is exploring as a way to maintain funding for existing capabilities, and provide better security and services to the trade and travel communities in the future.

The FY 2014 Budget also includes a series of legislative proposals to identify alternative sources of funding to provide for additional CBP officers and infrastructure requirements. These proposals complement the Resource Optimization Strategy and Workload Staffing Model, also released with the FY 2014 Budget, by creating a mechanism for CBP to engage in public-private partnerships to fund enhanced CBP services, support port improvements that would better facilitate flows of international trade and travel, and allow CBP to fund additional CBP officers.

Thank you again for your letter, CBP's study will thoroughly investigate all possible outcomes and will not propose any fee that may have negative consequences on cross-border economic activity. If I may offer further assistance, please contact my office at (202) 344-1620.

Sincerely,

David J. Murphy
Acting Assistant Commissioner
Office of Field Operations

[2] It should be noted that land border user fee refers to possible fees assessed on pedestrians, bus passengers, vehicle passengers, and rail passengers.

See below. This is the event I'd like to seek funding to attend. I would present the same testimony as was endorsed before, but this time instead of addressing the USTR it would be attended by negotiators from the other countries (the EU). I will pay my own way if necessary but hope to get CTPC funding. The cost would not exceed $350.

Sharon Anglin Treat
satreat@gmail.com
Sent from my iPad

From: FN-USTR-IAPE <IAPE@ustr.eop.gov>
Date: June 21, 2013, 12:29:37 PM EDT
To: FN-USTR-IAPE <IAPE@ustr.eop.gov>
Subject: Transatlantic Trade and Investment Partnership Stakeholder Events

Hello,

The Office of the United States Trade Representative will host a Direct Stakeholder Engagement event in conjunction with the first round of the Transatlantic Trade and Investment Partnership (TTIP) negotiations, scheduled to take place from **Monday, July 8 – Friday, July 12, 2013** in Washington, D.C.

Registration: Direct Stakeholder Event, Stakeholder Presentations
The Direct Stakeholder Engagement event will be held on Wednesday, July 10th from 11:30am – 2:30pm in Washington, D.C. at a TBD location and will be open to U.S. and EU stakeholders. This event will provide stakeholders with the opportunity to speak directly with TTIP negotiators. In addition, stakeholders will have an opportunity to give presentations to negotiators as well as other interested stakeholders.
To register for this event, please click here. Please also use this link if you would like to give a presentation. **Only individuals registered to make a presentation will be permitted to do so.**

Registration: Stakeholder Briefing
On Wednesday, July 10th from 4:30 – 5:15pm, USTR will host a separate stakeholder briefing in Washington, D.C. at a TBD location. During this briefing, the U.S. and EU chief negotiators will brief stakeholders and stakeholders will be given the opportunity to ask questions. Due to limited spacing, USTR registration for this event is on a first come, first serve basis.
To register for this event, please click here.

The **registration deadline for both stakeholder events is Friday, June 28th at 5:00pm EST**. We will be unable to accommodate any registrations received after this time. Due to security concerns, we will not be able to allow access to anyone who is not registered.

Confirmation of Information
Following the close of registration, we will follow up with confirmation of your participation and to provide further logistical details for the day of the event. For those registered to give presentations, you will also receive information regarding timing. Your registration will not be

confirmed until you receive the final confirmation email from us following the close of registration.

If you have questions about your registration, please email iape@ustr.gov. More information is posted on our website.

We look forward to hearing from you.

Sincerely,
Office of Intergovernmental Affairs and Public Engagement
Office of the United States Trade Representative

Auburn Manufacturing, Inc.
The Safest Name in Extreme Temperature Textiles
PO Box 220, Mechanic Falls, ME 04256 USA
Tel: 800-264-6689/Fax: 207-345-3380
www.auburnmfg.com

BACKGROUND INFORMATION

KATHIE M. LEONARD

June, 2013

POSITION: Founder and President/CEO
Auburn Manufacturing, Inc.

EDUCATION

University of Maine, Business Administration, 1983-86
Assoc. of Arts – St. Petersburg College, St. Petersburg, FL 1972

COMPANY BACKGROUND:

Kathie Leonard co-founded AMI in 1979, and is a 100% small woman-owned business with two manufacturing plants in Central Maine, with 50 employees. For over 30 years, the company has specialized in making a wide variety of heat-resistant textile products to save energy and protect people, plant and equipment from fire and extreme heat. Industries served include petrochemical, refining, utilities, shipbuilding, paper, steel, aluminum, glass and marine, in both maintenance and construction operations. The company's most recent innovation is a patented modularized insulation kit, designed for use in institutional and commercial markets.

INDUSTRY INVOLVEMENT:

Member, International Trade Action Committee 11, US Dept of Commerce, 2010-2014
Member, National Insulation Association (NIA) since 1995
Member, National Council of Textile Organizations (NCTO) (Previously AMTAC)
Steering Comm. Member: Government Textile Contracts Committee 2013-
Member, Industrial Fabrics Association International (IFAI)
Member, United States Industrial Fabrics Institute (USIFI)
Member and former Exec. Comm. Member, Welding Equipment Manufacturers Committee (WEMCO) of the American Welding Society, 1997-present
Member, National Fire Protection Association, 2000-present
Member, Women's Business Enterprise National Council (WBENC) 2007-present

Auburn Manufacturing, Inc.
The Safest Name in Extreme Temperature Textiles
PO Box 220, Mechanic Falls, ME 04256 USA
Tel: 800-264-6689/Fax: 207-345-3380
www.auburnmfg.com

COMMUNITY/PROFESSIONAL ACTIVITIES:

Present:

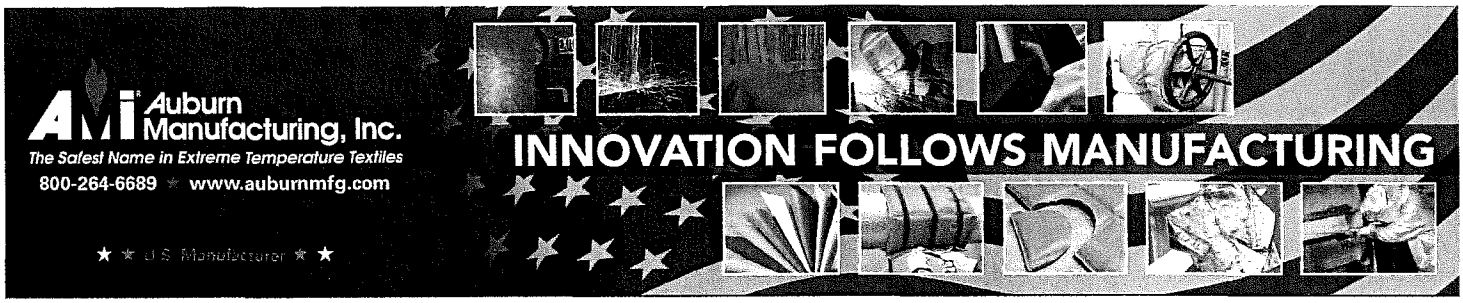
Member of the Board off Directors, Sun-Journal Newspaper, Lewiston, Maine
Board of Advisors, North Atlantic Seafood, Inc., 2/08 to present
Member and Former Co-Chair, Lewiston/Auburn Future Forum (part of LAEGC)
Chair, Leadership Council of the Garcelon Soecity, Bates College
Member and former Chair, Lewiston/Auburn Economic Growth Council (LAEGC)

Past:

Chair, Board of Directors of Central Maine Healthcare, Lewiston, Maine (2001-03)
Trustee, Central Maine Medical Center, Lewiston, 1998-2006
Board of Trustees, Thomas College, 10/96-2006
Chair, Central Maine Health Ventures Board of Directors, 1990-2000.
Member, Committee of 200, a national professional women's association (2001-03)
Council Member, Maine Health Care Performance Council, established in 2001 by Gov. Angus King
Director, Key Bank of Maine, 1988-2000
Member, Finance Committee, Lewiston/Auburn Economic Growth Council, 1996-2000
Member, Governor's Business Advisory Council, 1987-89
Chair, Small Business Advocacy Committee of the Maine Chamber, 1989-91
Member, Governor's Defense Realignment Task Force, 1990
Planning Committee, Colby College Institute for Management, 1986-91

SPECIAL HONORS:

2013 Maine Magazine's July Edition "50 People Who Have Made a Difference in Maine"
2009 Women To Watch Award by Mainebiz (Manufacturing Sector)
2007 Business Leadership Award, Androscoggin County Chamber of Commerce
2002 Economic Achievement Award, from Cities of Auburn & Lewiston
President's Award, National Insulation Association, 2000
SBA's Small Business Person of the Year, 1991
Governor's Award for Excellence, 1991



AMI FACTS

Auburn Manufacturing Inc. is a leading developer, manufacturer and marketer of the most advanced, safest and high-quality flexible barriers against extreme-temperature challenges. AMI's products are used in almost every major industry — primary metals, petroleum, chemicals, glass, paper, power generation, construction and transportation — wherever heat protection is required.

We were the first manufacturer to attain **third-party certification by FM Approvals of our hot work safety fabrics**, providing dependable protection from heat, sparks, and molten metal in the workplace. AMI also **helps industry save energy with our modularized thermal insulation blanket kits**, a new concept in removable and reusable insulation blankets for insulating bare piping and equipment components on steam and hot water distribution systems. (See Ever Green Insulation Kits on the reverse side)

AMI is a **U.S.-based small woman-owned business (SWOB)** that makes an exceptionally broad product line consisting of hundreds of standard and specialty textiles capable of withstanding temperatures from 225° to 3000°F.

Our products are used by major institutions and corporations including: U.S. Department of Defense, General Dynamics, Huntington Ingalls Industries, General Mills and Commonwealth Edison. In addition, hundreds of small and medium-sized businesses worldwide use our products for MRO and OEM applications.

