

United States Welcomes New Zealand's Decision to Join U.S. Challenge to Indonesia's Import Restrictions on Horticultural Products, Animals and Animal Products

August 30, 2013

Washington, D.C. – United States Trade Representative Michael Froman today announced two important developments in the ongoing U.S. challenge under the dispute settlement provisions of the World Trade Organization (WTO) to Indonesia's trade-restrictive measures applied to horticultural products, animals, and animal products. First, New Zealand is joining the dispute by filing its own request for consultations addressed to Indonesia's measures. Second, the United States is filing a revised consultations request to address recent modifications to Indonesia's measures and to facilitate coordination with co-complainant New Zealand. The United States filed an initial consultations request earlier this year.

“Consultations with Indonesia earlier this year failed to resolve our concerns with Indonesia's unjustified and trade-restrictive import licensing system,” said Ambassador Froman. **“To the contrary, although Indonesia has revised its measures, they continue to pose a serious impediment to U.S. agricultural exports. Accordingly, today the United States is submitting a revised consultations request addressed to Indonesia's most recent measures. I am also pleased that New Zealand, which is similarly harmed by Indonesia's restrictions, has decided to join the dispute by filing its own request for consultations.”**

“The Obama Administration is committed to protecting the rights of our farmers, ranchers and processors to compete on a level playing field,” Ambassador Froman added. **“The Interagency Trade Enforcement Center (ITEC), created by this Administration to enhance U.S. trade enforcement capabilities, has played a significant role in enabling us to follow through on this commitment.”**

Background:

Indonesia has adopted non-automatic import licensing requirements and quotas that serve as serious impediments to trade in horticultural products, animals, and animal products. As set out in the U.S. request for consultations, these measures appear to be inconsistent with Indonesia's WTO obligations, including under the General Agreement on Tariffs and Trade 1994 (GATT 1994), Agreement on Import Licensing Procedures, the Agreement on Agriculture, and the Agreement on Preshipment Inspection. Since the time the United States filed its original consultations request with Indonesia in January 2013, Indonesia has revised its import licensing and quota measures. These changes did not remove the trade restrictions and thus failed to address U.S. concerns. Instead, Indonesia's revised measures include new laws on food, beef, and other agricultural products that contain further import-restrictive provisions. The affected products include, but are not limited to, fruits, vegetables, flowers, dried fruits and vegetables, juices, cattle, beef, and other animal products.

Filing a revised consultations request, in coordination with New Zealand's filing of its own request, will allow the consultations with Indonesia to be held together. If the United States and New Zealand subsequently were to request the establishment of a WTO dispute settlement panel, the two disputes would be adjudicated before a single panel.

Ministerial Guidance Energizes Negotiators' Work During 19th Round of TPP Negotiations

Bandar Seri Begawan, Brunei – Trans-Pacific Partnership (TPP) negotiators intensified their work this week to close gaps between them as directed by their Ministers, who met last week in Brunei Darussalam to discuss possible landing zones on remaining sensitive and challenging issues and sequencing of issues in the final talks. A Ministerial meeting of the TPP countries – Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States and Vietnam – gave guidance to negotiators on achieving an ambitious and balanced 21st century agreement that will enhance trade and investment between them, promote innovation and competitiveness, economic growth and development, and support the creation and retention of jobs in their countries.

Buoyed by the ministerial engagement and their commitment to actively guide the negotiations, negotiators advanced their technical work this round on the texts covering market access, rules of origin, investment, financial services, intellectual property, competition, and environment. They also made progress on the packages providing access to each other's markets for goods, services, investment, financial services, temporary entry, and government procurement. Their discussions both jointly and bilaterally were successful in identifying creative and pragmatic solutions to many issues and further narrowing the remaining work. Also this week, negotiators covering labor issues continued their work on the outstanding issues in the chapter.

Having identified pathways forward, negotiators will meet again intersessionally in the coming weeks to further their work. Several other negotiating groups that did not meet during this round because they required additional time for domestic consultation before convening also will meet, including those covering technical barriers to trade, e-commerce, and legal issues. The intersessional work is intended to further advance the negotiations in the lead up to APEC Leaders meeting in Bali, Indonesia, on the margins of which TPP Leaders are expected to meet as they have in past years. This meeting will be an important milestone as the 12 countries work intensively to conclude this landmark agreement this year.

