



December 2015

## The TPP Attack on Commonsense Food Safety Standards

The Trans-Pacific Partnership (TPP) has new and expansive provisions governing food safety and agricultural protection rules that can weaken consumer protections, undermine U.S. food safety standards and expose U.S. crops and livestock to dangerous diseases and pests. This broad area of domestic law and regulation that includes food safety inspection, laboratory testing protocols and quarantines to prevent the entry of livestock diseases and crop pests would be subject to the TPP's Sanitary and Phytosanitary (SPS) provisions that make food safety rules more vulnerable to challenge at international trade tribunals.

The TPP is a twelve-nation trade pact covering 40 percent of the global economy and significant agriculture, food and fish producing countries in the Pacific Rim.<sup>1</sup> Agribusiness and food companies demanded that the TPP have tough provisions to attack food safety laws as illegal trade barriers. Food safety advocates and consumer groups have long criticized the SPS provisions in the World Trade Organization agreement (WTO) as a threat to rigorous food safety standards and enforcement, but the goal of the TPP SPS rules was to provide tougher, more aggressive language to attack these sensible food safety and agricultural protection measures in international trade tribunals established by the TPP.<sup>2</sup>

The TPP SPS chapter delivered on industry demands with more expansive, powerful language and provisions than are found in previous trade deals. These provisions in the TPP can be used to undermine, weaken or eliminate commonsense food safety and agricultural quarantine measures. While the justification from industry and U.S. trade negotiators for this language is to

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<sup>1</sup> The TPP nations include Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, Vietnam and the United States.

<sup>2</sup> In most places, we will discuss food safety measures and use “food safety” generically to describe the measures that would fall under the SPS provisions; animal and plant protection measures will be described as well in the TPP SPS provisions governing those types of protections explicitly.

attack food safety rules that are purportedly protectionist, the TPP can also be used to unravel domestic food safety standards. Because the TPP SPS provisions are considerably more industry friendly than prior trade deals like the WTO, it will be easier to successfully attack U.S. food safety laws, regulations and procedures under the TPP than under any other trade pact. These challenges to U.S. food safety will come in several areas:

*Imports overwhelm overtaxed inspectors; new mechanism to second guess border oversight:* The TPP will increase the volume of imported and potentially risky foods coming into the United States, but tie the hands of border inspectors. The TPP includes a so-called Rapid Response Mechanism that allows exporters to challenge and review border inspection determinations — like holding suspect shipments while awaiting laboratory test results. This would create a chilling effect on rigorous border inspection and enforcement of food safety standards on imports.

*Tougher rules make U.S. food safety standards more vulnerable to trade tribunals:* The TPP limits the domestic food safety policy goals and the level of protection that are acceptable under the trade agreement. The TPP food safety rules also include deregulatory language that is considerably stronger than the food safety rules in prior trade deals like the WTO. The provisions limit the ability of governments to establish strong food safety standards and make it easier for foreign countries to challenge food safety rules as illegal trade barriers.

*Encourage acceptance of “close enough” foreign food safety standards and a race-to-the-bottom global food safety deregulation:* The TPP expands on the goal of eliminating differences between countries’ food safety systems to encourage trade. The TPP has more stringent requirements to accept other nations’ food safety systems as “equivalent,” or essentially “close enough,” to U.S. standards to allow accelerated food imports. It directs the United States to expand the current policy of recognizing foreign food safety systems that are not as strong as ours, a process that is already compromised by the geopolitics of global trade. But this also allows a global race-to-the-bottom in food safety standards, locking in the worst deregulation like company self-inspection and spreading it worldwide.

Countries should be able to implement food safety standards, policies and procedures that maintain a level of food safety protection that is democratically established by their citizenry. The premise of the food safety language in the TPP and other trade deals is that food safety standards are presumptively illegitimate trade barriers. Although these standards are developed through a long, democratic process that involves legislation, regulation and, often, administrative judicial decisions, trade deals like the TPP are designed to provide new venues for the food and agribusiness industries to attack, weaken and eliminate food safety standards at foreign trade tribunals.

## I. The rise and rationale of trade oversight of Sanitary and Phytosanitary (SPS) food safety rules

The SPS language in trade agreements are designed to attack food safety standards as illegal trade barriers — and the TPP SPS language provides stronger tools to undermine, weaken and ultimately eliminate commonsense food safety standards. The SPS language provides a measuring stick to determine whether food safety and agricultural pest and disease protection laws and regulations constitute trade barriers. These standards govern protection from foodborne illness (like *Salmonella* and *E. coli*) and foodborne hazards (like illegal additives or drug residues), livestock and plant diseases and pests (like food and mouth disease and Mediterranean fruit fly), environmental contamination (like pesticides and toxics), as well as ecological damage from invasive species (like zebra mussels or Asian long-horned beetles).

The WTO Agreement on SPS Measures (WTO SPS) established the baseline for food safety and animal and plant protection provisions in trade deals for the past two decades. Trade agreements view food safety standards as illegitimate government interference in the free market, essentially equating important public health, environmental and food safety regulations to be the same as import tariffs.<sup>3</sup>

Although all free trade agreements have SPS measures, prior to the TPP, the SPS provisions in bilateral and regional free trade agreements have not been as extensive as the WTO SPS provisions.<sup>4</sup> The TPP breaks new ground by adding teeth to the WTO SPS: The language is tougher and the provisions are more expansive, making it easier for countries to win SPS trade disputes under the TPP SPS provisions than under the WTO. Additionally, the TPP has additional dispute mechanisms (one that covers all SPS issues and another specific to import inspection decisions) that give new tools for exporting countries (at the behest of their domestic agribusiness and food industries) to challenge importers food safety and agricultural protection measures.

The agribusiness and food industries have driven the demand for tough SPS provisions to undermine food safety standards. In part, this is because agricultural tariff levels have been falling (and in many cases eliminated entirely) from decades of free trade agreements, making the so-called food safety non-tariff barriers more significant in a relative sense.<sup>5</sup> Free trade proponents also contend that food safety rules are used as protectionist measures in the guise of food safety measures.

Although in some cases countries can use SPS and other technical standards to create preferences for domestic food and agriculture products by discriminating against imports,<sup>6</sup> most food safety measures reflect domestic demands for safer food. A 2012 study by the Australian National

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<sup>3</sup> Wirth, David A. “International trade agreements: Vehicles for regulatory reform.” *University of Chicago Legal Forum*. January 1997 at 333.

<sup>4</sup> Johnson, Renée. Congressional Research Service. “Sanitary and Phytosanitary (SPS) and Related Non-Tariff Barriers to Agricultural Trade.” R43450. March 31, 2014 at 8.

<sup>5</sup> Arita, Shawn, Lorraine Mitchell and Jayson Beckman. U.S. Department of Agriculture. Economic Research Service (ERS). “Estimating the Effects of Selected Sanitary and Phytosanitary Measures and Technical Barriers to Trade on U.S.-EU Agricultural Trade.” ERR No. 199. November 2015 at 1.

<sup>6</sup> Johnson (March 31, 2014) at 1.

University found that the strength of SPS measures reflected stronger democracies and more robust regulatory institutions establishing safeguards based on their citizen's desires. It found that protectionism "was a very minor motive" for SPS measures, much less important than the motivation for protecting consumers.<sup>7</sup>

The real motivation for aggressive SPS provisions is to provide an avenue to attack food safety, agricultural protection and environmental rules that are opposed by the U.S. agribusiness and food industries. Under the WTO, the Office of the U.S. Trade Representative (USTR), with support from the U.S. Department of Agriculture (USDA), has advanced the cause of agribusiness and food interests to attack and weaken foreign food safety regimes. Between 1995 and 2010, the USTR had filed nearly 8,200 WTO notifications against foreign SPS measures it considers illegal trade barriers.<sup>8</sup>

While USTR's purported goal is to break down protectionist measures to promote exports, foreign countries have also used SPS challenges to attack U.S. food safety and agricultural quarantine measures. The United States was a WTO SPS defendant nearly as often as it was an SPS plaintiff (7 and 10 cases, respectively) — and more than two-fifths of WTO SPS cases involved the United States as either a defendant or plaintiff.<sup>9</sup> The TPP will make it easier for other countries to launch trade disputes against U.S. laws, as well as for the USTR to attack the laws of other countries at the behest of powerful agribusiness and food industries.

*A. Industry demanded and received tougher TPP SPS provisions; TPP objectives put commerce ahead of food safety*

The agribusiness and food industries pushed for stronger SPS provisions in the TPP. In 2013, a coalition of big agriculture and food organizations and companies stated "The biggest potential value in such work is where TPP breaks new ground through 'WTO-plus' SPS provisions – that is, obligations that go beyond the WTO SPS Agreement on issues like risk assessment, risk management, transparency, border checks/laboratory testing and facilitating trade through regulatory coherence measures."<sup>10</sup>

The TPP text specifically includes the industry demands in its SPS objective to "reinforce and build on the [WTO] SPS Agreement."<sup>11</sup> The USDA stated that the TPP "builds on and enhances the rules of the World Trade Organization's (WTO) sanitary and phytosanitary agreement."<sup>12</sup> The TPP puts commerce on an equal or superior footing to commonsense food safety rules. The TPP SPS objective is to "protect human, animal or plant life or health [...] while facilitating and

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<sup>7</sup> Aisbett, Emma and Lee M Pearson. Crawford School of Public Policy. Australian National University. "Environmental and Health Protections, or New Protectionism? Determinants of SPS Notifications to WTO Members." Crawford School Working Paper No. 12-13. December 21, 2012 at 31 to 33.

<sup>8</sup> Johnson (March 31, 2014) at 23.

<sup>9</sup> *Ibid.* at 28 to 32.

<sup>10</sup> Coalition of food and agriculture organizations and companies. Letter to Michael Froman, Deputy National Security Advisor for International Economic Affairs. April 15, 2013.

<sup>11</sup> Trans-Pacific Partnership. Chapter 7—Sanitary and Phytosanitary Measures (TPP SPS). Art. 7.2(b).

<sup>12</sup> U.S. Department of Agriculture (USDA). Foreign Agriculture Service (FAS). "Agriculture-related provisions of the Trans-Pacific Partnership: Detailed summary." October 14, 2015 at 2.

expanding trade.”<sup>13</sup> The goal of ensuring a safe food supply is subservient to the primary goal of encouraging trade in food goods.

The TPP SPS food safety framework is more favorable to exporters even than the WTO SPS provisions. The preamble to the WTO SPS language affirmatively recognizes the right of countries to adopt and enforce food safety measures as long as they do not “constitute a means of arbitrary or unjustifiable discrimination” against imports or are “a disguised restriction on international trade.”<sup>14</sup> While the TPP grants members the same limited rights to have food safety rules as the WTO, it has stronger obligations to ensure that food safety rules do not constitute trade barriers. Not only are food safety rules prohibited from being unjustifiable or disguised trade restrictions, but the TPP highlights “unjustified obstacles to trade,” a formulation that suggests that food safety measures that slow or inconvenience exporters could be considered illegal trade barriers.<sup>15</sup>

The TPP SPS objectives set the tenor for the entire chapter: food safety rules are viewed as an impediment to commerce, rather than sensible measures to protect consumers from unsafe foods. The TPP’s broad scope allows countries to challenge “all sanitary and phytosanitary measures [...] that may, directly or indirectly, affect trade” as potentially illegal trade barriers.<sup>16</sup>

## II. Limits on import inspections and second-guessing border oversight

The TPP will increase the strain on already overtaxed food safety border inspectors while establishing new limits on acceptable border control policies and procedures. The volume of imported food has skyrocketed under the trade deals of the past two decades, greatly exceeding the ability of border inspectors to oversee the imports. The TPP will further increase food imports, further taxing U.S. border inspection.