MRO (Maintenance, Repair, Operations) Applications
- Welding Safety Fabrics — curtains, blankets, pads
- Pipe and Hose Coverings — cloth, tapes, tubing, removable pipe/valve insulation
- Gaskets/Seals — ropes, tapes
- Protective Apparel — industrial safety fabrics

OEM (Original Equipment Manufacturing) Applications
- Expansion joints for hot flue gas filtration systems
- Vehicle parts and accessories
- Theater lighting systems
- Marine accessories
- Rail car components
- Glass-making equipment
- Solar collectors
- Industrial belts
- Fire stopping systems
- Equipment Insulation

Meeting High Standards

Military
- MIL-C-20079H — Glass Cloth for thermal insulation components
- MIL-C-24576A — Cloth, Silica Glass for welding and cutting operations
- USCG164.009 — Test for Incombustibility
- NRC 1.36 — Nuclear Regulatory Commission Standard
- MIL I-24244B — Insulation Material with Special Corrosion, Chloride and Fluoride Requirements
- US DOE Safety Rule 10 CFR 851 — Worker Safety and Health Program (for DOE and National Nuclear Security Administration)
- US DOL 1910.252 — OSHA Standard on Welding, Cutting and Brazing

Industry
- ANSI/FM 4950 — Standard for Evaluating Welding Pads, Blankets and Curtains for Hot Work Operations
- NFPA 51B, 2009 Edition — Standard for Fire Prevention During Welding, Cutting and Other Hot Work
- California Code of Regulations, Title 8, Section 4848 Fire Prevention and Suppression Procedures
- ANSI Z49.1 — Safety in Welding, Cutting and Allied Processes
- API 2009 — Safe Welding, Cutting and Hot Work Practices in the Petroleum and Petrochemical Industries
- ASTM E84 — Standard Test Method for Surface Burning Characteristics of Building Materials
- ASTM C335 — Standard Test Method for Steady-State Heat Transfer Properties of Pipe Insulation
- ASTM C553 — Standard Specification for Mineral Fiber Blanket Thermal Insulation for Commercial and Industrial Applications
- ASTM C1695 — Standard Specification for Fabrication of Flexible Removable and Reusable Blanket Insulation for Hot Service
- ASTM E96, Procedure B — Standard Test Method for Water Vapor Transmission of Materials

Codes
Cage Code #9Y192
NAICS Code #313210

8

AMI is committed to providing the most advanced, safest and high-quality flexible barriers against extreme-temperature challenges worldwide, made by a team of friendly, knowledgeable US workers.

AMI FACTS

Ever Green® Insulation Kits

Ever Green® Cut 'n Wrap™ Insulation Kits — Hot Water Systems

Each Ever Green Cut 'n Wrap Insulation Kit, a patented technology, contains everything that's needed for quick and easy on-site fabrication of removable/reusable insulation blankets, providing a low-cost alternative for insulating bare piping components on steam and hot water distribution systems >120°F. Ideal for insulating valves and fittings requiring maintenance and inspection.

Industries Using Ever Green Cut 'n Wrap

- Pharmaceuticals
- Medical Centers
- Universities
- Food Processing
- Government Facilities
- OEMs

GSA Schedule Contract GS-07F-0007Y

For more information, visit **www.cutnwrap.com**

Interactive Website

The AMI website (www.auburnmfg.com) features an interactive "Search Wizard" to locate products by category. It allows user to quickly access application guidelines, safety ratings, performance specifications and competitive equivalency. MSDS and product data sheets are available for download. In addition, white papers, educational videos and case studies are available.

US MADE PRODUCTS. All AMI extreme temperature flexible barriers, hot work fabrics and Ever Green Insulation Kits are manufactured in the U.S and meet the Buy American Requirements

INTERNATIONAL DISTRICT ENERGY ASSOCIATION MEMBER

Certified WBENC Women's Business Enterprise

NIA National Insulation Association www.insulation.org

NFPA® MEMBER 2012-13

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E-mail: sales@auburnmfg.com
www.auburnmfg.com

AMI 3/12

Here's an actual email received by a US company from an Australian import/export firm:

It might be possible to ship silica material from JSC "Polotsk-Steklovolokno" Belarus via Montreal in Canada.

The goods can be shipped in neutral packaging and markings which will not show Belarus as the country of origin of the goods. We will also use different country fumigation stamps on the wooden pallets.

I'm not sure how you feel about importing the goods in this way. I do know from recent experience that you'd be unable to send any payments to Belarus from the US, but there seems to be no such restrictions for us in Australia. We've shipped a number of orders from Belarus in recent months without any payment problems.

I can quote you pricing DDU Montreal for container loads. I think the price should be competitive.

Of course, I'd be happy to proceed with the Chinese made materials if you prefer.

Kathie Leonard

From: Kathi Dutilh <kdutilh@millikendc.com>
Sent: Thursday, June 27, 2013 5:45 AM
Subject: The Hill: Free trade must be a two-way street

Free trade must be a two-way street

By Reps. Howard Coble (R-N.C.), Bill Pascrell (D-N.J.) and Mick Mulvaney (R-S.C.) - 06/25/13 06:49 PM ET

The future of American manufacturing and the millions of jobs it provides depends on the successful competition of American-made goods in foreign markets. Toward that end, we support free trade agreements that give participating countries the chance to compete on a level playing field, where no country has an unfair advantage over another.

Give American workers a fair chance to compete anywhere in the world, and they will succeed, helping our economy to thrive and create new jobs and opportunities. But a fair chance means everyone plays by the same rules, rules that make certain the trade agreements we make are fair as well as free.

The American textile and apparel industry has agreed to past trade agreements in instances when they ensured parties to the agreement could sell their goods and services in each others' markets as long as each country abided by the same set of effectively enforced rules. Those agreements resulted in greater demand for American textile and apparel exports and, consequently, greater job growth in the industry.

The textile and apparel sector employs more than 500,000 Americans in every part of our country, many of them in rural areas hardest hit by the recent recession and where well-paying jobs are scarcest. Textile and apparel manufacturing jobs typically pay much higher average wages than do jobs in service and retail industries, and they offer better health and retirement benefits as well. The industry's continued growth is vitally important to families in communities where textile mills operate, as well as to communities where our suppliers and domestic customers are located.

The U.S. is currently negotiating a new trade agreement, the Trans-Pacific Partnership (TPP), with 10 other nations: Canada, Mexico, Chile, Peru, Australia, New Zealand, Brunei, Singapore, Malaysia and Vietnam. By reducing tariffs and duties and eliminating other trade barriers, the TPP could lead to even greater demand for our textile exports, and to greater job creation in the U.S. But to achieve that, the TPP must adhere to the same rules on textiles as our previous trade agreements.

American jobs should be the first priority for American trade negotiators, just as job growth in their countries is our trade partners' first priority. Opening markets to exports benefits everyone, but we shouldn't forget that trade agreements are first and foremost job-creating policies, not foreign assistance programs.

One country involved in TPP negotiations — Vietnam — is seeking an unfair advantage over the U.S. and our other trade partners. It could cost the jobs of over 1 million textile and apparel workers in the U.S. and among our trading partners throughout the Western Hemisphere and Africa. We call on the Obama administration to insist that the TPP follows the successful practice of previous free trade agreements, which included a "yarn forward" rule of origin to ensure that only textile and apparel manufacturers in the countries that are party to a free trade agreement enjoy the benefits of the agreement.

"Yarn forward" requires that the yarns, fabrics and final garments exported within the TPP are produced in TPP countries. Vietnam wants to replace the "yarn forward" rule with a "flexible rule of origin," which requires that only the sewing of a garment must be done in TPP countries. This would allow Vietnam's state-owned industry to export apparel duty free to the U.S. and the other markets of the TPP made from yarns and fabric imported from the massive state-owned textile industry in China, which is not part of the TPP.

The "yarn forward" rule has been an essential component of every free trade agreement the U.S. has negotiated over the last 25 years, and it has created over $25 billion in two-way trade with our trade partners. This trade supports nearly 2 million jobs. Replacing it with a "flexible rule of origin" would more than quadruple Vietnamese exports to the U.S. while driving American textile and apparel jobs to Asia. Our Western Hemisphere free trade partners and African Growth and Opportunity Act partners would be big losers as well.

And, indefensibly, it would inevitably result in the outsourcing of more than 8,000 textile and apparel products made today by U.S. workers and U.S. companies for the U.S. military to Chinese manufacturers. These products amount to more than $2 billion a year in vital equipment for our fighting men and women.

We cannot support a trade agreement that gives one country and its state-owned and subsidized industry such an enormous and unfair advantage over privately owned American businesses and their workers, and gives an undeserved boost to a government-owned industry in a country that is not even a party to the TPP. The "yarn forward" rule must remain intact with no loopholes in the TPP.

Furthermore, as we have done in previous free trade agreements, the U.S. should insist that the TPP include extended tariff phase-outs for goods produced in TPP countries that heavily subsidize their apparel industry, as is the case in Vietnam. We should also require the agreement include an electronic customs enforcement system that will prevent countries from cheating.

With these provisions, the textile section of the TPP could be a landmark achievement for proponents of free and fair trade and an engine of job creation in the U.S. and all TPP countries. Without them, hundreds of thousands of American workers could lose their livelihoods to workers in countries that believe free trade is a one-way street. Now, more than ever, America must demand fair treatment for American made goods and for the rules and benefits of genuinely free and fair trade.

Coble has represented North Carolina's 6th congressional district in the House of Representatives since 1985. He serves on the Judiciary and Transportation and Infrastructure committees, and is co-chairman of the Textile Caucus. Pascrell represents New Jersey's 9th congressional district and has served in the House since 1997. He sits on the Budget and Ways and Means committees, and is co-chairman of the Textile Caucus. Mulvaney has represented South Carolina's 5th congressional district since 201. He serves on the Financial Services and Small Business committees, and is a member of the Textile Caucus.