On August 27, the TPP negotiations were temporarily adjourned so that negotiators could meet with 150 stakeholders on site from across the TPP region. Stakeholders made presentations to negotiators on a wide range of issues, and Chief Negotiators met informally with stakeholders to discuss in detail on specific issues of interest to them.

USTR Newsletter: 9/12/13

USTR, SBA Launch New Effort to Help U.S. Small Businesses Export to the European Union

Small Businesses to Offer Suggestions for Increasing Exports under the Transatlantic Trade & Investment Partnership (T-TIP)

Washington, D.C. – U.S. small businesses currently exporting to the European Union (EU) will have the opportunity to voice their concerns on existing barriers to trade with the EU through a series of roundtables across the country. The roundtables will be held as part of broader outreach efforts under the recently launched U.S.-EU Transatlantic Trade and Investment Partnership (T-TIP) negotiations. The objective of the roundtables is to listen to and better understand small business' suggestions on how to reduce and eliminate those barriers, and help expand U.S. small business exports to the EU.

In July, the United States and the European Union held the first round of T-TIP negotiations aimed at increasing jobs, economic growth, and international competitiveness on both sides of the Atlantic. 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, while supporting 13 million U.S. and EU jobs. In both the United States and the EU, small and medium businesses are critical motors of growth, job creation, and innovation. Negotiators intend to conclude an agreement that recognizes the important role small businesses play in the transatlantic relationship and enhances their ability to participate in and benefit from new trade and investment opportunities.

The roundtables were commissioned by the Office of the United States Trade Representative (USTR), which asked the U.S. International Trade Commission (USITC) to conduct a study on the existing trade barriers that disproportionately affect U.S. small business exporters. Since the President's National Export Initiative (NEI) goal to double exports by the end of 2014 has focused on increasing the current base of 295,000 small business exporters, an increase in small business participation could result in increased trade between two regions whose two-way trade already exceeds \$630 billion.

USITC responded by organizing the T-TIP roundtables, which will be held from September 9th through September 27th in key cities. The schedule for the roundtables is:

Month/Day	City	Month/Day	City
9/9	Detroit	9/19	Houston
9/10	Cleveland	9/20	Salt Lake City
9/11	Minneapolis	9/23	Philadelphia
9/12	Milwaukee	9/23	Los Angeles
9/13	Chicago	9/24	New York
9/16	Raleigh	9/24	Irvine

9/17	Raleigh	9/25	Long Island
9/18	Atlanta	9/25	Sacramento
9/17	Denver	9/26	Boston
9/19	Miami	9/27	Providence
9/18	Albuquerque	9/27	Fresno

If you'd like to take part in a roundtable, please contact sme@usitc.gov for more information.

In addition to participating in the roundtables, exporters will have other means to convey their concerns and suggestions through public hearings in San Jose, California (September 26th) and Washington, D.C. (October 8th). Business owners who are interested in having their voices heard but cannot attend the roundtables or public hearings can submit written statements by sending an email to sme@usitc.gov (by October 15, 2013) or by mail to EU-SME Project, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436 (no later than September 30, 2013).

For more detailed information, visit http://www.usitc.gov/332_541_Trade_Barriers.htm and http://www.usitc.gov/secretary/fed_reg_notices/332/332_541_notice07252013sgl.pdf. For more information on the Transatlantic Trade and Investment Partnership and U.S trade with the European Union, visit www.USTR.gov/TTIP.

Readout of TPP Call with U.S. Stakeholders

September 9, 2013

This afternoon, U.S. Trade Representative Michael Froman reached out to a broad cross-section of stakeholders to join him on a call to discuss the Trans-Pacific Partnership (TPP) negotiations. As U.S. negotiators press forward to complete a high-standard trade agreement that levels the playing field for U.S. workers and businesses in Asia-Pacific trade, Ambassador Froman set the stage for a deeper level of engagement with these and other stakeholders in the weeks and months ahead.

“We very much view stakeholder input, whether through our cleared advisers or other stakeholders, as absolutely critical,” said Ambassador Froman. **“We’re at a stage in TPP where we’re going to have to make difficult decisions. I imagine that not everyone will be 100 percent pleased with every decision, but we can guarantee that we will seek your input, we will consult with you. We won’t make these decisions in isolation. And we will be proactive about getting your participation in this process.”**

More than 170 participants, including stakeholders from key sectors such as business, labor, environment, public health, academia, advocacy groups, and some members of USTR’s Trade Advisory Committee system participated in the call. Many asked and received information about the status of U.S. proposals and prospects for advancing various issues in the talks - from agricultural market access to intellectual property - in the near future.