The volume of imported food has more than doubled over the past two decades, from about 52 billion pounds every year in the early 1990s to 124 billion pounds in 2015.<sup>17</sup> The steep increase in imports has outpaced border inspectors’ ability to ensure the safety of imported food. In 2004, the Deputy Food and Drug Administration (FDA) Commissioner admitted that “[B]ecause of free trade agreements, but also the World Trade Agreement of 1994, the amount of food moving in international trade is increasing greatly, and at the present time, in the United States, we have three times the number of imports we did before 1996, and it is still going up.”<sup>18</sup>

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<sup>13</sup> TPP SPS Art. 7.2(a).

<sup>14</sup> World Trade Organization. Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS) at Preamble.

<sup>15</sup> TPP SPS Art. 7.2(d).

<sup>16</sup> TPP SPS Art. 7.3 at para. 1; these are identical to the WTO SPS Art. 1 at para. 1.

<sup>17</sup> U.S. Department of Agriculture (USDA). Foreign Agriculture Service. Global Agricultural Trade System database. Includes meat/poultry, fish/seafood, dairy, vegetables, fruits/nuts, coffee/tea/spices, milling products, meat/fish preparations, animal/vegetable fats, sugars/confectionary, cocoa products, cereal/flour preparations, vegetable/fruit/nut preparations, miscellaneous edible preparations and beverages. Accessed December 2015.

<sup>18</sup> Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. Committee on Appropriations. U.S. House of Representatives. Hearing on Appropriation for 2005. Part 3. March 4, 2004 at 72.

Inspection rates have declined steadily. In 1992, the FDA inspected about 8 percent of imported food under its jurisdiction (generally, everything except meat, poultry and processed eggs).<sup>19</sup> By 2012, FDA inspected less than 2 percent of food imports.<sup>20</sup> On the meat and poultry side, there were 75 USDA border inspectors overseeing 2.5 billion pounds of meat and poultry imports in 1997.<sup>21</sup> But by 2015, only 66 USDA border inspectors oversaw the import of 4.4 billion pounds of meat and poultry products — about 10 percent fewer inspectors with nearly double the volume of imported meat and poultry.<sup>22</sup> By 2015, each USDA border inspector examined an average of 67 million pounds of meat and poultry annually or 184,000 pounds per day.<sup>23</sup>

The TPP sets tighter limits on the rigor of import inspection systems, known as control policies. The WTO requires food safety inspections to be prompt, applied equally to domestic and imported foods and be “limited to what is reasonable and necessary.”<sup>24</sup> The TPP is more proscriptive in what border inspections are considered trade-legal. The TPP requires that import inspection oversight programs be based on the risks of the imports.<sup>25</sup> Like the WTO, importing countries must ensure that stopping shipments that fail to meet domestic food safety standards “is limited to what is reasonable and necessary,” but it also must be based on “available science” and any testing of imports must be “appropriate and validated.”<sup>26</sup>

The stronger TPP language gives exporting countries more avenues to attack border inspection policies and procedures as illegal trade barriers. Exporters can challenge import screening protocols for not being adequately based on the risks of the imports. The FDA uses a computer-based screening program to determine which of the 20 million shipments of food, drugs, medical devices, cosmetics and other FDA-regulated goods will be inspected. The program generates a calculated risk score based on inherent risk, anomalies, data quality, product and exporting firm to determine which shipments are physically inspected.<sup>27</sup> The USDA uses a similar computer system to manage import inspections to screen imported meat, poultry and processed egg shipments and determine the meticulousness of the inspection for each shipment.<sup>28</sup> An exporting country that received significant border inspection scrutiny (say for farmed fish), could challenge FDA’s screening program or laboratory testing as exceeding the risk profile of the imported products, being insufficiently based on science and being un-validated.

Additionally, importers are required to disclose the criteria for determining what shipments get examined and what factors affect the imports that receive greater scrutiny.<sup>29</sup> Importing

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<sup>19</sup> Robertson, Robert E. General Accounting Office. Testimony before the Permanent Subcommittee on Investigations. Committee on Governmental Affairs. U.S. Senate. May 14, 1998 at 4.

<sup>20</sup> U.S. Food and Drug Administration (FDA). “2013 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices.” November 2013.

<sup>21</sup> USDA. Food Safety Inspection Service (FSIS). Annual Report. Committee on Agriculture, Nutrition and Forestry. U.S. Senate. November 1999 at 38.

<sup>22</sup> USDA FSIS. Quarterly Enforcement Report. July 1, 2015 through September 30, 2015 at Table 3; border inspector numbers from Food & Water Watch communication with USDA.

<sup>23</sup> *Ibid.*

<sup>24</sup> WTO SPS. Annex C at para. 1(a) and 1(c).

<sup>25</sup> TPP SPS. Art. 7.11 at para. 1.

<sup>26</sup> TPP SPS. Art. 7.11 at para. 5.

<sup>27</sup> FDA. Division of Import Operations & Policy. [Fact sheet]. “Imports.” Fact sheet #1. July 27, 2012.

<sup>28</sup> USDA FSIS. “FSIS Directive: Import Reinspection of Meat, Poultry, and Egg Products.” November 3, 2015. A similar computer system evaluates domestic products to manage inspections.

<sup>29</sup> TPP SPS. Art. 7.11 at para 2.

governments also must disclose the laboratory testing methods, quality controls, sampling protocols and laboratory facilities used to evaluate suspect imports.<sup>30</sup> The disclosure of U.S. import screening procedures could provide strategic guidance to allow exporting companies to evade U.S. inspectors, allowing unsafe imported food into the marketplace.

*A. Rapid Response Mechanism allows exporters to challenge specific food safety detentions at the border*

New language that replicates the industry demand for a so-called Rapid Response Mechanism requires border inspectors to notify exporters for every food safety check that finds a problem and give the exporter the right to bring a challenge to that port inspection determination. This is a new right to bring a trade challenge to individual border inspection decisions (including laboratory or other testing) that second-guesses U.S. inspectors and creates a chilling effect that would deter rigorous oversight of imported foods.

In 2013, a coalition of agribusinesses, commodity groups, food manufacturers and others repeatedly demanded a specific Rapid Response Mechanism in the TPP to provide a new tool to challenge border inspectors. An April letter signed by 55 groups including the American Meat Institute, Grocery Manufacturers Association and National Chicken Council demanded the RRM in the TPP “to help improve trade facilitation and resolve shipment-specific issues.”<sup>31</sup> A July letter signed by 37 groups including the American Frozen Food Institute, Cargill, JBS, Kraft and others identified as the goals of RRM “to provide for shipment specific trade facilitative obligations that address frustration of trade in perishable and time sensitive shipments of agricultural products.”<sup>32</sup> Purportedly, foreign government inspectors are frequently detaining food shipments that need to get into commerce either because of perishability or just-in-time shipment schedules. But the RRM can also be used to challenge U.S. import inspectors’ decisions and press the FDA and USDA to release shipments of suspected food safety violations.

The TPP text delivered on industry demands and provided a mechanism to dispute border inspectors’ food safety screening. Under the TPP, if an import shipment is stopped at the border by food safety inspectors, the importing country must promptly notify at least one of the importing firm, the exporting firm, the manufacturer or the exporting country.<sup>33</sup> The importing country that detains or refuses a suspect or unsafe imported food shipment must “provide an opportunity for a review of the decision.”

This review of food safety import shipment detentions creates a new dispute mechanism for exporters to challenge food safety oversight. This process second guesses U.S. border inspectors and subjects the food safety determinations of independent government inspectors to international trade disputes. The goal is to get shipments that have been stopped for legitimate food safety concerns to get promptly moved into commerce irrespective of the potential risks. The TPP text

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<sup>30</sup> TPP SPS. Art. 7.11 at para. 4.

<sup>31</sup> Coalition of food and agriculture organizations and companies. Letter to Michael Froman, Deputy National Security Advisor for International Economic Affairs. April 15, 2013.

<sup>32</sup> Food and agricultural coalition letter to Ambassador Mike Froman and Agriculture Secretary Thomas Vilsack. “Statement of core principles for a successful TPP agreement.” July 15, 2013.

<sup>33</sup> TPP SPS. Art. 7.11 at paras. 6 and 7.

gives foreign trade ministers the right to challenge the decisions of FDA and USDA border inspectors and interfere with their statutory mandate to protect U.S. consumers. Food safety inspectors will likely be less rigorous in inspecting, reviewing and testing imports suspected of violating food safety standards when their decisions can be overturned by a trade dispute.

In October 2015, the U.S. Trade Representative Michael Froman described the role of the RRM as “some mechanism for technical experts to get together immediately and clear up the problem and allow the shipments to move forward.”<sup>34</sup> USTR Froman demonstrates no concern about whether the shipments are safe, the food safety border inspection detention should be cleared up and then the shipments should be moved into commerce and ultimately America’s supermarkets and restaurants.

*B. Rapid Response Mechanism: state-to-state or business-to-state disputes over food safety detentions?*

These TPP provisions allow exporters to review the decision-making process and determination of import inspectors. That includes the exporting country and potentially (and perhaps likely) the firms exporting, importing or manufacturing the suspect or rejected imported food shipment. The Office of the U.S. Trade Representative (USTR) told consumer groups that the RRM was intended to be a state-to-state dispute process.<sup>35</sup> However, the vague language in the TPP likely allows for business-to-state disputes, as the agribusiness and food industry demanded.<sup>36</sup>

The TPP does not specify say which entity (government or industry) would receive the opportunity to review the border detention. If the intention was that only governments could participate in these border inspection disputes, the TPP would have explicitly stated that the “importing Party (government) shall provide the exporting Party (government) an opportunity for a review of the decision.” But it does not. This vagueness could permit exporting firms, importing firms and manufacturers to participate in these border inspection disputes.

Moreover, the relationship between the notification language and the review language suggests that any of the notified parties could pursue a border inspection dispute. The TPP specifically allows for commercial interests (exporting firm, importing firm or manufacturer) to be notified and does *not* require that the exporting government be notified at all (the notification requirement is “at least one of”). If the intention were only for governments to pursue these disputes, the notification would have included the government and any one of the commercial parties.

As a practical matter, it seems cumbersome for the trade ministers to intervene on perhaps hundreds or thousands of border detention cases. For example, the United States annually refuses

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<sup>34</sup> Council of Foreign Relations. [Transcript]. “The U.S. trade agenda and the Trans-Pacific Partnership.” October 15, 2015.

<sup>35</sup> USTR has suggested that these disputes would be governed by the Cooperative Technical Consultations provisions in TPP SPS Art. 7.18. But these provisions relate specifically to concerns raised by a Party (government) and the overly vague Rapid Response Mechanism language seems to allow private disputes over border inspection detentions. Moreover, prior reports suggested that USTR negotiators offered *both* a Rapid Response Mechanism as well as a consultative mechanism, and the TPP still has both provisions. Johnson (March 31, 2014) at 12.