New NSA allegations rile foreign allies

German weekly reports of alleged covert listening device installations in EU offices

BY LARA JAKES
and FRANK JORDANS
Associated Press

WASHINGTON — The Obama administration faced a breakdown in confidence Sunday from key foreign allies who threatened investigations and sanctions against the U.S. over secret surveillance programs that reportedly installed covert listening devices in European Union offices.

U.S. intelligence officials said they will directly discuss with EU officials the new allegations, reported in Sunday's editions of the German news weekly Der Spiegel. But the former head of the CIA and National Security Agency urged the White House to make the spy programs more transparent to calm public fears about the American government's snooping.

It was the latest backlash in a nearly monthlong global debate over the reach of U.S. surveillance that aims to prevent terror attacks. The two programs, both run by the NSA, pick up millions of telephone and Internet records that are routed through American networks each day. They have raised sharp concerns about whether they violate public privacy rights at home and abroad.

Several European officials — including in Germany, Italy, France, Luxembourg and the EU government itself — said the new revelations could scuttle ongoing negotiations on a trans-Atlantic trade treaty that, ultimately, seeks to create jobs and boost commerce by billions annually in what would be the world's largest free trade area.

"Partners do not spy on each other," said EU Justice Commissioner Viviane Reding. "We cannot negotiate over a big trans-Atlantic market if there is the slightest doubt that our partners are carrying out spying activities on the offices of our negotiators. The American authorities should eliminate any such doubt swiftly."

European Parliament President Martin Schulz said he was "deeply worried and shocked about the allegations of U.S. authorities spying on EU offices." And Luxembourg Foreign Minister and Deputy Prime Minister Jean Asselborn said he had no reason to doubt the Der Spiegel report and rejected the notion that security concerns trump the broad U.S. surveillance authorities.

"We have to re-establish immediately confidence on the highest level of the European Union and the United States," Asselborn told The Associated Press.

According to Der Spiegel, the NSA planted bugs in the EU's diplomatic offices in Washington and infiltrated the building's computer network. Similar measures were taken at the EU's mission to the United Nations in New York, the magazine said. It also reported that the NSA used secure facilities at NATO headquarters in Brussels to dial into telephone maintenance systems that would have allowed it to intercept senior officials' calls and Internet traffic at a key EU office nearby.

The Spiegel report cited classified U.S. documents taken by NSA leaker and former contractor Edward Snowden that the magazine said it had partly seen. It did not publish the alleged NSA documents it cited nor say how it obtained access to them. But one of the report's authors is Laura Poitras, an award-winning documentary filmmaker who interviewed Snowden while he was holed up in Hong Kong.

Britain's The Guardian newspaper also published an article Sunday alleging NSA surveillance of the EU offices, citing classified documents provided by Snowden. The Guardian said one document lists 38 NSA "targets," including embassies and missions of U.S. allies like France, Italy, Greece, Japan, Mexico, South Korea, India and Turkey.

In Washington, a statement from the national intelligence director's office said U.S. officials planned to respond to the concerns with their EU counterparts and through diplomatic channels with specific nations.

However, "as a matter of policy, we have made clear that the United States gathers foreign intelligence of the type gathered by all nations," the statement concluded. It did not provide further details.

Article notes: July 1, 2013 CTPC agenda

China Hints at Softening on Trade Talks (5/30/13)

- Contrary to a previous stance, China has officially indicated that it would be willing to consider participating in the TPPA;
- Previously, China had been quite wary of the TPPA negotiations, feeling that the TPPA might be aimed at curbing China's growing international trade presence;
- In an official statement, the Chinese government indicated that it hoped that the "TPP negotiations are able to increase transparency"; and
- Potential obstacles to China's participation in the TPPA include potential rules regarding state-owned enterprises and currency trading; both of which are staples of China's unique brand of "state-led capitalism".

Worlds Apart: Making Sure Trade Policies Improve Global Health | Commentary (5/31/13)

- This opinion piece is authored by U.S. Congressman (D) and physician Jim McDermott who lives in the State of Washington. Congressman McDermott expresses his deep reservations about the current USTR negotiating stance on intellectual property issues as they affect the availability of generic drugs;
- Current international trade agreements contain strong rules on intellectual property that properly protect innovations for the development of new drugs while at the same time providing adequate access for poorer, undeveloped nations to acquire generic drugs to fight current health threats such as AIDS;
- The current USTR stance for the TPPA advocates for very rigid and restrictive intellectual property rules which would significantly inhibit the availability of generic drugs that are critically needed by underdeveloped countries; and
- The USTR proposal disrupts the current status quo by significantly extending monopoly protections for newly developed drugs, requires patents for new versions of old medicines that do not do anything different and outlaws the practice of "pre-grant opposition" which allows doctors and patients to provide information about drug patents that do not meet national rules.

Obama's Covert Trade Deal (6/2/13)

- This article is an advocacy piece that maintains that President Obama and the USTR are flouting past traditions of relative transparency and adequate congressional oversight when it comes to the review and approval of the TPPA;
- Contrary to past practice of President George W. Bush, who released online the full draft text of the 2001 Free Trade of the Americas, the USTR has not released a draft of the nearly complete TPPA agreement. Instead, access to the draft treaty has been limited to a group of approximately 600 trade "advisers" – many of whom are representatives of big business;
- Big business has a vested interest in ensuring that the TPPA protect their interests to the detriment of the greater good of the American public and international free trade in general;
- There are numerous parts of the TPPA that could circumvent state and federal law and result in the restriction of the availability of generic medicines, more restrictive rules regarding patents and copyrights and the inclusion of incentives which would hasten the further relocation of domestic manufacturing to offshore sites;
- Members of the Senate have been denied access to the TPPA draft documents and are likely to have to pass judgment on the draft treat in an up or down vote which will be mandated by the co-called "fast-track authority" that president Obama is seeking for approval of the TPPA; and

- Former USTR Ron Kirk previously stated that his opposition to making the draft TPPA agreement public was because he felt that to do so would result in opposition sufficient to defeat the treaty.

Over Two-Thirds of Democratic House Freshmen Tell Party Leadership They Oppose Transferring Their Constitutional Trade Authority to the President (6/11/13)

- More than 2/3rds of freshmen Democrats in the U.S, House of Representatives have sent a letter to Representative Sander M. Levin, Ranking Member of the Ways and Means Committee and to Representative Nancy Pelosi, House Minority Leader, expressing their opposition to the proposal from President Obama to have Congress approve the TPPA through use of "fast track' authority which would require Congress to vote yes or no on the treaty in its entirety;
- The signees of the letter noted that after three years of TPPA negotiations that there have been no authorized releases of any of the TPPA draft sections and the few sections that have been leaked have stirred significant controversy; and
- The participating congressmen strongly object to the lack of adequate congressional oversight regarding the details of the TPPA and are opposed to the inappropriately broad delegation of Congress's constitutional trade authority via use of fast track authority.

Business Groups Urge Congress To Oppose Wave Of Buy American Requirements (6/12/13)

- Fifteen U.S. trade associations have asked Congress to oppose legislation that includes "Buy American' requirements;
- These groups include the Water and Wastewater Equipment manufacturers Association (WWEMA), U.S. Chamber of Commerce and the National Foreign Trade Council;
- "Buy American" legislation is opposed for several reasons including the reality that much of wastewater technology is comprised of components made outside of the United States. In addition, "buy American" requirements often result in retaliatory legislation in other countries thereby significantly hampering the ability of U.S. companies to engage in significant international trade opportunities; and
- In addition, "Buy American" requirements are opposed because of the real possibility that such requirements could undermine various international trade agreements such as the upcoming U.S.– European Union free trade agreement.

Obama trade dilemma: Scant support from Democrats (6/15/13)

- President Obama's efforts to promote free trade agreements such as the TPPA and the Trans-Atlantic Trade and Investment Partnership are likely to run into significant opposition from Congressional Democrats as well as some Republicans;
- Free trade agreements such as the TPPA usually have the support of Republicans but a number of congressional Republicans may oppose the upcoming trade agreements simply because they are opposed to the President;
- On the other hand, traditional democratic constituency groups such as labor unions, human rights and environmental groups have often opposed free trade agreements like NAFTA in the past and are likely to have significant reservations about the TPPA and the upcoming European Union agreement. The reservations from these groups centers on the possible loss of American jobs and various workplace and environmental abuses that often occur in foreign countries;
- Japan's inclusion in the TPPA was also opposed by lawmakers from auto manufacturing states which object to Japan's restrictions on auto imports; and
- In general, business in the U.S. tends to support free trade agreements while labor tends to oppose them.

http://stream.wsj.com/story/latest-headlines/SS-2-63399/SS-2-243529/

China Hints at Softening on Trade Talks

May 30, 2013

China has suggested it might be willing to join U.S.-led talks to strike an Asia-Pacific free-trade agreement, signaling a possible softening of its stance on the proposal shortly ahead of a key meeting between the U.S. and Chinese leaders.

BEIJING—China has suggested it might be willing to join U.S.-led talks to strike an Asia-Pacific free-trade agreement, signaling a possible softening of its stance on the proposal shortly ahead of a key meeting between the U.S. and Chinese leaders.

China's official press and academics in policy circles have generally been wary of talks to establish what is known as the Trans-Pacific Partnership. The talks include the U.S. and Japan and are focused on reducing trade and investment barriers among the 12 nations involved in the negotiations. Some critics in China say it is partly aimed at containing China's growing economic influence.

But this week a spokesman for China's Ministry of Commerce said that China would analyze the pros and cons as well as the possibility of joining the talks "based on careful research and according to the principles of equality and mutual benefit."

The spokesman, Shen Danyang, said in a statement posted on the ministry's website on Thursday that Beijing was also soliciting the views of other government departments.

On Friday, Foreign Ministry spokesman Hong Lei said "the Chinese side has an open-minded attitude with regard to the TPP... and other initiatives conducive to promoting Asia-Pacific economic integration and common prosperity."

Mr. Hong, speaking to reporters at a regular news briefing, said Beijing was paying close attention to the discussions and that it hopes that "TPP negotiations are able to increase transparency."