Ambassador Froman said that TPP negotiators have been working “around the clock” to keep moving forward toward an agreement. He noted that negotiations over number of sensitive issues will likely take to the end of the talks; he also reviewed the facts on the new U.S. proposal on tobacco in the TPP, which will for the first time in a trade agreement acknowledge the impact of tobacco on public health and include measures to address the issue. Ambassador Froman said that October meetings on the margins of the Asia-Pacific Economic Cooperation forum in Bali, Indonesia would be “an important milestone” in the process, offering a chance for Leaders of the TPP countries to come together and offer guidance to trade ministers and negotiators on dealing with remaining issues with the goal of finishing the negotiations this year.

USTR Froman underscored the President’s focus on making trade a driver of America’s economic recovery and a pillar of our future economic stability. He called the President’s trade agenda bold in scope, emphasis, and in ambition, with TPP as the cornerstone of the Obama Administration’s economic policy in the Asia-Pacific region. He committed to keep Americans informed and involved in the negotiating process as efforts continue this year.

Aug 28, 2013

Trans-Pacific Partnership: U.S. Negotiating 'Biologics' Proposal, Marking End to 'Period of Reflection'

Trans-Pacific Partnership (TPP)

Key Development: "Period of reflection" on biologics has ended.

What's Next: 19th round of TPP talks set to conclude Aug. 30.

By Len Bracken

The United States is negotiating the terms of the provisions it will propose in the Trans-Pacific Partnership (TPP) talks concerning intellectual property rights protections for the bio-pharmaceutical medicine commonly known as "biologics," a civil society source in Brunei for the 19th round of negotiations told BNA Aug. 27.

The negotiations mark the end of what U.S. trade officials have called a "period of reflection" in which, for longer than a year, the administration has been in consultations on the issue of biosimilar medicines that are envisioned as cheaper, follow-on or generic versions of expensive biologics.

"I think the United States is getting ready to table something on this," the source said, referring to a concrete yet confidential proposal on biologics in particular, and possibly on the pharmaceutical sector as a whole. "I don't think it will happen at this round, but the negotiations are taking place, and the proposal will be tabled soon."

U.S. trade negotiators have said their goal on the issue is to strike a balance between innovation that results in the development of new medicine and access to medicines for all people in the region. The period of reflection stemmed from strong opposition by the other TPP partners to a previous U.S. proposal, the source said.

Companies such as Baxter, Eli Lilly, Novartis and Pfizer are notable manufacturers of biologics, which are created using living organisms and often treat diseases such as cancer and diabetes.

"Push-Back From Consumers" Cited.

While current U.S. law provides for 12 years of test data protection, a form of nonpatent exclusivity, for biologics, there are indications that the United States may be willing to compromise on the issue with the other 11 TPP partners—Australia, Brunei Darussalam, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and Japan.

The data exclusivity means that potential manufacturers would have to

conduct their own clinical trials, as with a branded drug, and would therefore not have the cost savings afforded to generics.

“There has been push-back from consumers in developing and developed countries, so in order to get something on pharmaceuticals, the United States would have to give up something in another area,” the source said, referring to those who want to limit the length of data protections to make less-expensive generics more quickly accessible.

Certain House Democrats have in the past recommended that the United States refrain from negotiating any provisions related to exclusivity for biosimilar medicines in the TPP talks, arguing that it would thwart Congress's ability to trim that exclusivity to seven years without running afoul of U.S. trade obligations. Lawmakers on both sides of the aisle, however, have said that 12 years of regulatory data protection for biologics should be included in the TPP agreement.

Pharmaceutical Research and Manufacturers of America (PhRMA), which represents research-based pharmaceutical and biotechnology companies, told BNA that it expects the administration to propose 12 years of data protection for biologics in TPP because that is current U.S. law.

Mark Grayson, deputy vice president for international public affairs for PhRMA, said that it is important for the administration to take the time to “get the substance right” and ensure intellectual property rights are protected.

Trade-Offs Needed to Close Deal.