<sup>36</sup> Most SPS disputes are between governments, often at the behest of industry, but this language appears to be more in line with the investor-to-state disputes in the TPP’s investment chapter.

about 260 shipments of imported seafood alone for food safety reasons from TPP countries.<sup>37</sup> A USDA study found that seafood import refusals for food safety violations constituted about one-quarter of food safety refusals, meaning that the FDA may refuse over 1,000 food shipments from TPP countries annually.<sup>38</sup> Hundreds more shipments are likely temporarily detained before clearing laboratory testing. All of these shipments could be the basis for a review of border inspection that “prohibits or restricts the importation of a good.”<sup>39</sup> Even if a portion of these border detentions were contested in border inspection disputes, it would nonetheless constitute a considerable burden on international trade agencies like USTR.

The TPP language seems to allow for private parties (shippers and manufacturers) to pursue disputes over detentions of import shipments for food safety concerns. Second guessing import inspectors by foreign governments or companies hampers their ability to protect consumers from unsafe imported food and creates a chilling effect that deters rigorous oversight of potentially risky imports.

### *C. Real world TPP food safety threat: RRM could be used to push potentially unsafe food into supermarkets*

Under the RRM, seafood exporters like Vietnam or Malaysia or beef exporters like Canada or Australia could challenge detentions by U.S. import inspectors. The TPP requires border inspectors to notify exporters of a “decision to prohibit or restrict” within 7 calendar days (excluding holidays but not weekends).<sup>40</sup>

Laboratory tests can be time consuming. In 2011, the FDA Commissioner testified that the FDA tested a sample of string cheese in late 2010 and destroyed the shipment in early 2011 after laboratory tests found both *Listeria* and *Staphylococcus*.<sup>41</sup> In 2014, the Produce Marketing Association highlighted common delays in FDA import testing — two to three days for pesticides and up to ten days for microbial testing plus an additional 3 to 4 days for confirmation testing.<sup>42</sup> In 2012, USDA implemented a policy requiring import inspectors to hold all beef imports that were tested for microbiological pathogens or veterinary drug residues until the shipment received a negative test result in order to ensure that potentially tainted shipments did not enter the food supply.<sup>43</sup>

The TPP would allow exporters to demand a review of shipments that were delayed at least one week, which would include a sizeable portion of all shipments awaiting laboratory test results. If the review managed to “clear up the problem and allow the shipments to move forward,” in USTR Froman’s words, the risk that a tainted shipment would enter the food supply is significant.

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<sup>37</sup> Food & Water Watch analysis of FDA Import Refusal Report. U.S. Food and Drug Administration Import Refusal Reports for OASIS. 2008 to 2012 data.

<sup>38</sup> Buzby, Jean C., Laurian J. Unnevehr and Donna Roberts. USDA ERS. “Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports.” September 2008 at 10.

<sup>39</sup> TPP SPS. Art. 7.11 at para. 6.

<sup>40</sup> TPP SPS. Art. 7.11 at para. 7(b) at footnote 8.

<sup>41</sup> Hamburg, Margaret A. FDA Commissioner. Testimony before the Subcommittee on Oversight and Investigations. Committee on Energy and Commerce. U.S. House of Representatives. April 13, 2011.

<sup>42</sup> Produce Marketing Association. [Blog]. “PMA overview: FDA inspection of imports.” May 2014.

<sup>43</sup> USDA. FSIS. “Not applying the mark of inspection pending certain test results.” 77 Fed. Reg. 73401-73411. December 10, 2012.

Between 2003 and 2006, the FDA tested less than one percent of fish and seafood shipments, but 9 percent of the lab tests found microbiological, veterinary drug or chemical residues or other hazards that justified refusing the shipments.<sup>44</sup> Some countries and types of fish had much higher failure rates. More than 18 percent of the tested fish and seafood from TPP member Vietnam failed laboratory tests; lobster, crab and shrimp all frequently failed laboratory tests (16, 11 and 8 percent, respectively).<sup>45</sup> So, for every five times Vietnam successfully uses the Rapid Response Mechanism to push fish shipments across the border before screening and testing were complete, one unsafe shipment could arrive on supermarket shelves.

### III. Tougher “sound science” provisions make U.S. food safety standards more vulnerable to TPP challenge

The TPP limits the permissible level of food safety protection and imposes strict requirements for assessing the level of protection, a combination that makes it harder to establish and maintain strong food safety standards. The TPP constrains the goals of food safety rules, the level of food safety protection and the manner in which these policies can be implemented.

The use of trade deals like the TPP constrains democratic efforts to protect the public from unsafe foods. The U.S. food safety laws have been established and updated largely in response to public outcry over significant safety lapses by the food industry. The 2011 FDA Food Safety Modernization Act came after a series of foodborne illness outbreaks that showed the limitations and risks of FDA’s food safety system, including a 2008 *Salmonella* outbreak traced to a filthy peanut plant that sickened more than 22,000 and caused nine deaths.<sup>46</sup>

Countries should be able to set their own standards to protect consumers that address and establish levels of risk that reflect the level of protection demanded by their citizens. The TPP food safety provisions were pushed by the food and agribusiness industries, are more aggressive than the language in the WTO, mirror the broad-based industry attack on all regulatory safeguards and would make U.S. food safety laws more vulnerable to attack in international trade tribunals.

#### A. *Commonsense protections vulnerable to deregulatory “sound science” attack*

Most health, safety and environmental statutes do not require absolute scientific certainty to protect the public from known but imprecisely quantified risks; they merely require that there be sufficient scientific evidence to take action.<sup>47</sup> Agencies adopt precautionary approaches to protect against substantiated risks based on the preponderance of the evidence — but industry has repeatedly used a requirement for “sound science” to attack the studies that undergird public

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<sup>44</sup> Food & Water Watch. “Laboratory Error.” 2008 at 7.

<sup>45</sup> *Ibid.* at 8.

<sup>46</sup> Moss, Michael and Andrew Martin. “Food safety problems slip past private inspectors.” *New York Times*. March 6, 2009; Booth, Michael and Jennifer Brown. “Producers seldom hear of food-safety issues from their private auditors.” *Denver Post*. October 30, 2011.

<sup>47</sup> Shapiro, Sidney A. “OMB and the politicization of risk assessment.” *Environmental Law*. Vol. 73. November 2007 at 1087.

health and environmental rulemaking to muddy the water and create the impression of uncertainty.<sup>48</sup>

The “sound science” language of the TPP constrains the level of allowable food safety protections under trade rules. “Sound science” explicitly or implicitly suggests that regulators base their decisions on “junk science” if they act in a precautionary manner. A Wake Forest University law professor observed “Opponents of regulation have also exploited scientific uncertainty by mischaracterizing uncertainty as a lack of ‘sound science.’”<sup>49</sup> The politicization of “sound science” has been used to change scientific results, suppress scientific findings and alter regulatory risk assessments that conflict with ideologically driven deregulatory policy outcomes.<sup>50</sup> In the United States, the “sound science” attack has been used to delay or derail regulations over well-understood public and environmental health threats from asbestos, tobacco, lead and dioxin.<sup>51</sup>

Industry has embellished its attacks on regulations in the cloak of “sound science” for decades. In 1993, Philip Morris launched a covert public relations “sound science” campaign to block rules against second-hand smoke.<sup>52</sup> Newt Gingrich’s Contract with America included deregulation legislation built on industry’s “sound science” attack on environmental and public health safeguards, including more stringent risk assessments.<sup>53</sup> In 2015, the Republican House passed deregulation legislation that aligns with the risk assessment and sound science language in the TPP.<sup>54</sup> The comprehensive deregulation push has largely failed, but the TPP effectively binds U.S. laws and regulations to “sound science” deregulation that the Congress has rejected.

The “sound science” framework allows the industry to challenge the scientific integrity of regulators, attack the evidence and scientific certainty behind regulations and promote risk management (which really means controlling the effects of exposure to often preventable hazards). Industry can use the “sound science” attack to successfully delay, challenge and weaken regulatory oversight.<sup>55</sup> Researchers with the Institute for Health Policy Studies at University of California, San Francisco concluded “The [sound science] movement reflects sophisticated public relations campaigns controlled by industry executives and lawyers to manipulate the scientific standards of proof for the corporate interests of their clients.”<sup>56</sup>

#### *B. TPP food safety science and risk provisions tougher than prior trade deals*

U.S. trade negotiators have awarded industry a deregulation victory in the TPP with strong trade disciplines on risk assessments and “sound science.” These provisions allow foreign countries to

<sup>48</sup> Neff, Roni A and Lynn R. Goldman. “Regulatory parallels to *Daubert*: Stakeholder influence, ‘sound science,’ and delayed adoption of health-protective standards.” *American Journal of Public Health*. Vol. 95, No. S1. 2005 at S82.

<sup>49</sup> Shapiro (2007) at 1090.

<sup>50</sup> *Ibid.* at 1086.

<sup>51</sup> Neff and Goldman (2005) at S82 to S84; Ong, Elisa K. and Stanton A. Glanz. “Constructing ‘sound science’ and ‘good epidemiology’: Tobacco, lawyers, and public relations firms.” *American Journal of Public Health*. Vol. 91, No. 11. November 2001 at 1749 to 1753.

<sup>52</sup> Ong and Glanz (2001) at 1749 to 1753.

<sup>53</sup> Heritage Foundation. Antonelli, Angela et al. “Making regulatory reform a reality.” The Heritage Lectures No. 559. January 31, 1996.

<sup>54</sup> Regulatory Accountability Act of 2015. H.R. 185. 114<sup>th</sup> Congress. §3(b)(3), §3(k)(1).

<sup>55</sup> Neff and Goldman (2005) at S83.

<sup>56</sup> Ong and Glanz (2001) at 1754.

bring trade attacks on the science behind food safety and consumer standards at the behest of agribusinesses and food companies.<sup>57</sup> The TPP includes aggressive language on risk, risk management, risk assessment and “sound science” that is considerably stronger and more binding than the language in the WTO.

Industry demanded tougher deregulatory SPS science rules in the TPP. The U.S. Chamber of Commerce’s Global Regulatory Cooperation Project TPP working group highlighted that “regulations that are not based on sound science or evidence of significant risk can become obstacles to international trade.”<sup>58</sup> A 2013 agribusiness and food industry coalition letter to USTR Froman noted, “Risk based scientific decision-making, regulatory convergence, and equivalence are critically important” and “Non-science based SPS measures cannot continue to restrict trade.”<sup>59</sup>

The final TPP text delivered on these deregulatory demands. USDA Secretary Vilsack noted that the TPP would “deter non-science based sanitary and phytosanitary barriers.”<sup>60</sup> The USDA promotional materials on the TPP said the agreement “promotes the development and application of SPS measures in a risk-based, scientifically sound manner.”<sup>61</sup>

The TPP is designed to make it easier to lodge trade disputes against food safety measures. A Boston College law professor noted, “the tests of scientific validity found in recent trade agreements are intended to circumscribe the regulatory authority of national governments.”<sup>62</sup> Food safety oversight would be assessed based not on the extent to which it protected consumers but primarily on the extent it impacted trade, and the language favors regulatory approaches that put trade before food safety. Exporters could use these provisions to attack food safety rules as illegal trade barriers.

***TPP limits goals of food safety policy and scientific justification:*** The WTO established the idea that international trade tribunals should determine the “appropriate” level of food safety protection.<sup>63</sup> Food safety standards are only allowed under the WTO if they are based on a risk assessment using “available scientific evidence”<sup>64</sup> The TPP substantially expands the deregulatory sound-science requirements for food safety standards and sets more rigorous benchmarks for the scientific justification for food safety rules. Food safety rules must be “based on scientific principles” and be based on risk assessments that are “appropriate to the circumstances of the risk” and “takes into account reasonably and relevant scientific data.”<sup>65</sup> The TPP gives exporters even more leverage over importing countries. If an importing country does not accept a good for food

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<sup>57</sup> Winickoff, David E. and Douglas M. Bushey. “Science and power in global food regulation: The rise of the Codex Alimentarius.” *Science, Technology & Human Values*. Vol. 35, No. 3. 2010 at 360.