It wasn't immediately clear how much of a policy shift this might prove to be, and China would face major hurdles in joining the talks. Talks would most likely include issuing rules covering matters such as state-owned enterprises and currency trading—fixtures of China's unusual brand of state-led capitalism.

But the change in tone was evident. While Chinese officials have been circumspect about the TPP in public comments, state media has been more critical. In February, the People's Daily, the mouthpiece of the Communist Party, said in a commentary that "the U.S. effort to bring in Japan to the TPP is aimed at curbing the influence of China in the Asia-Pacific region."

The remarks from the Chinese ministries came shortly before a meeting between China's president and Communist Party leader Xi Jinping and U.S. President Barack Obama in the U.S.

next week. Mr. Xi is already on his way to the Americas, making stops in Trinidad and Tobago, Costa Rica and Mexico ahead of the meetings with Mr. Obama at an estate in California.

China could offer other moves to assuage the U.S. ahead of the talks. Currency markets in recent weeks have bid up the value of China's currency, the yuan, partly on expectations that China may move to give it greater flexibility in daily trading.

Ma Xiaoping, an economist at HSBC, called the change in tone a gesture, though cautioning against excessively high expectations. "It won't have any substantial impact on China or global trade any time soon. It's more like China's gesture of openness."

Another analyst said that Beijing's position on the trade talks has indeed been changing. "The government comments represent the view that China shouldn't miss any global trade negotiations no matter who is leading them," said Citigroup economist Ding Shuang, adding that there is a growing view that if Beijing wants to have a say in the pact, it needs to participate in the rules making.

"It's a start, but the TPP threshold is high and China is still far away from participating in it substantially," he said.

Japan is joining 11 nations already in talks on the TPP: the U.S., Canada, Mexico, Peru, Chile, Vietnam, Malaysia, Singapore, Brunei, Australia and New Zealand. Members hope to reach a deal by the end of this year. The addition of Japan would boost the proposed agreement to one covering nearly 40% of world economic output.

Some state media and prominent experts in China include the TPP among other signs of what they say see as a policy of containment by the U.S. against China. They point to the recent U.S. military and diplomatic pivot toward Asia, which has included deployment of an early-warning radar system in Japan that U.S. officials say is aimed at North Korea, as well as deployment of U.S. Marines in Australia.

Mr. Xi is a vocal proponent of a rejuvenation effort called the China Dream. Experts say the China Dream includes a prominent military and economic role for China in the Asia-Pacific region.

–Yajun Zhang, Brian Spegele and William Kazer

CQ NEWS – OPINION
May 31, 2013 – 12:56 p.m.
CQ NEWS – OPINION
May 31, 2013 – 12:56 p.m.
Worlds Apart: Making Sure Trade Policies Improve Global Health | Commentary
By Rep. Jim McDermott

As a member of Congress and a physician, I am very proud of the enormous generosity of the American people. Through their engagement, and their tax dollars, Americans help millions of disadvantaged people around the world by providing access to medical care and essential drugs. Unfortunately, we are also currently negotiating sweeping international trade agreements that may curtail our ability to continue helping the poorest of the poor.

Working as a doctor in sub-Saharan Africa during the 1980s, I witnessed the AIDS epidemic devastate entire communities. I saw adults die far too young and watched women pass HIV to their newborns without a cure or a compressive response. Amazingly, assuring an AIDS-free generation is not only within reach today; it is, in fact, an official policy goal of the U.S. government. And while the global progress of HIV/AIDS treatment and prevention is impressive, it is just one of many global disease control efforts that the United States has spearheaded and pursued.

With America's record of global health leadership in mind, I am troubled by what may happen to access to medicines for the poor around the world as a result of our new trade agreements.

The Trans-Pacific Partnership is being negotiated right now. It includes 10 countries of the Pacific Rim, including developing countries such as Peru, Malaysia and Vietnam. If the TPP agreement is done right, it will encourage and support American exports and create needed jobs in the United States. The critical intellectual property provisions of the pact should protect inventors and developers of breakthrough innovations, but they cannot be so restrictive that they cost millions of lives in less developed countries.

At the beginning of TPP negotiations two years ago, for reasons that are unclear, the U.S. asked the other 10 countries to accept new and very rigid intellectual property measures that would greatly limit availability of the affordable generic medicines that the success of U.S.-supported global health programs require. For example, more than 98 percent of HIV/AIDS medicines used to fight AIDS in Africa are generics, mostly made in Asia.

The United States is currently party to many international agreements that include strong intellectual property protections. These agreements protect innovation, including 20-year patents on new drugs, but they also allow enough flexibility for poorer countries to respond to public health needs with accessible, low-cost drugs. We worked hard to get these rules in place and they are working well.

But the U.S.' current TPP proposal on medicines upends the present well-structured balance by extending monopoly protections much further. It would force people in developing countries to wait longer for affordable medicines, if they can access them at all. It would extend patents beyond the current 20-year norm and block national regulators from using existing clinical trial data to approve the production of generic or "bio-similar" drugs.

Alarmingly, the proposal also outlaws "pre-grant opposition" that allows doctors and patients to provide information to their governments about patents they believe do not meet national rules, an important democratic safeguard. The proposal also requires the patenting of new versions of old medicines, even when the new versions offer no additional therapeutic benefits. It even

requires patenting of surgical, therapeutic and diagnostic methods, which not only is unethical but also could increase medical liability and the cost of practice.

Six years ago, my congressional colleagues and I battled similar issues during negotiations on trade pacts with Peru, Colombia and Panama, and we reached bipartisan agreement to protect public health. The "May 10th Agreement," as it's called, is working but now some are insisting on abandoning that effective approach.

The TPP may create millions of jobs here in the U.S. It also must facilitate even broader access to lifesaving medicine in our partner nations. The current U.S. proposal is being revisited now; it must be modified to reflect the beneficial balance we established years ago.

Global health, innovation and access to medicines are top priorities for many members of Congress and should be for this administration.

A TPP agreement that exacerbates already-delayed access to generic medicines is unacceptable. TPP has been called a "21st Century Agreement," but it will be anything but fresh if it makes crucial medicines even scarcer throughout the developing nations of the world.

Rep. Jim McDermott, D-Wash., is co-chairman of the bipartisan Congressional HIV/AIDS Caucus.

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Source: **CQ News**
Round-the-clock coverage of news from Capitol Hill.

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Obama's Covert Trade Deal
By LORI WALLACH and BEN BEACHY
Published: June 2, 2013

WASHINGTON - THE Obama administration has often stated its commitment to open government. So why is it keeping such tight wraps on the contents of the Trans-Pacific Partnership, the most significant international commercial agreement since the creation of the

The agreement, under negotiation since 2008, would set new rules for everything from food safety and financial markets to medicine prices and Internet freedom. It would include at least 12 of the countries bordering the Pacific and be open for more to join. President Obama has said he wants to sign it by October.

Although Congress has exclusive constitutional authority to set the terms of trade, so far the executive branch has managed to resist repeated requests by members of Congress to see the text of the draft agreement and has denied requests from members to attend negotiations as observers - reversing past practice.

While the agreement could rewrite broad sections of nontrade policies affecting Americans' daily lives, the administration also has rejected demands by outside groups that the nearly complete text be publicly released. Even the George W. Bush administration, hardly a paragon of transparency, published online the draft text of the last similarly sweeping agreement, called the Free Trade Area of the Americas, in 2001.

There is one exception to this wall of secrecy: a group of some 600 trade "advisers," dominated by representatives of big businesses, who enjoy privileged access to draft texts and negotiators.

This covert approach is a major problem because the agreement is more than just a trade deal. Only 5 of its 29 chapters cover traditional trade matters, like tariffs or quotas. The others impose parameters on nontrade policies. Existing and future American laws must be altered to conform with these terms, or trade sanctions can be imposed against American exports.

Remember the debate in January 2012 over the Stop Online Piracy Act, which would have imposed harsh penalties for even the most minor and inadvertent infraction of a company's copyright? The ensuing uproar derailed the proposal. But now, the very corporations behind SOPA are at it again, hoping to reincarnate its terms within the Trans-Pacific Partnership's sweeping proposed copyright provisions.

From another leak, we know the pact would also take aim at policies to control the cost of medicine. Pharmaceutical companies, which are among those enjoying access to negotiators as "advisers," have

long lobbied against government efforts to keep the cost of medicines down. Under the agreement, these companies could challenge such measures by claiming that they undermined their new rights granted by the deal.

And yet another leak revealed that the deal would include even more expansive incentives to relocate domestic manufacturing offshore than were included in Nafta - a deal that drained millions of manufacturing jobs from the American economy.

The agreement would also be a boon for Wall Street and its campaign to water down regulations put in place after the 2008 financial crisis. Among other things, it would practically forbid bans on risky financial products, including the toxic derivatives that helped cause the crisis in the first place.

Of course, the agreement must eventually face a Congressional vote, which means that one day it will become public.

So why keep it a secret? Because Mr. Obama wants the agreement to be given fast-track treatment on Capitol Hill. Under this extraordinary and rarely used procedure, he could sign the agreement before Congress voted on it. And Congress's post-facto vote would be under rules limiting debate, banning all amendments and forcing a quick vote.

Ron Kirk, until recently Mr. Obama's top trade official, was remarkably candid about why he opposed making the text public: doing so, he suggested to Reuters, would raise such opposition that it could make the deal impossible to sign.

Michael Froman, nominated to be Mr. Kirk's replacement, will most likely become the public face of the administration's very private negotiations and the apparent calculation that underlies them. As someone whose professional experience has been during the Internet era, he must know that such extreme secrecy is bound to backfire.

Whatever one thinks about "free trade," the secrecy of the Trans-Pacific Partnership process represents a huge assault on the principles and practice of democratic governance. That is untenable in the age of transparency, especially coming from an administration that is otherwise so quick to trumpet its commitment to open government.

Lori Wallach is the director of Public Citizen's Global Trade Watch, where Ben Beachy is the research director.