James Love, director of Knowledge Ecology International (KEI), told BNA that so far President Obama has not proposed 12 years—or any specific term—for test data protection in the TPP.

“The president's own domestic budget assumes billions of savings from rolling back the 12-year period that is now U.S. law to seven years,” Love said, referring to the potential cost savings to Medicare and Medicaid if generic versions of expensive biologics could be made in seven years rather than 12.

“Many members of Congress, all receiving ample money from the pharmaceutical industry, have pushed for 12 years, but there is opposition from OMB [Office of Management and Budget], which has to budget to pay for drugs, and opposition from some companies that want to market biosimilars, and from businesses concerned about exploding USA health care costs.”

Love said the United States could seek different deals with different countries, as there is considerable opposition to some of the U.S. positions. He noted that transition periods have varied in past agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and side letters have been used to provide for special understandings about certain issues.

“The thing is that the TPP has a lot of chapters in it—there is more to it

than just pharmaceuticals—and there are a lot of countries that are not of a like mind on many issues,” he said. “The United States will have to make trade-offs regarding different sectors of the economy in the final end game—not everybody gets everything, so it becomes a question of whose interests will be sacrificed to get a deal.”

KEI views the 12 years of data exclusivity as a mistake and opposes what it sees as the worldwide rapid rise in drug prices. The group advocates that trade policy be used to encourage countries to contribute more to the cost of public sector medical research and to follow the National Institute of Health lead with regard to publicly releasing the results of studies.

“Other countries are beginning to think this is a productive way because they don't want a future in which no one can afford cancer drugs,” KEI's Love told BNA. “Apparently 11 out of the last 12 cancer drugs to hit the market were priced at over \$100,000 per course of treatment.”

President's 2013 Budget Has Biologics Component

The president's 2013 budget has two subsections concerning biologics that, if enacted, the administration claims would generate \$15 billion in savings over 10 years.

The first subsection is entitled “Prohibit ‘Pay for Delay’ Agreements to Increase the Availability of Generic Drugs and Biologics.”

It reads as follows: “The high cost of prescription drugs places a significant burden on Americans today, causing many to skip doses, split pills, or forgo needed medications altogether. The Administration proposes to increase the availability of generic drugs and biologics by authorizing the Federal Trade Commission to stop companies from entering into anti-competitive deals, known also as ‘pay for delay’ agreements, intended to block consumer access to safe and effective generics. Such deals can cost consumers billions of dollars because generic drugs are typically priced significantly less than their branded counterparts. These agreements reduce competition and raise the cost of care for patients both directly, through higher drug and biologic prices, and indirectly through higher health care premiums. The Administration's proposal facilitates greater access to lower-cost generics and will generate \$11 billion over 10 years in savings to Federal health programs including Medicare and Medicaid.”

The second subsection is entitled “Modify the Length of Exclusivity to Facilitate Faster Development of Generic Biologics.”

It reads: “Access to affordable lifesaving medicines is essential to improving the quality and efficiency of health care. The Administration's proposal accelerates access to affordable generic biologics by modifying the length of exclusivity on brand name biologics. Beginning in 2013, this proposal would award brand biologic manufacturers seven years of exclusivity rather than 12 years under current law and prohibit additional periods of exclusivity for brand biologics due to minor changes in product formulations, a practice often referred to as ‘evergreening.’ Reducing the exclusivity period increases the availability of generic biologics by

encouraging faster development of generic biologics while retaining appropriate incentives for research and development for the innovation of breakthrough products. The Administration's proposal strikes a balance between promoting affordable access to medications and encouraging innovation to develop needed therapies. The proposal will result in \$4 billion in savings over 10 years to Federal health programs including Medicare and Medicaid."

By Len Bracken

Inside U.S. Trade - 09/06/2013

TPP Countries Will Consult Internally On Tobacco Proposals, Official Says

Posted: September 5, 2013

BANDAR SERI BEGAWAN, Brunei -- The United States and Malaysia simultaneously tabled competing proposals at a chief negotiators' meeting during the 19th round of Trans-Pacific Partnership (TPP) talks here that aim, with varying degrees, to give countries greater flexibility to put in place tobacco control measures.

TPP countries intend to discuss these proposals internally before holding further talks on them, a U.S. trade official said in an Aug. 28 interview with Inside U.S. Trade.