<sup>58</sup> U.S. Chamber of Commerce. Global Regulatory Cooperation Project. “TPP Coalition — Regulatory Coherence Working Group.” Undated at 2.

<sup>59</sup> Food and agricultural coalition letter to Ambassador Mike Froman and Agriculture Secretary Thomas Vilsack. “Statement of core principles for a successful TPP agreement.” July 15, 2013.

<sup>60</sup> Vilsack, Tom. U.S. Secretary of Agriculture. [Press release]. “Statement from Agriculture Secretary Tom Vilsack regarding the agreement on the Trans-Pacific Partnership.” October 5, 2015.

<sup>61</sup> USDA FAS (2015) at 2.

<sup>62</sup> Wirth (1997) at 333.

<sup>63</sup> See WTO SPS. Art. 5 at paras. 3, 4

<sup>64</sup> WTO SPS. Art. 5 at paras. 1 to 2.

<sup>65</sup> TPP SPS. Art. 7.9 at paras. 1 and 5.

safety reasons, exporters can force importers to expeditiously launch and complete a risk assessment based, at least on part, on information provided by the exporter.<sup>66</sup>

***TPP limits food safety standards to those that minimize trade effect:*** The WTO requires that even appropriate food safety protections be designed to achieve “the objective of minimizing negative trade effects.”<sup>67</sup> Any food safety measure must not be “more trade restrictive” than necessary to accomplish the appropriate level of protection, which means that a country should both consider the trade effects of a food safety policy and adopt any policy alternative that is less trade restrictive, even if it may be a less effective, more expensive or more cumbersome food safety policy.<sup>68</sup> The TPP takes the least trade restrictive language further. It requires countries to “consider risk management options” (policies that do not protect against the risk but manage with the known risk) including “the facilitation of trade by not taking *any* measure” (emphasis added).<sup>69</sup>

***TPP pushes United States to lower food safety standards to international norms:*** International trade deals push nations to set their food safety standards to a global standard, effectively creating a global race-to-the-bottom in food safety rules. The TPP dictates that countries “shall ensure” that food safety rules “conform to the relevant international standards,” language that is considerably stronger than the WTO language to harmonize food safety rules to international standards “on as wide a basis as possible.”<sup>70</sup> The international standard is set at the Codex Alimentarius (Codex), a UN-affiliated organization designed to promote food trade by creating a floor for food safety standards. The Codex food safety standards are presumptively trade legal, but the TPP only permits countries to have more protective standards if they are based on “documented and objective scientific evidence” and be “rationally related” to the food safety policy.<sup>71</sup>

Codex has a reputation for being especially cozy with the food and chemical industries that make up the majority of non-governmental participants and influence the scientific determinations by delaying or weakening the international baseline standards.<sup>72</sup> Codex standards are often lower than

<sup>66</sup> TPP SPS. Art. 7.9 at para. 7.

<sup>67</sup> WTO SPS. Art. 5 at para 4.

<sup>68</sup> WTO SPS. Art. 5 at para. 6 and at footnote 5.

<sup>69</sup> TPP SPS. Art. 7.9 at para 6(b).

<sup>70</sup> TPP SPS. Art. 7.9 at para. 2; WTO SPS. Art. 3 at para. 1.

<sup>71</sup> TPP SPS. Art. 7.9 at para. 2. The TPP specifically exempts the “based on documented and objective scientific evidence that is rationally related to the measure” language from dispute settlement at footnote 3 at Art. 7.9 para. 2. The drafters of trade agreements rarely exempt language entirely from dispute settlement. Although a country could not bring a dispute against that specific paragraph (for implementing a food safety standard stronger than international standards unless it was based on “documented and objective” science and “rationally related to the measure”), it may be possible for the paragraph to be brought into a dispute that was lodged against another provision by contending the language modified or provided definitions to other SPS paragraphs. For example, if a country challenged the United States for a food safety standard that was stronger than the Codex standards (under Art. 7.9 at para. 6(a) taking international standards into account, para. 6(b) not more trade restrictive than necessary and para. 5, requiring risk assessments to consider reasonable and available science), it would generally set a higher bar for standards that provided more protection than Codex. But, if a disputant could contend that the para. 2 language of “documented and objective scientific evidence rationally related to the measures” modified or provided clarity to in considering the other paragraphs, then the scientific integrity of the challenged measures could be brought into the dispute more easily. This would potentially weaken or nullify the power of the footnote to exempt the paragraph from dispute. Moreover, the TPP Institutional Arrangements demonstrate that the TPP is a living agreement that will continue to be negotiated (Art. 27.2 at para. 1(b-c)), meaning that the footnote on this paragraph could be removed in subsequent negotiations.

<sup>72</sup> Halabi, Sam F. “The Codex Alimentarius Commission, corporate influence, and international trade: A perspective on FDA’s global role.” *American Journal of Law & Medicine*. Vol. 41. 2015 at 407 to 408, 416.

U.S. standards. A 2012 study found that Codex pesticide standards on commonly imported fruits and vegetables were weaker than U.S. pesticide residue limits on apples, cucumbers, grapes, melons, bananas and squash for dozens of pesticides — including many with critical health effects.<sup>73</sup> The Codex also reinforces trade agreements’ deregulatory science ideology grounded in “sound science” based risk assessments.<sup>74</sup>

***Stronger TPP risk and science language can trump U.S. food safety laws in international trade science court:*** Trade tribunals adjudicate the scientific merits of risk assessments and allow industry backed science and scientists to challenge the validity of government regulatory decisions, unlike U.S. courts, which typically are deferential to the scientific judgment of regulatory agencies

The agribusiness and food industries specifically wanted especially binding dispute resolution to force countries to change their laws. A 2013 coalition letter stated that “Without the threat of penalties for noncompliance, trading partners are unlikely to adhere to their obligations; this is of course why dispute settlement exists. SPS commitments should not be given short-shrift in this regard; they too must be enforceable requirements.”<sup>75</sup>

The TPP explicitly allows dispute panels to sit in judgment of science by allowing panels to establish an advisory group of technical experts and let either party recommend experts.<sup>76</sup> The U.S. regulatory process already has considerable risk assessment and cost benefit requirements, the TPP science, risk assessment and risk management language allows foreign countries to challenge the regulatory scientific determinations and analysis used in making U.S. standards.

***New, secret TPP food safety trade court:*** The TPP has a special new dispute procedure to pressure countries into changing their food safety laws and policies without all the cost and hassle of lodging an international trade dispute. The TPP includes a “Cooperative Technical Consultations” section designed to adjudicate SPS trade tensions that have not yet risen to the level of a full-blown dispute.<sup>77</sup> It allows countries to “discuss any [SPS] matter” the exporter thinks “may adversely affect its trade” and the disputes under the Cooperative Technical Consultations “shall be kept confidential.”<sup>78</sup>

### C. *Industry bias in agriculture and food research taints trade disputes*

Trade tribunals effectively act as science courts, but adjudicating the scientific merit of food safety and consumer protections can be tainted by the widespread bias in agricultural and food research. The majority of agricultural and food research is performed by the industry. In 2009, more than three-fifths (61 percent) of the funding for agricultural science came from the private sector and

<sup>73</sup> Neff, Roni A. et al. “A comparative study of allowable pesticide residue levels on produce in the United States.” *Globalization and Health*. Vol. 8, No. 2. 2012 at 7 to 8.

<sup>74</sup> Winickoff and Bushey (2010) at 358.

<sup>75</sup> Coalition of food and agriculture organizations and companies. Letter to Michael Froman, Deputy National Security Advisor for International Economic Affairs. April 15, 2013.

<sup>76</sup> TPP SPS. Art. 7.18 at para. 2.

<sup>77</sup> TPP SPS. Art. 7.17. Further, it requires all SPS disputes to go through the Cooperative Technical Consultations process before the countries can bring a full-fledged dispute. Art. 7.17 at para. 8.

<sup>78</sup> TPP SPS. Art. 7.17 at paras. 2 and 6.

commodity groups — about triple the funding provided by USDA.<sup>79</sup> Agribusiness and food companies have also invested millions of dollars in public agricultural university buildings and endowed chairs and industry funding constitutes a large portion of the funding at many departments, which gives industry considerable sway over the research agenda and findings.<sup>80</sup>

Individual examples of pro-industry research abound. A study supported by the National Soft Drink Association found that soda consumption by school children was not linked to obesity; an Egg Nutrition Center-sponsored study found that frequent egg consumption did not increase blood cholesterol levels.<sup>81</sup> Candy manufacturer Mars donated more than \$15 million to the University of California's Nutrition Department to study things like the nutritional benefits of cocoa.<sup>82</sup> A 2015 *New York Times* series documented Coca Cola's "science-based" campaign to minimize the role of soda consumption on obesity by providing millions of dollars in financial support to scientists and non-profit groups that focused on exercise over diet (one research center shuttered after it returned Coke's funding over the lack of transparency and apparent conflict of interest).<sup>83</sup>

Industry-funded studies are much more likely to arrive at pro-industry conclusions. A 2013 study found that beverage-industry funded studies were five times more likely to deny a link between consuming sugary drinks and obesity.<sup>84</sup> A 2007 study found that industry-funded nutrition studies are four to eight times more likely to reach favorable conclusions to the sponsors' interests.<sup>85</sup> Another study found that around half of authors of peer-reviewed journal articles about the safety of genetically engineered foods had an identifiable affiliation with industry.<sup>86</sup> All of these produced favorable results to industry sponsors, while very few acknowledged having received industry funding.<sup>87</sup>

Trade disputes over food safety science often weight the preponderance of evidence, but in the food and agricultural arenas, industry funded science greatly outnumbers independent scientific research. In the long-running WTO beef hormone case, the United States defended one of the chemicals banned by the European Union, the growth promoter Zilmax, based on its widely understood and scientifically documented safety.<sup>88</sup> But in reality there had been virtually no

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<sup>79</sup> Executive Office of the President. President's Council of Advisors on Science and Technology. "Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise." December 2012 at 20 and 21.

<sup>80</sup> Food & Water Watch. "Public Research, Private Gain." April 2012.

<sup>81</sup> Nestle, Marion. "Food company sponsorship of nutrition research & professional activities: A conflict of interest?" *Public Health Nutrition*. 2001 at 1021 to 1022.

<sup>82</sup> Mars, Inc. [Press Release]. "Cocoa Flavanols Could More Than Double Cells Associated With Repair & Maintenance Of Blood Vessels, According To Mars, Incorporated Research." July 5, 2010; Food & Water Watch analysis of University of California grants obtained through Freedom of Information Act requests.

<sup>83</sup> O'Connor, Anahad. "Coca-Cola funds scientists who shift blame for obesity away from bad diets." *New York Times*. August 9, 2015; O'Connor, Anahad. "University returns \$1 million grant to Coca-Cola." *New York Times*. November 6, 2015.

<sup>84</sup> Bes-Rastrollo, Maira et al. "Financial conflicts of interest and reporting bias regarding the association between sugar-sweetened beverages and weight gain: A systematic review of systematic reviews." *PLOS Medicine*. December 31, 2013 at Methods and Findings.

<sup>85</sup> Lesser, Lenard et al. "Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles." *PLOS Medicine*. January 2007 at Discussion.