Over Two-Thirds of Democratic House Freshmen Tell Party Leadership They Oppose Transferring Their Constitutional Trade Authority to the President

Citizens Trade Campaign□June 11, 2013

Washington, DC — More than two-thirds of Democratic freshmen in the U.S. House of Representatives expressed serious reservations today about the Trans-Pacific Partnership Free Trade Agreement (TPP FTA) negotiations and the prospect of delegating Fast Track "trade promotion authority" to the President. They voiced their concerns in a letter sent to House Democratic Leader Nancy Pelosi and Ranking Ways and Means Member Sander Levin that was spearheaded by Wisconsin Congressman Mark Pocan and signed by 35 other House freshmen.

"The administration has yet to release draft texts after more than three years of negotiations, and the few TPP FTA texts that have leaked reveal serious problems," the letter reads. "Thus, we are especially concerned about any action that would transfer Congress's exclusive Constitutional trade authority to the president."

The TPP is poised to become the largest Free Trade Agreement in U.S. history. The twelve countries currently involved — the United States, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam — already cover approximately 40% of the global economy, and the TPP also includes a "docking mechanism" that could enable other countries to join over time. The TPP's seventeenth major round of negotiations concluded in Lima, Peru last month, and negotiators are racing to complete their work by an October deadline set by President Barack Obama and others.

Under Article 1, Section 8 of the U.S. Constitution, Congress possesses exclusive authority to determine the terms of international trade agreements, but the Obama administration wants Congress to transfer that authority to the executive through a new delegation of Fast Track "trade promotion authority." The President's nominee for U.S. Trade Representative, Michael Froman, reiterated that request during his Senate confirmation hearing last Thursday.

Fast Track delegates Congress' constitutional trade authority to the executive branch, allowing negotiators to determine the contents of trade agreement and to sign them before Congress has a vote on the matter. The rarely-used procedure also allows trade agreements to circumvent ordinary Congressional review, with the White House writing lengthy implementing legislation that is not amendable in committee or on the floor and must be voted on within 90 days of submission, leaving Congress with only take-it-or-leave-it approval of a completed package that, in the case of the TPP, is expected to be at least hundreds of pages long and cover some 29 separate chapters, affecting everything from food safety standards and medicine patents to energy regulations and public procurement decisions.

"It's encouraging that so many new Members of Congress recognize the problems inherent with Fast Track, and are demanding a more meaningful role in trade policymaking for themselves and their constituents," said Arthur Stamoulis, executive director of Citizens Trade Campaign. "Congressman Pocan and these other freshmen have demonstrated a real commitment to creating fair trade agreements that promote job creation and economic prosperity. That type of leadership is desperately needed if we're going to stop letting big corporations ship our jobs overseas and dump our wages and benefits overboard along the way."

A copy of the letter and its signatories follows:

The Honorable Sander M. Levin
Ranking Member
Ways and Means Committee
1106 Longworth House Office Building
Washington, D.C. 20515

Cc: The Honorable Nancy Pelosi

Dear Ranking Member Levin:

We look forward to working with you to establish United States trade policies that promote the creation of American jobs and support our national economic interests while safeguarding Congress's prerogatives to determine what domestic policies best promote the public interest.

As the economy continues to recover from the greatest financial crisis since the Great Depression, we can all agree that we cannot afford to have American production and American jobs sent offshore because of unfair trade agreements that undermine our economic growth. When jobs and production factories are offshored, American wages are lost, American-made products decline, and our international interests are compromised.

Job offshoring was a major issue in the previous election that unites our constituents – Democrats, Republicans and Independents alike. Polling consistently shows that Americans oppose our past model of "trade" agreements that facilitate offshoring, undermine Buy American policies, and subject American laws to review by foreign tribunals empowered to order payment of unlimited U.S. tax dollars to foreign firms that seek to avoid playing by the same rules as U.S. firms.

Thus, we write with serious concerns about both the Trans-Pacific Partnership Free Trade Agreement (TPP FTA) now being negotiated by the Obama administration and the prospect of Congress delegating wide swaths of its Constitutional authority to

regulate trade (Article 1, Section 8) to the president through "Fast Track" or any other open-ended delegation of "trade promotion" authority.

In the last Congress, two-thirds of House Democrats joined together on a letter to President Obama demanding access to the draft TPP FTA texts and raising concerns about how the pact could internationally preempt Congress's domestic policymaking prerogatives. They wrote:

"Since the United States will be obliged to bring existing and future U.S. policies into compliance with the norms established in the TPP FTA, the negotiations USTR is pursuing will create binding policies on future Congresses in numerous areas. These could include those related to labor, patent and copyright, land use, food, agriculture and product standards, natural resources, the environment, professional licensing, state-owned enterprises and government procurement policies, as well as financial, healthcare, energy, telecommunications and other service sector regulations."

Unfortunately, today TPP FTA talks continue in extreme secrecy. The administration has yet to release draft texts after more than three years of negotiations, and the few TPP FTA texts that have leaked reveal serious problems. Thus, we are especially concerned about any action that would transfer Congress's exclusive constitutional trade authority to the president.

Congress needs to work together to get American trade policy back on track – not give away its authority to do so. Reducing our authority to ensure our trade agreements serve the public interest will undermine our efforts to create American jobs and to reform a misguided trade policy that has devastated our manufacturing base through the offshoring of American production and American jobs.

Indeed, given the vast scope of today's "trade" agreements, we do not believe that a broad delegation of Congress's constitutional trade authority is generally appropriate. Negotiations on the TPP FTA delve deeply into many non-trade matters under the authority of Congress and state legislatures. If completed, the TPP FTA would lock in policies on these non-trade matters that could not be altered without consent of all other signatory countries. Thus, ensuring Congress has a robust role in the formative aspects of trade agreements is vital.

We are all deeply committed to creating jobs in our communities and across the country. To do so effectively, we believe it is critical that Congress maintains its authority to ensure American trade agreements are a good deal for the American people.

Sincerely,

U.S. Reps. Mark Pocan (WI-02), Ron Barber (AZ-02), Joyce Beatty (OH-03), Ami Bera (CA-07), Julia Brownley (CA-26), Tony Cardenas (CA-29), Matthew A. Cartwright (PA-17), William L. Enyart (IL-12), Bill Foster (IL-11), Lois Frankel (FL-22), Tulsi Gabbard

(HI-02), Pete P. Gallego (TX-23), Joe Garcia (FL-26), Alan Grayson (FL-09), Steven A. Horsford (NV-04), Jared Huffman (CA-02), Hakeem S. Jeffries (NY-08), Joseph Kennedy, III (MA-04), Ann Kirkpatrick (AZ-01), Annie McLane Kuster (NH-02), Alan S. Lowenthal (CA-47), Michelle Lujan Grisham (NM-01), Daniel B. Maffei (NY-24), Patrick Murphy (FL-18), Gloria Negrete McLeod (CA-35) , Richard M. Nolan (MN-08), Beto O'Rourke (TX-16), Donald M. Payne Jr. (NJ-10), Raul Ruiz (CA-36), Carol Shea-Porter (NH-01), Kyrsten Sinema (AZ-09), Eric Swalwell (CA-15), Mark Takano (CA-41), Dina Titus (NV-01), Juan Vargas (CA-51), and Marc A. Veasey (TX-33).

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"...The fact that foreign companies could be shut out of municipal projects funded by the U.S. federal government is particularly troubling to some U.S. trading partners. For instance, Canada has tabled legal language in the Trans-Pacific Partnership negotiations that would require that projects carried out by sub-federal entities with money provided by the central government be open to competition from firms within TPP countries (*Inside U.S. Trade*, March 8)..."

Daily News

Business Groups Urge Congress To Oppose Wave Of Buy American Requirements

Posted: June 12, 2013

Fifteen trade associations last week urged House and Senate lawmakers to oppose legislation containing "Buy American" requirements, in an effort aimed in the near term at two pieces of legislation pending before the House that would impose such restrictions on federal funds for water infrastructure projects carried out at the municipal level.

In their June 5 letter, the groups did not refer to any specific legislation pending before Congress. But Dawn Champney, president of the Water and Wastewater Equipment Manufacturers Association (WWEMA), which spearheaded the letter, said in an interview that it was prompted in part by two pieces of water infrastructure legislation under consideration in Congress that contain Buy American language identical to that included in the 2009 stimulus bill.

WWEMA and the other signatories of the June 5 letter argued against Buy American provisions for two reasons. First, they noted that such provisions may restrict the ability of U.S. companies to participate in covered procurements since their products contain components manufactured abroad. Champney said WWEMA members sell complex systems for water treatment plants that depend on technologies from around the world.

Second, the letter argued that imposing Buy American restrictions in the United States could prompt other countries around the world to impose similar measures, to the detriment of U.S. exporters. Champney pointed out that countries such as Brazil, Malaysia and Canada imposed domestic content rules for certain procurements after the U.S. included Buy American requirements in the 2009 stimulus bill, in some cases citing the U.S. measures as a basis for their actions.

The letter, which was also signed by the U.S. Chamber of Commerce and the National Foreign Trade Council (NFTC), implored lawmakers to "resist temptation and oppose legislation containing any new or more stringent protectionist measures, such as Buy American, which create regulatory burdens on municipalities and industry, impede technology advancements, and restrict market growth."

One of the bills that the letter is partially aimed at is the Water Resources Development Act, which passed the Senate on May 15 but has not yet been taken up by the House. The bill deals principally with flood protection and waterway projects but would also establish a five-year pilot program for funding water infrastructure projects that are $20 million or larger.

Projects funded through this Water Infrastructure Finance and Innovation Authority program would be subject to Buy American provisions that require the use of steel, iron and manufactured goods produced in the U.S., with limited exceptions.

Similar language is included in a House bill that would provide $13.8 billion in federal funds over five years to so-called "Clean Water State Revolving Funds," which provided subsidized loans to communities for wastewater infrastructure. That bill, H.R. 1877, was introduced by Rep. Timothy Bishop (D-NY) and has thus far gained 29 co-sponsors.