They are expected to resume discussion on the proposals at the technical level during a meeting of the negotiating group on legal issues slated to take place in Washington during the second week of September, sources said.

The Malaysian proposal would completely carve out tobacco control measures from any TPP obligations, thereby precluding state-to-state or investor-state challenges against such measures under the deal. An informed source said it would also exclude tobacco products from tariff reductions on TPP.

This would go far beyond the U.S. proposal, which has come under fire domestically from business groups who oppose it and public health organizations who think it does not go far enough. Both these stakeholder groups are pressing TPP countries to back their respective demands (see related story).

The U.S. proposal would simply reaffirm that tobacco control measures would fall within the scope of an already existing general exception for measures necessary to protect human life or health.

Malaysia's language also goes farther than the "safe harbor" from dispute settlement for tobacco regulations that the U.S. had considered last year, but ultimately scaled back in favor of the proposal tabled at the 19th round. The "safe harbor" would have only applied to tobacco control regulations -- not legislation -- and would not have protected governments from investor-state challenges, only state-to-state dispute settlement cases.

The Malaysian government was under pressure to table a tobacco carveout from the Malaysian Council for Tobacco Control (MCTC), which had as one of its goals to ensure that nothing in the TPP would

prevent countries from implementing the World Health Organization Framework Convention on Tobacco Control (FCTC). All TPP countries have ratified the FCTC except for the United States, which has signed the deal but not ratified it.

The FCTC requires parties to adopt and maintain price and tax measures to reduce the demand for tobacco, as well as non-price measures such as regulation of the contents of tobacco products as well as packaging and labeling requirements.

Public health advocates point out that the FCTC is the world's first and only global public health treaty, reflecting the unique status of tobacco as the world's single most deadly product. This is one reason why these groups believe that tobacco should be treated differently than other products in trade agreements.

The U.S. trade official did not respond directly when asked whether the U.S. would maintain its position in light of the stronger Malaysian proposal. "We are going to reflect on the proposals that we got and then decide how we're going to proceed," the official said.

In an interview, MCTC President Molly Cheah said there was "broad support" for the Malaysian proposal among the countries she spoke to during the 19th round here. But she conceded that some said they needed to take the proposal back to their governments and legal experts for further consultations.

One informed source said even Japan expressed support for the proposal, despite the fact that the Japanese government owns a minority stake in the Japan Tobacco company. Japan has indicated that its stake in the company has no bearing on its position on this issue, this source said. Vietnam also has a state-owned tobacco company.

At the same time, this source said several TPP countries expressed worries about the implications the Malaysian proposal might have on market access negotiations, although they did not elaborate.

This source speculated that some TPP countries may feel that a move to exclude their tobacco tariffs from elimination could affect the balance of their market access negotiations. For instance, if one TPP member is facing pressure to lower tobacco tariffs from the United States or another TPP country, but opts not to do so, it may be forced to make concessions to that country on other tariff lines, this source said.

Cheah welcomed her government's proposal. "To me, that proposal that was put up by Malaysia just completely satisfies us, because that is what we wanted all along," she said. "I'm just overwhelmed; to me,

it's a milestone for tobacco control globally."

During the course of the TPP negotiations, anti-tobacco groups have met with all participants except Japan to discuss the possibility of including specific language protecting tobacco regulation, and none of these countries has been "hostile" to that idea, one source said.

Anti-tobacco groups do not expect Australia to lead the charge on including tobacco-related language in TPP due to the fact that its plain cigarette packaging law is currently being challenged both in the World Trade Organization and in an investor-state case brought by tobacco giant Phillip Morris under the Hong Kong-Australia bilateral investment treaty.

Australia fears that advocating for new language in TPP to protect anti-tobacco regulations would give the impression that current trade rules are insufficient to protect a country's right to regulate tobacco, sources said. This could undermine its legal argument that the plain packaging law is consistent with WTO rules, they said.

Malaysia had already decided to move forward with its tobacco proposal when the U.S. announced on Aug. 21 that it intended to unveil its tobacco-specific language at the Brunei round, according to an informed source. Malaysian public health groups were worried that if the U.S. tabled its proposal first, it would become the basis for negotiations and Malaysia would get squeezed out of the discussion, this source said.

The groups urged the Malaysian government to table its proposal first, but ultimately the chief negotiators from both countries worked out an arrangement where they would table the two proposals at the same time, sources said.