<sup>86</sup> Diels, Johan. "Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products." *Food Policy*. November 22, 2010 at 200 to 201.

<sup>87</sup> *Ibid.*

<sup>88</sup> Much has been written about the beef hormone dispute; here we focus on the flawed use of scientific evidence for one of the chemicals banned by the EU. United States. Comments of the United States on the Responses of the Scientific Experts. United

independent, peer-reviewed studies into the safety of the drug for cattle. Most of the available research examined commercial dimensions of Zilmax, such as the drug's impact on beef quality, and more than three-quarters of the studies were authored and/or funded by industry groups.<sup>89</sup> Despite USTR's confidence in the scientific safety of Zilmax, in 2013 Tyson Foods abruptly stopped accepting cattle raised with Zilmax because of widespread concerns about livestock health and a few days later the drug's manufacturer suspended all Zilmax sales.<sup>90</sup>

*D. Real world TPP food safety threat: Vietnam could successfully challenge FDA's bans on importing seafood with unapproved antibiotics*

Several TPP countries produce farmed seafood that can be raised with chemicals and antibiotics that are prohibited in the United States. The FDA has not approved several classes of drugs for farmed fish (known as the red list) and the use of these drugs is prohibited for fish and seafood marketed in the United States<sup>91</sup> The FDA is increasingly concerned that U.S. fish imports contain residues of these drugs and chemicals, which can cause cancer and allergic reactions and contribute to the development of antibiotic-resistant bacteria.<sup>92</sup> But the FDA's outright prohibition on these drugs for aquaculture is vulnerable to a TPP SPS challenge. The FDA protection for some of the banned drugs is higher than the international standard, the underlying science is hotly disputed by the food animal industry and the outright ban is far from the least trade restrictive policy.

In Vietnam, fish farmers use veterinary drugs and fungicides that are unapproved in the United States in order to combat disease in overcrowded fish pens and ponds. Vietnam has approved 32 veterinary drugs for aquaculture.<sup>93</sup> A 2013 survey found that 100 percent of Vietnamese catfish farms used antibiotics that were unapproved in the United States.<sup>94</sup> A 2015 *Consumer Reports* survey found that 80 percent of the bacteria commonly found on shrimp from Vietnam were resistant to one or more classes of antibiotics, suggesting the shrimp were exposed to these antibiotics in their environment.<sup>95</sup> The survey also found residues of several classes of antibiotics on shrimp from Vietnam and 72 percent of the shrimp with antibiotic residues in the study were from Vietnam.<sup>96</sup>

The Vietnam Association of Seafood Exporters and Producers has admitted that there are problems with antibiotic use in the aquaculture industry but rather than recommending that fish farms eliminate the use of illegal veterinary medicines and chemicals, instead recommends that the farms seek less discriminating export markets and keep the residues of these illegal chemicals

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States — Continued Suspension of Obligations in the EC-Hormones Dispute. World Trade Organization. WT/DS320. June 30, 2006 at 50.

<sup>89</sup> Food & Water Watch. "Corporate Control in Animal Science Research." April 2015.

<sup>90</sup> "U.S. beef production in disarray after Zilmax sales halted." *Food Chemical News*. August 23, 2013.

<sup>91</sup> 21 CFR § 530.41; FDA. Center for Food Safety and Applied Nutrition (CFSAN). "Fish and Fishery Products Hazards and Controls Guidance." Fourth Edition. April 2011 at 188.

<sup>92</sup> Government Accountability Office. "Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources." GAO-11-286. April 2011 at 1, 5 and 7.

<sup>93</sup> *Ibid.* at 7.

<sup>94</sup> Rico, Andreu et al. "Use of veterinary medicines, feed additives and probiotics in four major internationally traded aquaculture species farmed in Asia." *Aquaculture*. Vol. 412-413. 2013 at 234.

<sup>95</sup> Consumer Reports. "Shrimp Report." April 2015 at 35 to 36.

<sup>96</sup> *Ibid.* at 45.

within limits.<sup>97</sup> In 2008, FDA inspectors in Vietnam found widespread use of these banned antibiotics and asked government officials to test all seafood bound for the United States, but the officials refused and instead planned to offer training materials and additional enforcement against violators.<sup>98</sup> In late 2015, the Vietnamese Minister of Agriculture and Rural Development suggested its catfish exports would follow U.S. standards if they conform to international standards and if they are based on scientific evidence, all areas ripe for SPS dispute.<sup>99</sup>

Currently, the FDA has an Import Alert that orders all shipments from 13 Vietnamese seafood exporters to be seized without physical examination for the illegal use of the fluoroquinolone enrofloxacin for violations dating back to 2009.<sup>100</sup> FDA banned the use of fluoroquinolones in fish and other food animals “based on evidence” that widespread use “would promote the evolution of drug-resistant pathogens” and consumers could be exposed to this risk on their food because the drug-resistant bacteria would remain on the fish when they were processed.<sup>101</sup> People who develop antibiotic resistant infections are sick longer and have greater risks of hospitalization and death.<sup>102</sup>

Vietnam could challenge the FDA’s ban on fluoroquinolones under the TPP SPS provisions — and it would stand a good chance of prevailing. First, the FDA standard is higher than the presumptively trade legal international standard. Codex has no recommended maximum residue limit or “no safe level” determination for four veterinary drugs prohibited by the FDA for use in aquacultured fish and seafood — including fluroquinolones, clenbuterol, diethylstilbestrol, and glycopeptides.<sup>103</sup> Since the FDA’s level of protection is higher than the non-existent Codex standard, Vietnam could challenge the underlying scientific justification for FDA’s ban on fluoroquinolones.

Second, despite the FDA’s contention that its prohibition is “based on evidence,” the livestock and meat industry vehemently disputes the scientific link between antibiotic use in food animals and antibiotic-resistant bacteria and antibiotic-resistant infections.<sup>104</sup> A 2015 study by the agribusiness-friendly USDA reported, “at present, the extent to which antibiotic use in livestock production contributes to human health problems is unknown.”<sup>105</sup> Vietnam could dispute the causal links

<sup>97</sup> “Vietnamese exporters should limit antibiotic residues in seafood, find new markets: Association.” *Tuoi Tre News* (Vietnam). April 26, 2015.

<sup>98</sup> GAO (2011) at 15.

<sup>99</sup> “Vietnam strives to ensure smooth export of tra, basa fish.” *Vietnam News Agency*. December 8 2015.

<sup>100</sup> FDA. “Detention without physical examination of aquaculture seafood products due to unapproved drugs.” Import Alert 16-124. November 16, 2015.

<sup>101</sup> FDA. “Enhanced Aquaculture and Seafood Inspection — Report to Congress.” November 20, 2008.

<sup>102</sup> United Nations. Food and Agriculture Organization, World Health Organization and World Organization for Animal Health. “Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment.” Geneva. December 1 to 5, 2003 at 15.

<sup>103</sup> FDA CFSAN. “Fish and Fishery Products Hazards and Controls Guidance.” Fourth Edition. April 2011 at 188; Codex Alimentarius. “Maximum residue limits (MRLs) and risk management recommendations (RMRs) for residues of veterinary drugs in foods.” CAC/MRL 2-2015. Updated as of the 38<sup>th</sup> Session of the Codex Alimentarius Commission. July 2015 at 39 to 40. Codex has a maximum residue limit for tetracyclines in fish and giant prawns (200 µg/kg at 8) and the antiparasitic emamectin benzoate in salmon and trout (100 µg/kg at 18). For three of the drugs on FDA’s red list, Codex has determined there is “no safe level of residues” (chloramphenicol, dimetridazole/ipronidazole and furazolidone/nitrofurazone) and recommends that these drugs not be used in food producing animals.

<sup>104</sup> See National Institute for Animal Agriculture. “Antibiotic use in food animals.” 2011. White paper synthesized from symposium “Antibiotic use in food animals: A dialogue for a common purpose.” Chicago. October 26-27, 2011.

<sup>105</sup> Sneeringer, Stacy et al. USDA Economic Research Service. “Economics of Antibiotic Use in U.S. Livestock Production.” November 2015 at 5.

between antibiotic use in aquaculture, the rise of antibiotic-resistant bacteria in the environment and antibiotic-resistant infections and there would be ample agriculture industry-funded expertise to critique the FDA science, risk assessments and risk management plans.

Third, the FDA's prohibition on seafood with residues of the prohibited drugs is not the least trade restrictive approach. The TPP reemphasizes the WTO prohibition on policies that are more trade restrictive than necessary to meet the goal of the food safety measure. Additionally, the TPP requires the FDA to consider risk management alternatives to a complete ban, even including having no standard at all in order to facilitate trade. These directives essentially require the FDA to prove that the fluoroquinolone ban is a superior policy to all other less trade restrictive alternatives. But adopting a risk management strategy for antibiotic use in farmed fish is to essentially permit the use of a drug that the FDA believes is too dangerous to human health to allow even at low levels. If Vietnam were to bring a TPP SPS challenge against the FDA ban on fluoroquinolones, it would likely prevail and it would be more likely to succeed under the TPP SPS rules than under the WTO rules.

#### **IV. TPP reinforces flawed equivalency model of “close enough” to U.S. standards, locks in global food safety race-to-the-bottom**

Trade agreements press countries to accept the food safety standards and systems of exporters as comparable or good enough to facilitate more trade, even when they are potentially weaker than those of the importing country. The WTO introduced this notion of “equivalence” that directed countries to accept foreign food safety policies as close enough to domestic standards. The WTO SPS text says countries “shall accept” foreign food safety measures as equivalent, even when they are different, if the food safety system achieves the importer’s “appropriate level of sanitary or phytosanitary protection.”<sup>106</sup> In essence, importers are expected to accept foreign safety policies as equivalent if they are close enough to domestic rules even if they do not have the same structures, protocols or systems and thus encourage food imports from the equivalent exporter with less oversight of the imports than from non-equivalent systems.

But the rush to approve foreign food safety systems as equivalent to accelerate food imports from potentially less protective food safety regimes could pose risks for consumers. Unless the food safety systems of these exporting countries actually meet U.S. standards, these free trade agreements are putting U.S. consumers in jeopardy and placing severe strains on our import inspection system.

The corporate-trade driven equivalency exposes consumers to unnecessary food safety risks and locks in food safety deregulation that will be difficult if not impossible to reverse. The USDA already has a process for approving equivalence of foreign inspection systems for meat, poultry and egg imports and the FDA is developing a process for all other foods that is akin to USDA's equivalency determinations. But the USDA process is often overly generous and awards equivalency for meat inspection systems even when the audits find considerable food safety lapses or concerns. Congressional efforts to provide necessary review and oversight to this process have

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<sup>106</sup> WTO SPS Art. 4 at para. 1.

been successfully challenged at the WTO and the tougher equivalency language in the TPP will make it even harder for Congress to intervene in misguided equivalency determinations.

Moreover, the equivalency process has effectively become a one-way ratchet downwards for food safety oversight, as the United States' shift towards company-inspected, privatized food safety oversight has become a model for other countries that have been granted equivalency to export to the United States. The USDA has already found more food safety violations on some of these privately inspected imports than under the prior government-inspected regime.

The TPP also contains language that encourages the use of private, third party certifications to attest to the safety of imported food. Private certifiers have a financial incentive to certify safety even when there are food safety problems — firms with outstanding food safety certifications have been the cause of recent significant foodborne illness outbreaks from peanuts, cantaloupes and eggs. The United States is expanding the misguided reliance on third party certifications and the TPP equivalency rules will lock this privatized system in place.