Both bills state that Buy American requirements must be carried out in accordance with U.S. obligations under international agreements. But Champney argued that this caveat is misleading because most public works projects, particularly in the area of water infrastructure, are carried out at the municipal level.

That is because the procurement of municipalities is not covered under the World Trade Organization's Government Procurement Agreement (GPA) or U.S. free trade agreements, although procurement by several major U.S. cities is covered under a 1995 memorandum of understanding with the European Union.

The fact that foreign companies could be shut out of municipal projects funded by the U.S. federal government is particularly troubling to some U.S. trading partners. For instance, Canada has tabled legal language in the Trans-Pacific Partnership negotiations that would require that projects carried out by sub-federal entities with money provided by the central government be open to competition from firms within TPP countries (*Inside U.S. Trade*, March 8).

Separately, NFTC is charging that a proliferation of Buy American bills at the state level could undermine pending trade negotiations. In a June 7 press briefing, NFTC Vice President Dan O'Flaherty warned that such state efforts could undermine negotiations for a U.S.-European Union free trade agreement and talks on China's GPA accession.

He said that is because they amount to the U.S. placing new barriers on government procurement at the same it is urging these partners to further open their procurement markets to U.S. companies.

Buy American bills have been introduced in 20 states this year, up from just 5 states last year, O'Flaherty said. But he conceded that only two states – Maryland and Ohio – have actually approved such legislation. In addition, Texas Governor Rick Perry last month signed into law a bill that contains Buy American requirements for water projects funded by the Texas Water Development Board, according to Champney.

Both Maryland and Texas cover some of their procurement under the GPA, while Ohio does not.

NFTC is reaching out to state attorneys general in its efforts to oppose the bills.

O'Flaherty noted that the drive for Buy American legislation at the state level has been led by the Alliance for American Manufacturing, which is funded in part by the United Steelworkers.

Champney said U.S. ductile iron pipe companies have also supported Buy American requirements for water infrastructure projects.

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Obama trade dilemma: Scant support from Democrats

Saturday, June 15, 2013 -- The Associated Press

U.S. Politics

Saturday, June 15, 2013
Author(s):
Associated Press

WASHINGTON — President Barack Obama is aggressively pushing an ambitious agenda to liberalize global trading.

But already political trade wars are forming, and they're with fellow Democrats rather than with Republicans, his usual antagonists.

Obama is promoting free-trade proposals with Europe and Asia that could affect up to two-thirds of all global trade.

The ambitious deals would reduce or eliminate tariffs and other trade barriers. But there's trouble ahead for both the Trans-Pacific Partnership and the Trans-Atlantic Trade and Investment Partnership — at the negotiating table and from Congress.

The deal with Europe will be a top item this coming week in Northern Ireland at the Group of Eight summit of major industrial democracies. But French and other objections have recently surfaced which could delay the planned launch of the negotiations.

The Asia pact was brought up pointedly by the new Chinese president, Xi Jinping, in his California meetings with Obama last weekend.

Republicans historically have supported free-trade agreements far more than have Democrats, and a politically weakened Obama may not have enough second-term clout to successfully twist the arms of enough Democratic lawmakers.

Some Republicans who usually vote for easing trade barriers may vote "no" just because the agreements will bear Obama's signature.

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Both deals generally have the support of U.S. businesses. But labor unions and human rights and environmental groups — core Democratic constituencies — have so far viewed them cynically.

These organizations, and Democrats in general, say that free-trade deals can cost American jobs and lead to environmental and workplace abuses that would not be tolerated in the U.S.

"We certainly have concerns," said Celeste Drake, a trade and policy specialist at the AFL-CIO, the nation's largest labor federation. "I think Obama realizes this problem about Republicans always being the big supporters (on trade liberalization) and he would like to have our support. But overall we're skeptical. We wish we'd see more."

It's not a new problem.

President Bill Clinton powered the U.S.-Mexico-Canada North American Free Trade Agreement through Congress in 1993 only by heavily courting Republicans and overcoming stiff Democratic opposition, including from House Democratic leaders and unions.

As he campaigned for president in 2008, Obama courted blue-collar votes by criticizing NAFTA. Since then, he's changed his tune.

Obama worked to overcome Democratic resistance to win passage in 2011 of trade pacts with South Korea, Panama and Colombia, completing negotiations begun by his Republican predecessor, President George W. Bush.

The talks for a new Asia-Pacific free-trade zone came up in the Obama-Xi meetings last weekend.

At first, the deliberations involved the United States and 10 Pacific Rim nations: Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. More recently, Japan has sought to join the talks, drawing the keen interest of the Chinese leader. Until now, China hasn't been included in the process.

"We have a half-a-trillion-dollar-a-year trade relationship with China," said Tom Donilon, Obama's national security adviser. "President Xi's point ... was that the Chinese would like to be kept informed and have some transparency into the process."

But the possible inclusion of Japan, the third-largest economy, after the U.S. and China, generated heat from auto-state lawmakers, who criticized Japan's efforts to restrict auto imports.

Sen. Debbie Stabenow, D-Mich., pledged to fight ratification if Japan won't "stop blocking American companies from its markets."

Michael Froman, a White House international economics adviser nominated to be the next U.S. trade representative, said the auto industry concerns are "well-founded" and he suggested they would be addressed.

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Backers of a sweeping U.S. trade deal with the 27 European Union countries hoped to get an enthusiastic sendoff from the G-8 summit in Northern Ireland on Monday and Tuesday.

British Prime Minister David Cameron, the host, has made trade liberalization a priority, and many European nations are hoping the promise of expanded trade will help reverse Europe's spreading recessions.

"An EU-US trade deal could add tens of billions to our economies," Cameron told reporters. "Everything is on the table, with no exception."

But there already are serious divisions in Europe.

Despite Cameron's and Obama's assertions that everything should be on the table, the European Union Parliament bowed to strong French concerns and recently voted to exclude TV, movies and other cultural "audiovisual services" from the trade talks even before formal negotiations begin next month.

France stuck to this "cultural exception" at a meeting of the EU members in Luxembourg on Friday.

Also, some members of the European Parliament are urging that data protection provisions be made a key part of the negotiations — in response to recent disclosures of widespread snooping by the U.S. intelligence community on telephone and Internet communications at home and abroad.

Other potential roadblocks include longstanding arguments over genetically engineered food and other agricultural issues, as well as "Buy American" provisions in recent U.S. legislation, climate change and a squabble over government subsidies involving plane makers Boeing in the U.S. and Airbus in Europe.

"Both sides know that they need to work very hard," said Philipp Rosler, vice chancellor of Germany and minister of economics and technology.

"And only if the people understand that, and only if we don't end up just having discussions on tiny details — like chickens — only then will we have the opportunity of not only negotiating, but also of concluding a good agreement," Rosler told a conference at the Brookings Institution, a U.S. think tank.

Obama, with the backing of Michigan Rep. Dave Camp, the Republican chairman of the House Ways and Means Committee, is also pushing for renewal of an expired law that allowed the White House to submit trade deals to Congress for a straight yes-or-no vote without amendments.

"This is a Congress that's pro-trade. But it's also highly polarized," said James Thurber, a political science professor at American University. "Business has been pushing these trade deals for a long time. Labor has not. So that splits things in a difficult manner for Obama."

"He's got people who don't want him to win on anything. And then he's got some people from labor who are skeptical about expansionistic trade policies and their effect on the workforce here," Thurber said. "So it will be tough."

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10 §11. MAINE JOBS, TRADE AND DEMOCRACY ACT

1. Short title. This section may be known and cited as "the Maine Jobs, Trade and Democracy Act."

[2003, c. 699, §2 (NEW) .]

2. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Commission" means the Citizen Trade Policy Commission established in Title 5, section 12004-I, subsection 79-A. [2003, c. 699, §2 (NEW).]

B. "Trade agreement" means any agreement reached between the United States Government and any other country, countries or other international political entity or entities that proposes to regulate trade among the parties to the agreement. "Trade agreement" includes, but is not limited to, the North American Free Trade Agreement, agreements with the World Trade Organization and the proposed Free Trade Area of the Americas. [2003, c. 699, §2 (NEW).]

[2003, c. 699, §2 (NEW) .]

3. Purposes. The 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.

[2003, c. 699, §2 (NEW) .]

4. Membership. The commission consists of the following members:

A. The following 17 voting members:

(1) Three Senators representing at least 2 political parties, appointed by the President of the Senate;

(2) Three members of the House of Representatives representing at least 2 political parties, appointed by the Speaker of the House;

(3) The Attorney General or the Attorney General's designee;

(4) Four members of the public, appointed by the Governor as follows:

(a) A small business person;

(b) A small farmer;

(c) A representative of a nonprofit organization that promotes fair trade policies; and

(d) A representative of a Maine-based corporation that is active in international trade;

(5) Three members of the public appointed by the President of the Senate as follows:

(a) A health care professional;

(b) A representative of a Maine-based manufacturing business with 25 or more employees; and

(c) A representative of an economic development organization; and

(6) Three members of the public appointed by the Speaker of the House as follows:

(a) A person who is active in the organized labor community;

(b) A member of a nonprofit human rights organization; and

(c) A member of a nonprofit environmental organization.

In making appointments of members of the public, the appointing authorities shall make every effort to

appoint representatives of generally recognized and organized constituencies of the interest groups mentioned in subparagraphs (4), (5) and (6); and [2003, c. 699, §2 (NEW).]

B. The following 4 commissioners or the commissioners' designees of the following 4 departments and the president or the president's designee of the Maine International Trade Center who serve as ex officio, nonvoting members:

(1) Department of Labor;

(2) (rp)

(3) Department of Environmental Protection;

(4) Department of Agriculture, Food and Rural Resources; and

(5) Department of Human Services. [2007, c. 266, §1 (AMD).]

[2007, c. 266, §1 (AMD) .]