The Malaysian proposal originated in the Ministry of Health, which also drafted its legal language, according to one informed source. The Malaysian Ministry of International Trade and Industry (MITI) deferred to the health ministry on the tobacco carveout, the source said.

"The carveout means that the tobacco industry will not be able to use any provisions in the TPP to sue governments or to threaten governments, and that's what they have been doing," Cheah, head of the Malaysian tobacco control group, said in an interview here.

She pointed to the investor-state challenge and WTO dispute against Australia's plain packaging law, among other cases. "We want to ensure that the proposal is broad enough not to allow loopholes ... for the tobacco industry to take advantage of," she added.

The Malaysian proposal has already garnered the support of several U.S. public health groups, as well as an explicit endorsement by The New York Times in an Aug. 31 editorial. Nine U.S. groups, including Action on Smoking and Health and the Center for Policy Analysis on Trade and Health, endorsed the Malaysian proposal in an Aug. 27 joint press release, while the Campaign for Tobacco-Free Kids praised it in a separate Aug. 26 statement.

"Now that Malaysia has offered this proposal, we urge the United States to work with Malaysia and others to support a proposal that will provide real protection for tobacco control measures, rather than press for its own language," Susan Liss, executive director of the Campaign for Tobacco-Free Kids, said in the Aug. 26 statement.

In an earlier statement e-mailed to Inside U.S. Trade on Aug. 25, Liss said her group would also press other TPP countries to strengthen the "weaker" U.S. proposal, although this secondary goal was not mentioned in the group's Aug. 26 statement. -- Matthew Schewel

Daily News

FDA Takes More Active Role In TTIP, TPP Talks; Establishes Trade Team

Posted: September 3, 2013

The U.S. Food and Drug Administration (FDA) is taking a more offensive role in ongoing trade talks with countries in the Asia-Pacific and the European Union as negotiators increasingly focus on regulatory issues in those initiatives, according to an FDA official.

Mary Lou Valdez, director of FDA's Office of International Programs, earlier this month said the agency has typically taken a more "defensive" posture in past trade negotiations involving the United States. But that has changed with the Trans-Pacific Partnership (TPP) and the more recently launched Transatlantic Trade and Investment Partnership (TTIP), she explained.

With those agreements likely to include new rules on regulatory coherence and transparency, and with TTIP especially focusing on how to more closely align the U.S. and EU regulatory systems, FDA is evaluating, "How do we move away from just the defensive posture, to really a much more comprehensive and proactive [one]," Valdez said.

The agency is also weighing what kind of proposals it can put on the table during negotiations, "so that we're champions and we're trying to promote a different kind of alternative thinking within a trade agreement," she added.

Officials at the Department of Health and Human Services, which houses FDA, have also said they are taking a more active role in shaping trade policy by advocating interagency proposals seeking to safeguard tobacco regulations and intellectual property protections for pharmaceuticals (*Inside U.S. Trade*, April 26).

As examples of how FDA is operating more proactively in the trade arena, Valdez said FDA is communicating more with other foreign regulators directly, and also emphasizing the importance of their measures being based on science.

FDA has also set up a special public health and trade team within the Office of International Programs and has been conducting direct stakeholder outreach that in the past would have been handled exclusively by the Office of the U.S. Trade Representative, according to Valdez.

"You need to hear us, and we need to hear you guys," she said, speaking in an Aug. 15 presentation to members of the Alliance for a Stronger FDA, which advocates for more agency funding. USTR and FDA are also sometimes jointly meeting with Congressional committees with jurisdiction over FDA, so that lawmakers can hear about "the intersection between trade and regulatory systems within these negotiations," Valdez added.

In what appeared to be a veiled reference to the EU, Valdez said that "some other [foreign] governments" evaluate the relevant science in issuing their regulation but then put a "cultural overlay" on top of their rules.

"And that's what I think is going to bring us some challenges in these new, 21st-century free trade agreements," she added. "I'm not sure what the answer is, but we think that there is some opportunity to really look at ways that we can align. Because we all understand the [scientific] underpinning."

The U.S. and EU have clashed over a number of food and health related issues, typically in the area of agricultural trade. For example, the EU bans the use of the growth-promoting veterinary drug ractopamine in meat production; the drug was approved for use in the U.S. by the FDA in 1990s.