Ultimately, the equivalency process is intended to essentially offshore U.S. food safety oversight to foreign food safety systems. The USDA does not allow meat, poultry or egg imports from countries without equivalency determination and provides less border inspection to nations with more favorable equivalency ratings.<sup>107</sup> The FDA granted “systems recognition” to New Zealand in 2013, which reduces the level of FDA border inspection for food from New Zealand and lowers the number of FDA inspections of New Zealand food establishments.<sup>108</sup> In theory, border re-inspections could be eliminated entirely, but a pilot program to allow Canadian meat products to enter the United States without any re-inspection had to be cancelled in 2015 due to considerable food safety problems with Canada's exports.

#### A. *TPP equivalency provisions more aggressive than the WTO*

Countries are expected to develop protocols to determine the equivalency of foreign food safety policies, evaluate the equivalency of foreign food safety programs and award equivalency status to exporters. The equivalency directives in the TPP and WTO are designed to bring food safety standards and systems into convergence to maximize global food trade.<sup>109</sup> The TPP equivalency language expands on the WTO directive to accept potentially less health-protective food safety systems as good enough to satisfy U.S. food safety standards.

The WTO SPS requires countries to “accept [SPS] measures as equivalent” but the TPP text says importers “shall recognize the equivalence” of policies that provide “the same level of protection” (the same as the WTO) or “the same effect in achieving the objective.”<sup>110</sup> This language effectively requires countries to establish procedures to award equivalency status not just to policies that are different but achieve similar levels of protection but also to policies that do not

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<sup>107</sup> USDA only accepts meat, poultry and egg products from countries that receive an audit grade of “adequate,” “average,” or “well performing” and subjects countries with “adequate” ratings to more scrutiny than the higher audit scores. Salvage, Bryan.

“Canada's food safety system gets low marks.” *Meat & Poultry*. January 9, 2014.

<sup>108</sup> Clapp, Stephen. “FDA actively looking for ‘systems recognition’ with more countries.” *Food Chemical News*. February 15, 2013.

<sup>109</sup> Winickoff and Bushey (2010) at 359.

<sup>110</sup> TPP SPS Art. 7.8 at para. 6, 6(a-b).

ensure the same level of protection but purportedly have the same effect.<sup>111</sup> In practice, this could mean that the United States would be required to accept a food system that did not have a zero tolerance standard for fecal matter on meat and poultry products but purportedly could achieve the same result, which would provide a lower level of protection for consumers.

The TPP is more proscriptive than the WTO in forcing countries to promptly accept not only individual food safety policies (for example, a standard for processed meat) but classes or systems of food safety programs (for example, all meat and poultry food safety measures).<sup>112</sup> It also requires countries to consider the “available knowledge, information and relevant experience, as well as the regulatory competence” of the foreign governments.<sup>113</sup> These provisions could mean that the United States would have to assess foreign food safety systems more leniently to account for weaker oversight systems.

*B. TPP could lock in weak USDA equivalency determinations, resisting or reversing equivalency could be ruled a trade barrier*

The TPP could weaken the USDA equivalency determination process, which could enable weaker food safety regimes to export meat, poultry and processed egg products to the United States. The USDA equivalence process evaluates the food safety policies and oversight provided by the potential exporting country and certifies specific plants to export regulated meat, poultry and egg products to the United States.

Currently, only 40 countries are approved to export meat, poultry or processed eggs to the United States, although it is not uncommon for USDA border inspectors to stop shipments from countries or establishments that are not approved to export meat or poultry to the United States.<sup>114</sup> The USDA’s equivalency procedure too often is based on flawed procedures and inadequate or dated audits that can allow considerably weaker foreign food safety measures to export meat and poultry products to the United States.

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<sup>111</sup> The TPP specifically exempts the “same effect in achieving the objective” language from dispute settlement at footnote 2 at Art. 7.8 para. 6(b). The drafters of trade agreements rarely exempt language *entirely* from dispute settlement. Although a country could not bring a dispute against that specific paragraph (for a country failing to accept imports from a system that has the same effect as a domestic standard), it may be possible for the paragraph to be brought into a dispute that was lodged against another provision by contending the language modified or provided definitions to other SPS paragraphs. For example, if a country challenged the United States for failing to determine or grant equivalence promptly (under Art. 7.8 at para. 5) stating that countries are required to take available knowledge, information, experience or regulatory competency into account when determining equivalence, it could mean generally that importers should be lenient in assessing equivalence given the capacity of the exporting countries food safety regime. But if a disputant could contend that the para. 6(b) language of having the “same effect in achieving the objective” modified or provided clarity in considering how to take Art. 7.8 para. 5 into account, then weaker measures that had the purported same effect would demonstrate that the capacity of the exporter was sufficient to grant equivalency. This would somewhat mitigate the power of the footnote to exempt the paragraph from dispute. Moreover, the TPP Institutional Arrangements demonstrate that the TPP is a living agreement that will continue to be negotiated (Art. 27.2 at para. 1(b-c)), meaning that the footnote on this paragraph could be removed in subsequent negotiations.

<sup>112</sup> TPP SPS Art. 7.8 at paras. 1 to 2.

<sup>113</sup> TPP SPS Art. 7.8 at para. 5.

<sup>114</sup> USDA FSIS. “Countries/Products Eligible for Export to the United States.” November 15, 2015. The USDA lists Wales, Scotland and Northern Ireland separately, so there are really only 40 nations eligible to export meat although the USDA lists 43; USDA FSIS. [Press release]. “Victory Kitchens Ltd. recalls products containing chicken from an ineligible country.” May 1, 2015; USDA FSIS. [Press release]. “Boa Vida Imports recalls pork and beef products imported from an ineligible country without benefit of import inspection.” March 20, 2015; USDA FSIS. [Press release]. “Greenland Trading Corp. recalls squab products produced without benefit of import inspection.” June 30, 2015

Some equivalency determinations seem motivated in part by international trade politics that may compromise the robustness of the equivalency review and approval process. As the United States is negotiating a trade deal with the European Union, the USDA re-authorized Ireland to export beef to the United States after a long-standing prohibition because of mad cow disease concerns, approved Lithuanian red meat exports and announced the intention to grant equivalency to Poland's poultry inspection system.<sup>115</sup> The equivalency audit for Lithuania failed to include assessments of the approved meatpacking plants, did not adequately address its' less-restrictive import oversight of adjoining countries with known livestock diseases including foot and mouth disease and recognized that it needed improved verification for compliance with zero tolerance requirements for fecal matter, ingesta (stomach contents) and milk on carcasses and meat.<sup>116</sup>

Similarly, the USDA approved a partial equivalency determination for Namibia as the Africa Growth and Opportunity Act was reauthorized despite the fact that the two audits previous to awarding equivalence found significant food safety deficiencies. Namibia had a recent outbreak of foot and mouth disease and the approval specifically disallows ground meat imports, suggesting the USDA is not entirely comfortable with extending equivalency for all red meat products.<sup>117</sup> The USDA also approved privatized meat inspection programs in Canada, Australia and New Zealand despite the fact that company self-inspection creates a conflict of interest that can compromise food safety and is not the standard for most meat inspection in the United States.

The TPP equivalency requirements will make it harder to strengthen the USDA equivalency determination process and make it potentially more difficult for the USDA to reject applications for equivalency from TPP members. Currently the USDA is evaluating the equivalency application from TPP members Singapore, Peru, Mexico (for poultry and eggs) and Australia (eggs) as well as for countries that have expressed interest in joining the TPP including Korea (poultry), the Philippines and Thailand.<sup>118</sup> The stronger TPP disciplines for equivalency (and science and risk) direct USDA to promptly review and approve equivalency requests unless there is overwhelming scientific evidence that the imports pose significant human health impacts. Foreign governments could bring trade disputes against the United States for the failure to act on requests to expeditiously make equivalency determinations or the refusal to grant equivalency status. The United States has already lost WTO disputes over equivalency and would be more vulnerable to challenge under the stronger TPP equivalency rules.

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<sup>115</sup> USDA FSIS. "FSIS finds Ireland beef process equivalent to the U.S." *FSIS Constituent Update*. Vol. 18, No. 13. January 9, 2015; 80 Fed. Reg. 52375-52379; USDA FSIS. "FSIS publishes final audit report for Poland poultry inspection system equivalence." *FSIS Constituent Update*. Vol. 18, No. 48. September 18, 2015.

<sup>116</sup> USDA FSIS. "Final Report of an Initial Equivalence Follow-up Audit Conducted in Lithuania." September 16-24, 2013 at 3, 9 and 13.

<sup>117</sup> Hauter, Wenonah. Food & Water Watch. Letter to Agriculture Secretary Tom Vilsack. November 16, 2015; "Namibia: Foot-and-mouth disease poses threat of 'national disaster.'" *New Era* (Namibia). May 26, 2015.

<sup>118</sup> USDA FSIS. Status of Initial Equivalence. Available at <http://www.fsis.usda.gov/wps/portal/ffsis/topics/international-affairs/importing-products/equivalence/status-of-initial-equivalence>. Accessed December 2015; "Takenaka, Kiyoshi. "Thailand says 'highly likely' it will seek TPP membership." *Reuters*. November 27, 2015; Satake, Minoru. "Philippines moves closer to decision on Pacific Rim pact." *Nikkei*. November 12, 2015.

### C. Congressional oversight of equivalency process ruled illegal trade barrier: United States could be forced to accept flawed equivalency judgments

The United States has already lost two equivalency cases at the WTO. China prevailed against the United States after Congress stalled the approval of cooked chicken imports from China and Argentina won a case over the USDA's refusal to grant equivalency because of concerns over frequent food and mouth disease outbreaks. These WTO rulings make it more difficult for Congress to exercise its necessary oversight role to ensure USDA only awards equivalency to countries that do not pose a food safety, disease or pest risk, especially in light of the department's weakness in approving both foreign privatized inspection systems and other approvals of questionable meat inspection programs.

In 2006, USDA granted equivalence to the Peoples Republic of China to export poultry products to the United States processed exclusively from poultry from countries eligible to export to the United States (primarily processing U.S.-raised and slaughtered chickens for re-export to the United States). The equivalency determination appeared to be based in part on commercial and political considerations, rather than the result of an assessment of China's food safety protocols. USDA documents revealed that the approval was in part swapped for China's willingness to re-admit U.S. beef exports after the discovery of mad cow disease led China to stop imports of U.S. beef.<sup>119</sup> USDA appeared to bow to political pressure to rush the approval.<sup>120</sup> The approval was based on a single audit from 2004 that found that a majority of the visited Chinese processing plants had serious problems.<sup>121</sup>

Congress blocked USDA from implementing the equivalency for several years. China successfully challenged the failure to implement the flawed equivalency determination at the WTO because the failure to implement equivalency was determined to be unscientific and discriminatory.<sup>122</sup> China applied no tariffs because by 2010 the USDA had already re-initiated the equivalency process for certain chicken processed in China, which was finalized in 2013.<sup>123</sup>

A similar situation is occurring with USDA's attempt to approve imports of fresh beef from regions of Argentina and Brazil that are purportedly free of foot and mouth disease (FMD), although the disease is not controlled throughout the country.<sup>124</sup> The United States has not had an outbreak of the highly communicable livestock disease since 1929 and the USDA estimates a future outbreak could cost the livestock industry between \$15 and \$100 billion.<sup>125</sup>

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<sup>119</sup> Food & Water Watch. "Citizen Petition for Rulemaking to Remove the Peoples Republic of China as Being Eligible to Export Poultry Products to the United States Under 9 CFR 381.196(b)." January 19, 2011 at 4 to 6.