5. Terms; vacancies; limits. Except for Legislators, commissioners and the Attorney General, who serve terms coincident with their elective or appointed terms, all members are appointed for 3-year terms. A vacancy must be filled by the same appointing authority that made the original appointment. Appointed members may not serve more than 2 terms. Members may continue to serve until their replacements are designated. A member may designate an alternate to serve on a temporary basis.

[2003, c. 699, §2 (NEW) .]

6. Chair; officers; rules. The first-named Senate member and the first-named House of Representatives member are cochairs of the commission. The commission shall appoint other officers as necessary and make rules for orderly procedure.

[2003, c. 699, §2 (NEW) .]

7. Compensation. Legislators who are members of the commission are entitled to receive the legislative per diem and expenses as defined in Title 3, section 2 for their attendance to their duties under this chapter. Other members are entitled to receive reimbursement of necessary expenses if they are not otherwise reimbursed by their employers or others whom they represent.

[2003, c. 699, §2 (NEW) .]

8. Staff. The Office of Policy and Legal Analysis shall provide the necessary staff support for the operation of the commission. After one year, the commission shall assess the need for and qualifications of a staff person, for example, an executive director. If the commission determines that it requires such a person, it may request additional funds from the Legislature.

[2003, c. 699, §2 (NEW) .]

9. Powers and duties. The commission:

A. Shall meet at least twice annually; [2003, c. 699, §2 (NEW).]

B. Shall hear public testimony and recommendations from the people of the State and qualified experts when appropriate at no fewer than 2 locations throughout the State each year on the actual and potential social, environmental, economic and legal impacts of international trade agreements and negotiations on the State; [2003, c. 699, §2 (NEW).]

C. Shall every 2 years conduct an assessment of the impacts of international trade agreements on Maine's state laws, municipal laws, working conditions and business environment. The assessment must be submitted and made available to the public as provided for in the annual report in paragraph D; [2007, c. 266, §2 (AMD).]

D. Shall maintain active communications with and submit an annual report to the Governor, the

Legislature, the Attorney General, municipalities, Maine's congressional delegation, the Maine International Trade Center, the Maine Municipal Association, the United States Trade Representative's Office, the National Conference of State Legislatures and the National Association of Attorneys General or the successor organization of any of these groups. The commission shall make the report easily accessible to the public by way of a publicly accessible site on the Internet maintained by the State. The report must contain information acquired pursuant to activities under paragraph B and may contain information acquired pursuant to activities under paragraph C; [2007, c. 266, §3 (AMD).]

E. Shall maintain active communications with any entity the commission determines appropriate regarding ongoing developments in international trade agreements and policy; [2003, c. 699, §2 (NEW).]

F. May recommend or submit legislation to the Legislature; [2003, c. 699, §2 (NEW).]

G. May recommend that the State support, or withhold its support from, future trade negotiations or agreements; and [2003, c. 699, §2 (NEW).]

H. May examine any aspects of international trade, international economic integration and trade agreements that the members of the commission consider appropriate. [2003, c. 699, §2 (NEW).]

[2007, c. 266, §§2, 3 (AMD) .]

10. Outside funding. The commission may seek and accept outside funding to fulfill commission duties. Prompt notice of solicitation and acceptance of funds must be sent to the Legislative Council. All funds accepted must be forwarded to the Executive Director of the Legislative Council, along with an accounting that includes the amount received, the date that amount was received, from whom that amount was received, the purpose of the donation and any limitation on use of the funds. The executive director administers any funds received.

[2003, c. 699, §2 (NEW) .]

11. Evaluation. By December 31, 2009, the commission shall conduct an evaluation of its activities and recommend to the Legislature whether to continue, alter or cease the commission's activities.

[2003, c. 699, §2 (NEW) .]

SECTION HISTORY
2003, c. 699, §2 (NEW). 2007, c. 266, §§1-3 (AMD).

10 §12. QUORUM

For purposes of holding a meeting, a quorum is 11 members. A quorum must be present to start a meeting but not to continue or adjourn a meeting. For purposes of voting, a quorum is 9 voting members. [2007, c. 266, §4 (NEW).]

SECTION HISTORY
2007, c. 266, §4 (NEW).

10 §13. LEGISLATIVE APPROVAL OF TRADE AGREEMENTS

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Commission" means the Citizen Trade Policy Commission established in Title 5, section 12004-I, subsection 79-A. [2009, c. 385, §1 (NEW).]

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B. "Trade agreement" means an agreement reached between the United States Government and any other country, countries or other international political entity or entities that proposes to regulate trade, procurement, services or investment among the parties to the agreement. "Trade agreement" includes, but is not limited to, any agreements under the auspices of the World Trade Organization, all regional free trade agreements, including the North American Free Trade Agreement and the Central America Free Trade Agreement and all bilateral agreements entered into by the United States, as well as requests for binding agreement received from the United States Trade Representative. [2009, c. 385, §1 (NEW).]

[2009, c. 385, §1 (NEW) .]

2. State official prohibited from binding the State. If the United States Government provides the State with the opportunity to consent to or reject binding the State to a trade agreement, or a provision within a trade agreement, then an official of the State, including but not limited to the Governor, may not bind the State or give consent to the United States Government to bind the State in those circumstances, except as provided in this section.

[2009, c. 385, §1 (NEW) .]

3. Receipt of request for trade agreement. When a communication from the United States Trade Representative concerning a trade agreement provision is received by the State, the Governor shall submit a copy of the communication and the proposed trade agreement, or relevant provisions of the trade agreement, to the chairs of the commission, the President of the Senate, the Speaker of the House of Representatives, the Maine International Trade Center and the joint standing committees of the Legislature having jurisdiction over state and local government matters and business, research and economic development matters.

[2009, c. 385, §1 (NEW) .]

4. Review by commission. The commission, in consultation with the Maine International Trade Center, shall review and analyze the trade agreement and issue a report on the potential impact on the State of agreeing to be bound by the trade agreement, including any necessary implementing legislation, to the Legislature and the Governor.

[2009, c. 385, §1 (NEW) .]

5. Legislative approval of trade agreement required. Unless the Legislature by proper enactment of a law authorizes the Governor or another official of the State to enter into the specific proposed trade agreement, the State may not be bound by that trade agreement.

[2009, c. 385, §1 (NEW) .]

SECTION HISTORY
2009, c. 385, §1 (NEW).

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

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

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 17countries – 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

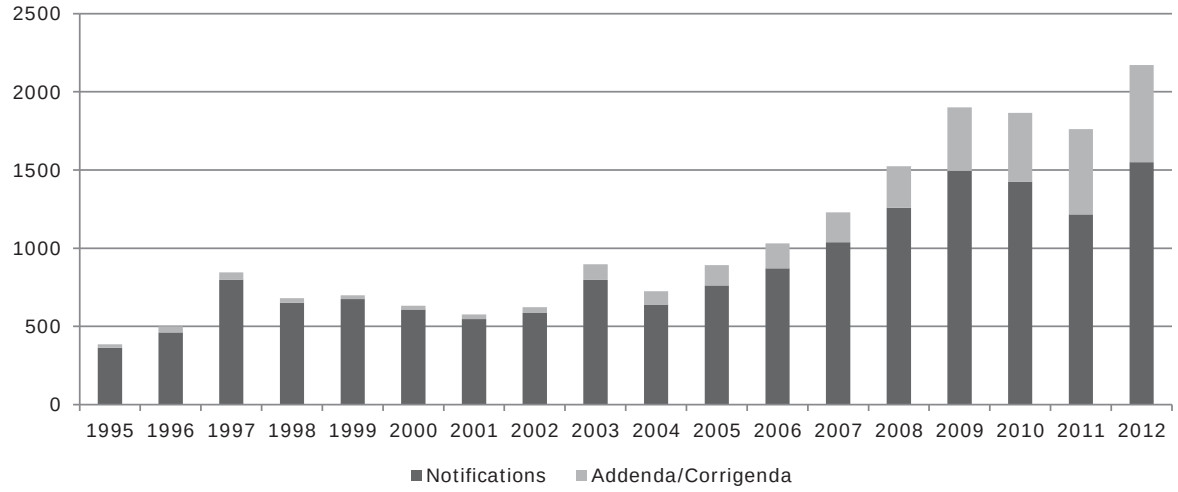
[5] Depending on the WTO Member's domestic processes, interested parties may participate directly in that Member's process for developing new standards-related measures, for example, by submitting written comments to the Member, or indirectly by working with their own governments to submit comments.

[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 1995***[10]



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

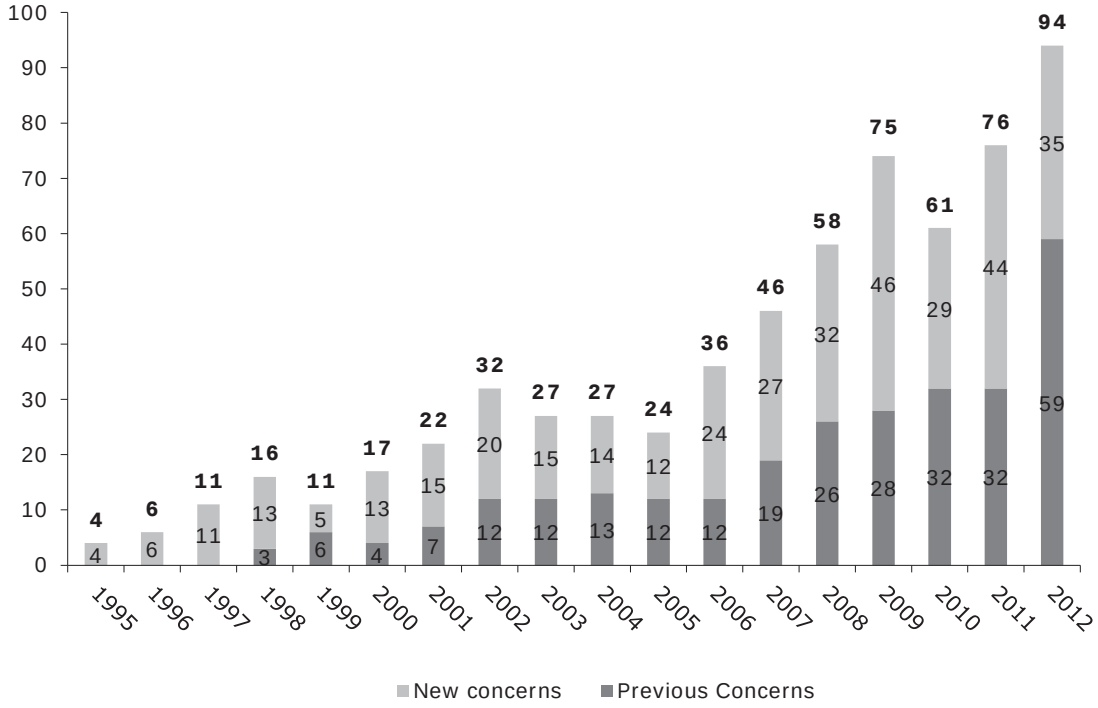
[11] See G/TBT/GEN/1/Rev.11 for a list of Members' submissions on the measures they have taken to implement and administer the TBT Agreement.