The ractopamine ban has been a friction point between the EU and U.S., although USTR and the U.S. Department of Agriculture have typically been the agencies in the administration that have pressed the issue most aggressively.

Valdez conceded that some of FDA's interests are still defensive. The agency is keen to ensure that nothing in a trade agreement, for example, would hinder its ability to implement the far-reaching Food Safety Modernization Act (FSMA), she said. Private-sector sources have also said that FDA has resisted industry demands to make rules on sanitary and phytosanitary (SPS) measures enforceable, for fear that it could hinder its ability to regulate on health matters.

FDA is already behind on rolling out regulations under FSMA, which, among other things, requires the agency to drastically expand the number of overseas inspections it conducts and implement new requirements for food importers to show that what they are bringing in is safe (*Inside U.S. Trade*, Aug. 9).

Valdez appeared to implicitly endorse the overarching goal laid out by TTIP negotiators to bring the U.S. and EU regulatory systems more in line with each other, in an early public sign that at least some U.S. regulators are on board with the initiative. While House Republicans and business officials have lauded this aim, some Democratic lawmakers and non-governmental groups have expressed fear that it could lead to back-door deregulation.

"One of the things we're hearing loud and clear from industry ... particularly in TTIP, the Europeans or the U.S., is how do we really better align our approaches so that we can gain efficiencies," Valdez said. "I think there's a couple ways that we can do that. One is really to better understand, and dig deep so that we can really leverage our respective regulatory processes, and ... by having that knowledge seeing how we can maybe bring them closer together."

Valdez did not elaborate on what types of proposals FDA is advocating and an FDA spokeswoman declined a request for a follow-up interview for this article.

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EDITORIAL

The Hazard of Free-Trade Tobacco

By THE EDITORIAL BOARD
Published: August 31, 2013

Give thanks to Malaysia for heading off, at least temporarily, an American effort to weaken the ability of countries to impose stiff rules on the sale of cigarettes and other tobacco products within their own borders. The Malaysian proposal to preserve that ability led to a stalemate at a Trans-Pacific Partnership trade meeting in Brunei last week and forced the deferral of the issue to future meetings.

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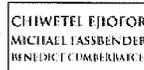
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The United States and 11 countries bordering the Pacific Ocean had been engaged in the latest round of negotiations over a treaty intended to lower tariffs and other barriers to commerce. One of the issues was whether tobacco should be included in such a treaty or “carved out” so that health considerations could take precedence over expanded trade. The issue pits health advocates against the tobacco industry and other commercial interests.



Related in Opinion

Op-Ed Contributor: Why Is Obama Caving on Tobacco? (August 23, 2013)

On public health grounds, tobacco ought to be excluded from whatever rules are designed to increase trade in agricultural products. Reducing trade barriers to tobacco, a uniquely dangerous product, would serve to increase tobacco consumption and lead to many additional deaths on top of an already high total. Tobacco killed an estimated 100 million people in the 20th century and is projected to kill 1 billion people in this century unless strong action is taken to mitigate the damage. A carve-out from trade rules is only one tactic, but it could save millions of lives, especially in developing countries vulnerable to the industry's pressure.

The United States, which in advance of the meeting had favored a relatively strong proposal to protect a nation's tobacco control measures from being challenged as violations of trade agreements, offered a weaker proposal in Brunei. The American proposal simply refers to other international agreements that allow exceptions for public health and requires health officials from the 12 Trans-Pacific Partnership countries to consult each other before making trade challenges. It would not prevent the challenges from moving forward.

Mayor Michael Bloomberg, a strong advocate of tobacco control in this country and abroad, rightly denounced the American proposal as “weak half-measures at best.” The proposal leaves the door open for multinational tobacco companies to challenge legitimate tobacco control measures, as they

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 m ; various tobacco products, among
 ot r Tobacco-Free Kids and several
 ot ps, including the American College of
 O led the Malaysian proposal. It would
 pr osts of fending off trade challenges
 and from potentially stiff financial penalties if they lose. And it would remove
 the danger that some countries might not enact strong tobacco control
 measures in order to avoid any possibility of challenges.

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American trade officials need to toughen their stance when Trans-Pacific Partnership negotiations resume. They should be siding with the public and those concerned about public health, not the makers of products known to be lethal and highly addictive.

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