<sup>120</sup> *Ibid.* at 6 to 10.

<sup>121</sup> USDA FSIS. Final Report of an Initial Equivalence Audit Carried Out in China Covering China's Poultry Inspection System: December 1 through 17, 2004. May 17, 2005.

<sup>122</sup> Lynn, Jonathan. "UPDATE 2—WTO raps U.S. ban on Chinese chicken imports." *Reuters*. September 29, 2010.

<sup>123</sup> Healy, Amber. "China moving closer to poultry equivalency." *Food Chemical News*. October 14, 2011; Wingfield, Brian and Shruit Date Singh. "Chicken processed in China triggers U.S. food safety protests." *Bloomberg News*. September 26, 2013.

<sup>124</sup> USDA. Animal and Plant Health Inspection Service (APHIS). [Press release]. "APHIS to allow the importation of fresh beef from Northern Argentina and 14 states in Brazil." June 29, 2015.

<sup>125</sup> Clayton, Chris. "Argentina and Brazil beef imports approved despite FMD risks." *Progressive Farmer*. June 29, 2015.

The United States has had a ban on fresh beef from Argentina since the country experienced an FMD outbreak in 2001 and despite several resurgences of the disease. In 2011 the World Organization for Animal Health (OIE) has determined that Northern Argentina is recognized as being FMD-free where vaccination is practiced.<sup>126</sup> Argentina brought a WTO case against the United States for its refusal to recognize some regions as FMD-free under international standards, its lack of scientific justification for continuing the ban, its delay in approving equivalency status and that the ban on imports was not least trade restrictive.<sup>127</sup> The WTO ruled against the United States on all of these counts.<sup>128</sup>

A broad range of cattle, farm and consumer groups oppose the approval of fresh beef equivalency for these regions of Brazil and Argentina.<sup>129</sup> In 2015, the House Agricultural Appropriations bill for fiscal year 2016 directed USDA to perform additional risk assessments and site visits to these regions.<sup>130</sup> But the recent WTO case and the TPP language make it more difficult for Congress to provide the necessary oversight to USDA equivalency determinations. These kinds of cases would be easier to bring under the TPP, which has specific provisions on regionalization and directs importers to identify and recognize disease- or pest-free regions and areas of low-prevalence, in part based on information from the exporting country.<sup>131</sup>

*D. Ultimate goal of equivalence is to offshore U.S. inspection to foreign governments, but pilot program demonstrates perils of offshoring food safety responsibilities*

Imports from equivalent foreign food safety regimes are expected to receive less intense border inspection scrutiny, and perhaps, ultimately, no scrutiny at all. The end goal of equivalency appears to be a system where importers trust the food safety oversight of the exporting countries enough that there is no border re-inspection. In effect, this would offshore U.S. food safety oversight responsibility to foreign governments. The lack of border inspection would speed the flow of goods across borders and benefit the exporting and importing companies but pose potential risks to consumers from uninspected imported foods.

The first significant attempt to totally offshore food safety responsibility has been a troubled pilot program between the United States and Canada known as “Beyond the Border” (BtB) that demonstrates the hazards of offshoring food safety oversight. Launched in 2011, the BtB pilot program was intended to allow selected Canadian plants to export meat to certain U.S. processing plants through an “expedited clearance process,” but the plan was intended to expand to all Canadian meat plants and lower the border inspection rates for other foods rapidly.<sup>132</sup>

<sup>126</sup> International Centre for Trade and Sustainable Development. “WTO panel grants victory to Argentina in beef dispute with US.” *Bridges*. Vol. 19, No. 28. July 30, 2015.

<sup>127</sup> World Trade Organization. United States—Measures Affecting the Importation of Animals, Meat and Other Animal Products from Argentina. Report of the Panel. WT/DS447/R. July 24, 2015 at 37 to 44.

<sup>128</sup> *Ibid.* at 223 to 225.

<sup>129</sup> Clayton (2015).

<sup>130</sup> U.S. House of Representatives. H.R. 3049 §749. Making appropriations for Agriculture, Rural Development, Food and Drug Administration and Related Agencies for fiscal year ending September 30, 2016. 114<sup>th</sup> Congress. Report. No. 114-205. July 14, 2015.

<sup>131</sup> TPP SPS. Art. 7.7 at paras. 4 to 10.

<sup>132</sup> The White House. “United States-Canada Beyond the Border: A Shared Vision for Perimeter Security and Economic Competitiveness—Action Plan.” December 2011 at 12.

The plan would have allowed the chosen Canadian plants to be “cleared to continue to their destination” without border inspection.<sup>133</sup> One of the Canadian pilot plants had received a scathing USDA audit in 2009 that found poor sanitation, poor food handling practices and deficient food safety enforcement by Canadian inspectors.<sup>134</sup>

The pilot ran into trouble almost immediately when a Canadian meatpacker exported 2.5 million pounds of *E.coli* tainted beef to the United States in 2012.<sup>135</sup> The USDA downgraded its assessment of Canada’s food safety system in 2013, warning that Canada might become ineligible to export meat at all, let alone with minimal import inspection.<sup>136</sup> Although the USDA initially intended to continue to finalize the preclearance inspection-free pilot despite the many food safety problems in Canada, by 2015 the pilot was finally scrubbed because of “policy challenges and several logistical impediments.”<sup>137</sup>

The reality is that U.S. border inspection works well and regularly prevents the entry of unsafe food products into the United States — including many tainted meat shipments from Canada over the past few years. The Beyond the Border program demonstrates that the goal of equivalency is to eliminate all border inspection but that even with a partner like Canada, eliminating border oversight poses an unacceptable risk for consumers.

#### *E. Equivalency has justified a cascade effect of food safety deregulation, privatization*

Global food safety equivalency not only promotes the trade in food that may not meet U.S. standards, it has been the primary vehicle to spread the food industry backed deregulation and weakening of food safety oversight. In the 1990s, the equivalency regime of the WTO helped to foster a global policy shift towards oversight that focused on the paperwork used for food safety plans rather than continuous inspection of the slaughter process. In the past decade, there has been a shift from independent, government inspection to private, company inspectors performing food safety oversight. The move to privatized inspection represents a significant rollback of U.S. food safety standards and potentially exposes consumers to more foodborne hazards. Now, equivalency dictates are spreading privatized meat inspection as a replacement for independent, government inspection worldwide. As the United States adopts privatized inspection and recognizes other countries’ privatized inspection systems, the equivalency dictates of the TPP will make it difficult or impossible to return to independent, government inspection.

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<sup>133</sup> Shipments would be generally unimpeded by border inspection but might be subject to pre-assigned sampling and/or physical examination at the final destination. United States Embassy. Ottawa, Canada. [Press release]. “USDA, CFIA announce preclearance pilot project.” July 16, 2012.

<sup>134</sup> USDA FSIS. Foreign Establishment Audit Checklist: Maple Leaf Consumer Foods Inc. September 24, 2009.

<sup>135</sup> USDA FSIS. “FSIS expands public health alert for imported Canadian beef from XL Foods.” September 28, 2012, updated October 5, 2012.

<sup>136</sup> Healy, Amber. “Questions arise about Canadian equivalency in FSIS audit report.” *Food Chemical News*. January 17, 2014; Binkley, Alex. “USDA report card on CFIA — OK but should try harder.” *Alberta Farm Express*. January 17, 2014.

<sup>137</sup> Clapp, Stephen. “FSIS plans to implement Beyond the Border despite opposition.” *Food Chemical News*. June 17, 2014; Murphy, Joan. “Beyond the Border preclearance meat pilot dies in light of ‘policy challenges.’” *Food Chemical News*. May 22, 2015.

**U.S. push to privatize meat and poultry inspection exposes consumers to unsafe food:** In 1998, the United States launched an industry-backed pilot program that allowed two-dozen poultry (chicken and turkey) and six hog slaughter plants to replace government safety inspectors with company staff to perform key safety oversight. At the same time, poultry companies were allowed to increase the line speed at the plants upwards of 200 birds per minute for chickens, compared to conventional government inspected plants that typically run at 115 birds per minute.<sup>138</sup>

The pilot program cut the number of government inspectors in half and increased the line speed by 20 percent.<sup>139</sup> Employees examined birds for fecal matter, ingesta (stomach contents) and other blemishes while government inspectors focused on the plant's safety plans and oversaw bacteriological testing at the end of the process.<sup>140</sup> Government inspectors were removed from the slaughter lines so they were unable to spot and remove diseased and contaminated birds.<sup>141</sup> A 2013 USDA Inspector General review of a similar program at hog plants observed, "We question whether [the reliance on testing] is a better measure for food safety because some signs of disease and contamination can be detected only through manual inspection."<sup>142</sup>

The USDA failed to assess the performance of the poultry pilot program and data from the end-of-line inspectors demonstrated that the program failed to meet USDA standards or protect consumers from known hazards. Company employees may have been missing substantial defects on the poultry carcasses. Two-thirds thirds of the company inspected birds that USDA checked had feathers, lungs, oil glands, trachea and bile on the carcass and the overwhelming number of non-compliance records was for fecal contamination on the carcasses.<sup>143</sup> The USDA had "not thoroughly evaluated the performance" of the privatized inspection projects even after fifteen years of the pilot's operation, according to the Government Accountability Office.<sup>144</sup> GAO concluded that USDA "could not determine whether an inspection system based on the pilot project would ensure equivalent, if not better, levels of food safety and quality than currently provided."<sup>145</sup>

Three of the plants in the hog pilot program were among the ten worst food safety violators for problems such as allowing fecal matter on meat, according to a study by the USDA Inspector General.<sup>146</sup> Although the company inspectors were supposed to be providing quality control, the company inspectors allowed carcasses with tuberculosis lesions, septic injuries and fecal smears to remain on the line.<sup>147</sup> Some of the pilot plants had hundreds of violations and repeat violations that would have resulted in a written warning or plant shutdown in government inspected plants.<sup>148</sup>

<sup>138</sup> USDA. FSIS. "Evaluation of HACCP Inspection Models Project (HIMP)." August 2011 at 8 and 11.

<sup>139</sup> Kindy, Kimberly. "USDA pilot program fails to stop contaminated meat." *Washington Post*. September 8, 2013.

<sup>140</sup> Nixon, Ron. "Changes to poultry rules are flawed, report says." *New York Times*. September 9, 2013.

<sup>141</sup> *Ibid.*

<sup>142</sup> Genoways, Ted. "The truth about pork and how America feeds itself." *Bloomberg News*. December 5, 2013.

<sup>143</sup> USDA FSIS. Data from HIMP Form 1. March 1 through August 31, 2011. Obtained by Food & Water Watch through Freedom of Information Act. Food & Water Watch.

<sup>144</sup> GAO. "Food Safety: More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections." GAO-13-775. August 2013 at 10.

<sup>145</sup> *Ibid.* at 13.

<sup>146</sup> Kindy (2013).

<sup>147</sup> Genoways (2013).