[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 year***[14]



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.

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[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 and 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.

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[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 use[21] voluntary consensus standards[22] 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 competition[24] 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*, 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 organizations[31] 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 CITEL (Inter-American Telecommunication Commission) MRA with respect to the United States. Under the CITEL MRA, two or more CITEL 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 CITEL. If Brazil implemented the CITEL 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 CITEL 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 (KMVSS) 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-KMVSS 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 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 Sates 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.

<u>Overview of Trade Obligations an Standards-Related Measures (page 9)</u>

- 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-tarriff 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 incombustibility 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

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Trade Policy Committee	
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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***

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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 Intent[1] 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 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.

- 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.

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)

Transatlantic Trade and Investment Partnership
Without prejudice, 20 June 2013

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 comes 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.

Without prejudice, 20 June 2013

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 andconformity 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 hat 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*

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.

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Initial position paper

Limited

TTIP – Rules Group Without prejudice, 19 June 2013

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 2013[1] 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 TTIP[2]. 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 HLRCF[3]. 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 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.

Non-Paper

Limited

Without Prejudice

20 June 2013

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

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

- 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.

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 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

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

Limited

Without prejudice, 17.06.2013

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 WTOs 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 **competiveness** 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 compatability/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 thought he 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 though 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 cold 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

amplif[ies] 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.

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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 Medronic, 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

CEO

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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 business 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 skip 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 dizzying 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 interest[2] – 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]

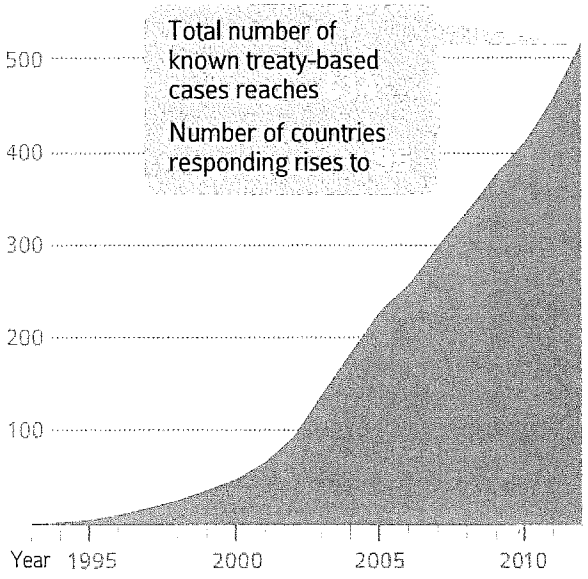
Corporations versus public health – Achmea v. the Slovak Republic: At the end of 2012, Dutch insurer Achmea (formerly Eureko) was awarded €22 million in compensation from Slovakia. In 2006, the Slovak government had reversed the health privatisation policies of the previous administration and required 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 negotiators[14]

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 negotiators[17]

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 US[21]; 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 Parliaments 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 force[26]

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 Council[31] 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 Institute[34]

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 Citizen[36]**

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 & Democrats[40]**

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 US[42]**

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 negotiate[45]	Translation: what it means in practice[46]
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 patent[47]. 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.

The arbitrators who decide investor-state claims should be independent.	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.
There should be a "possibility of binding interpretation of the Agreement by the Parties".	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]
Investors should be able to use "as wide a range of arbitration fora as is currently available under the Member States' bilateral investment agreements".	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?
"The investor-to-state dispute settlement mechanism should contain safeguards against manifestly unjustified or frivolous claims".	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]
"Consideration should be given to the possibility of creating an appellate mechanism applicable to investor-to-state dispute settlement under the Agreement".	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.

Endnotes

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Brussels/Amsterdam, October 2013

Published by The Seattle to Brussels Network (S2B), Corporate Europe Observatory and the Transnational Institute

> 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

Seattle to Brussels Network

The Seattle to Brussels Network (S2B) includes development, environmental, human rights, women and farmers organisations, trade unions and social movements working together for a truly sustainable, just and democratic trade policy in Europe.
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CEO

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TNI

The Transnational Institute was founded in 1974. It is an international network of activist-scholars committed to critical analyses of the global problems of today and tomorrow.
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.[i]

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

[i] *Inside U.S. Trade*, November 4, 2011.

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

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. A fully referenced version of this article can be found at monbiot.com

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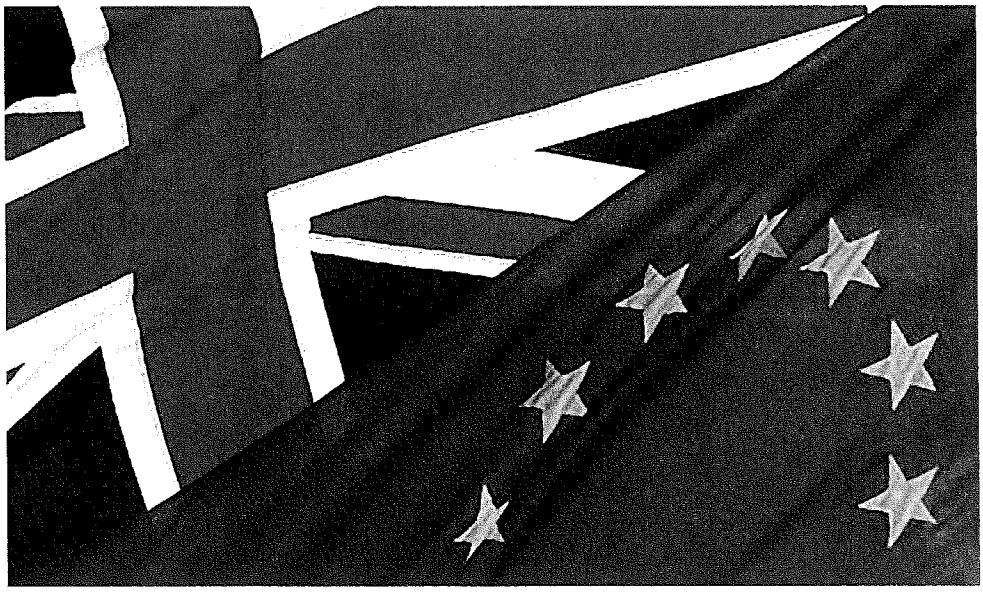
theguardian

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.

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.

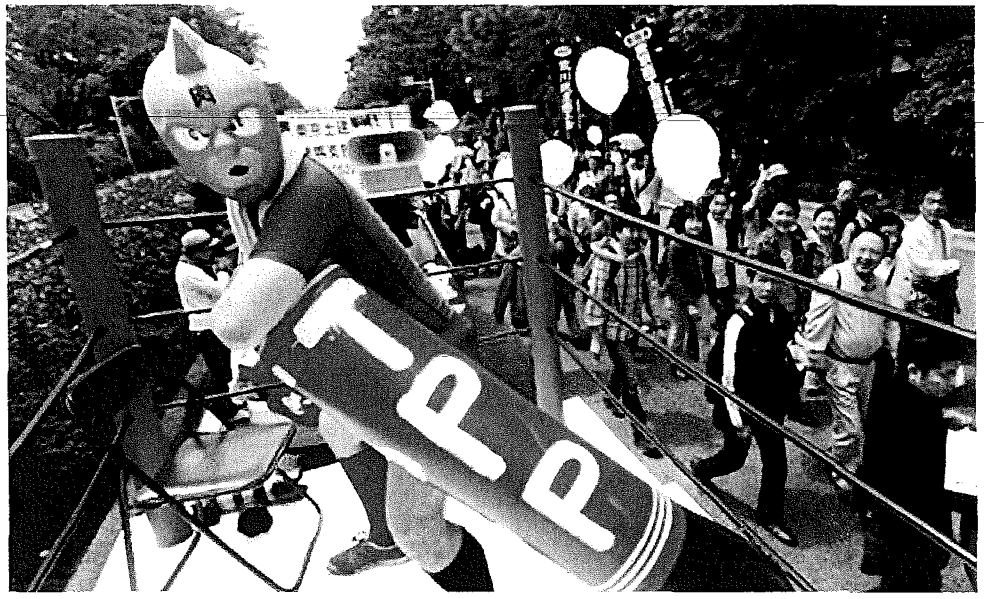
Access (AccessNow.org)
American Medical Student Association
Center for Digital Democracy
Center for Effective Government
Center for Financial Privacy and Human Rights
Center for Food Safety
Center for International and Environmental Law
Center for Media and Democracy
Center for Rights
Citizens for Ethics 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
Sunlight Foundation
U.S. PIRG
World Privacy Forum

theguardian

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 then."

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 negotiatons 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."

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.

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

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.

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

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.

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.

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,

Troy Jackson (SIP) Sharon Anglin Treat (DP)

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 TTP 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

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

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

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:

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[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

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