<sup>148</sup> *Ibid.*

The report also found that USDA failed to actually oversee the pilot's performance and "did not critically assess whether the new inspection process had measurably improved food safety" at the pilot plants.<sup>149</sup> The Inspector General concluded that the privatized hog inspection program "revealed a systemic failure and not a sporadic problem, including recurring zero-tolerance violations."<sup>150</sup>

Although the privatized inspection pilots had significant problems, the USDA moved forward with the model — even expanding it to the entire industry for poultry. The USDA did not abandon or even revisit the hog pilot program; instead it dismissed the Inspector General's concerns and continued the program.<sup>151</sup> In 2014, USDA expanded the privatized poultry inspection pilot to the entire poultry industry with a maximum line speed of 140 birds per minute for chickens (although the original chicken pilot plants could run at the pilot speed of 175 birds per minute and up to 55 birds per minute for turkeys, the old cap was 51), meaning the USDA inspector at the end of the line would examine more than two chickens a second to look for food safety defects.<sup>152</sup> The USDA is purportedly also interested in expanding the hog privatized inspection system nationwide.

***Privatized inspection pilot adopted by exporters, certified equivalent, ships unsafe meats to U.S. consumers:*** The USDA's flawed pilot privatized inspection system has been used as the basis for other countries to be deemed equivalent to export meat under their own privatized inspection systems, including Canada, Australia and New Zealand.<sup>153</sup> The USDA could approve these deregulated systems because they purportedly provide a comparable level of inspection to the USDA privatized pilot inspection programs. In 2014, TPP member Chile considered developing a private poultry inspection system in line with the privatized inspection system being implemented in the United States.<sup>154</sup> New Zealand government inspectors have contended that their private inspection plants are sometimes producing contaminated meat because of high line speeds and inadequate oversight by company inspectors.<sup>155</sup> The equivalent, privatized inspection systems in Canada and Australia have already been exporting unsafe meat to the United States. The primary reason more of this tainted meat has not entered the United States is the more robust inspection process at the USDA, but that might be challenged as well under the TPP.

***Equivalent Canadian privatized system sends 2.5 million pounds of E.coli tainted beef:*** In 2006, the USDA awarded Canada's privatized beef inspection program equivalence based on USDA's privatized hog inspection pilot program.<sup>156</sup> One of the equivalent privatized inspection plants, the XL Foods plant in Brooks, Alberta, had problems right from the start. A 2009 USDA audit of the

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<sup>149</sup> Gabbett, Rita Jane. "OIG report says FSIS does not deter swine slaughter plants from repeat violations." *MeatingPlace*. May 17, 2013.

<sup>150</sup> Genoways (2013).

<sup>151</sup> Clapp, Stephen. "USDA gives green light to continuing HIMP hog slaughterhouses." *Food Chemical News*. November 18, 2014.

<sup>152</sup> USDA FSIS. Modernization of Poultry Slaughter Inspection. 79 Fed. Reg. 49566-49637.

<sup>153</sup> Kindy (2013).

<sup>154</sup> "Chile aims to modernize poultry slaughter inspection." *World Poultry*. November 28, 2014.

<sup>155</sup> Kindy (2013).

<sup>156</sup> *Ibid.*

XL plant found that it had poor sanitation and recordkeeping and the few assigned Canadian government inspectors failed to cite the plant for food safety and sanitation violations.<sup>157</sup>

U.S. border inspectors found the biggest food safety failure. In 2012, USDA recalled 2.4 million pounds of beef products tainted with *E.coli* imported from the XL plant — a food safety lapse that was detected by U.S. border inspectors who informed their Canadian counterparts who ultimately determined the beef was produced “under insanitary conditions” with an “unusually high frequency of positive” *E.coli* test results.<sup>158</sup> Canadian meat inspectors reported that they had been removed from monitoring the slaughter line to oversee paperwork and the company inspectors.<sup>159</sup> An independent review by Canadian officials found “a weak food safety culture” “unprepared to handle what turned out to be the largest recall in Canadian history.”<sup>160</sup>

The USDA downgraded its rating of the Canadian food safety system to “adequate” in 2013 partially as a result of the XL recall, the lowest audit rating eligible to export meat to the United States.<sup>161</sup> Despite the failures of the privatized inspection at the XL plant, when JBS bought the plant out of bankruptcy, the company continued to rely on self-inspection.<sup>162</sup> In 2014, another shipment of beef from the XL plant tested positive for *E.coli* in laboratory tests performed by U.S. border inspectors.<sup>163</sup>

*Private inspection in Australia delivers tainted meat:* In 1999, USDA approved an Australian pilot privatized beef inspection system based on the U.S. privatized poultry inspection pilot as equivalent and eligible to export beef to the United States.<sup>164</sup> The Australian program allowed company inspectors to perform many inspection steps and government inspectors provided a final examination but focused on verifying paperwork compliance.<sup>165</sup> In 2011, based on the performance at the single pilot plant, USDA re-affirmed and expanded the equivalence determination.<sup>166</sup> But a USDA audit of the pilot plant after the equivalency was expanded found that the company inspectors received financial bonuses in the form of profit sharing tied to the performance of the meatpacker, creating a conflict of interest with their food safety responsibilities.<sup>167</sup>

Problems emerged with Australia’s privatized inspection program right after it went into effect in 2012. The number of violations of the U.S. zero tolerance standard for fecal and other contaminants rose dramatically — all at plants operating under the new private inspection program.<sup>168</sup> Two Australian plants were removed from the list of establishments eligible to export

<sup>157</sup> USDA FSIS. Foreign Establishment Audit Checklist: Lakeside Packers, A Division of XL Foods. September 10-11, 2009.

<sup>158</sup> USDA FSIS. “FSIS expands public health alert for imported Canadian beef from XL Foods.” September 28, 2012, updated October 5, 2012.

<sup>159</sup> Kindy (2013).

<sup>160</sup> Lewis, Ronald John, Andre Corriveau and W. Ronald Osborne. Government of Canada. Independent Expert Advisory Panel. “Independent Review of XL Foods Inc. Beef Recall 2012.” May 2013.

<sup>161</sup> Healy (January 17, 2014).

<sup>162</sup> Stephenson, Amanda. “E.coli incidence rate down at Brooks plant: JBS.” *Calgary Herald*. July 19, 2013.

<sup>163</sup> Hauter, Wenonah. Food & Water Watch. Letter to Agriculture Secretary Tom Vilsack. October 27, 2014 at 1.

<sup>164</sup> USDA FSIS. Australia’s Meat Safety Enhancement Program: Notice of Equivalence Decision. 64 Fed. Reg. 20399-30303, June 7, 1999.

<sup>165</sup> “FSIS confirms Australia’s meat inspection system equivalence.” *Food Chemical News*. March 3, 2011.

<sup>166</sup> USDA FSIS. 76 Fed. Reg. 11752-11755. March 3, 2011.

<sup>167</sup> USDA FSIS. Foreign Establishment Audit Checklist: Nolan Meats Pty. Ltd. March 21, 2011.

<sup>168</sup> Kindy (2013).

to the United States in the first half of 2012, relisted and then delisted again.<sup>169</sup> In November 2012 alone, USDA border inspectors found five violations of U.S. zero tolerance on fecal and ingesta material standards.<sup>170</sup>

After only one year of the privatized inspection program, USDA labeled Australia “the worst performer of all exporting countries.”<sup>171</sup> A 2013 USDA equivalency audit awarded Australia’s privatized inspection system the lowest grade that still is eligible to export meat to the United States (adequate) and found that Australia’s system failed to control for zero tolerance violations and that “products shipped to the United States from Australian meat establishments continue to be involved in violations of United States food safety standards.”<sup>172</sup>

That year the European Union also blocked imports from Australia because its privatized meat inspection did not meet the EU food safety regulations and because of the inherent conflict of interest in having company employees inspect beef carcasses.<sup>173</sup> In 2015, Japan refused to accept beef from the Australian plants with private inspectors.<sup>174</sup> Despite the significant problems with Australia’s program of privatized inspection, it planned to expand the flawed model. In 2015, Australia announced it was considering elimination of the 250 remaining government inspectors at the exporting plants with private third-party inspectors — a move viewed with skepticism even by some meatpacking companies like JBS.<sup>175</sup>

***TPP locks in the trend towards the use of private certifications for food safety instead of government inspection:*** The TPP includes new language that encourages the use of private certifications of food safety assurances — either third party certifications or potentially even self-certification — that would meet the same food safety objectives. The TPP allows private “assurances” and “certificates” as well as other systems to meet food safety objectives, meaning that both certification processes but also other assurances could meet food safety goals.<sup>176</sup> The TPP further encourages members to “work cooperatively to develop model certificates,” implement electronic certification and utilize WTO and Codex standards to implement certification policies that recognize private, third-party assessments to attest to the safety of imported food.<sup>177</sup>

Together, these TPP provisions encourage a move towards using private, third-party or even self-certification as an alternative to independent, government inspection. In some respects, the TPP language codifies and reinforces some of the worst trends in U.S. domestic food safety governance — the shift away from inspection to private oversight — and expands it multilaterally.

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<sup>169</sup> Healy, Amber. “F&WW reiterates concerns about contaminated beef from Australia.” *Food Chemical News*. July 12, 2012.

<sup>170</sup> Dr. Jones, Ronald K. USDA FSIS. Office of International Affairs. Letter to Greg Read. Australian Quarantine and Inspection Service. December 12, 2012.

<sup>171</sup> Kindy (2013).

<sup>172</sup> USDA FSIS. “Australia: Final Audit Report.” September 9, 2014 at 2.

<sup>173</sup> Larsen, Linda. “EU rejects Australian privatized meat inspection system.” *Food Poisoning Bulletin*. November 8, 2013.

<sup>174</sup> Neales, Sue. “Export quality fears over meat inspection privatization.” *The Australian*. March 23, 2015.

<sup>175</sup> *Ibid.*

<sup>176</sup> TPP SPS. Art. 7.12 at para. 1.

<sup>177</sup> TPP SPS. Art. 7.12 at paras. 3, 6 and 7.

Third-party or self-certified food safety assurances are considerably weaker than independent, government oversight because of the conflict of interest that creates a financial incentive to certify the food as safe. Food companies typically pay for their own audits and may set audit standards, which creates an inherent conflict; at least one prominent food safety-certifying firm had food manufacturing clients on its board of directors.<sup>178</sup> The *Denver Post* reported “Many of the most notorious food-illness outbreaks in recent years were preceded by glowing private safety audits of the producers.”<sup>179</sup>

- ***Cantaloupe 2011:*** The 2011 *Listeria* cantaloupe outbreak, which sickened 146 people and led to 30 deaths and one miscarriage, came from a farm that received two successive “superior” ratings from its third-party certifier — it was one of the deadliest foodborne illness outbreaks in a quarter century.<sup>180</sup>
- ***Eggs 2010:*** A *Salmonella* outbreak sickening more than 1,900 people and causing a recall of 500 million eggs was traced to a company that received 7 “superior” private food safety certifications over three years. FDA inspectors subsequently found hen barns fouled with flies, maggots and rodents as well as towering manure piles.<sup>181</sup>
- ***Peanuts 2008:*** A company-paid auditor awarded Peanut Corporation of America a “superior” food safety certification, although the plants continued to ship tainted peanuts months after internal testing found *Salmonella*, causing an outbreak that sickened more than 22,000 and caused nine deaths.<sup>182</sup>

It is difficult to provide adequate oversight of private certification — especially in the global food chain. Food safety agencies must divert resources from direct food safety oversight to developing, monitoring and enforcing standards and training for the private entities that might perform the job of attesting to the safety of food. In 2011, the FDA reviewed a pilot third-party certification for imported shrimp and found that most of the certifiers were not using FDA standards as a basis for ensuring food safety protocols, 70 percent of the audits of processing plants were unable to identify food safety hazards or plant deficiencies and three-quarters of the auditors did not understand which veterinary medicines the FDA had approved or prohibited for shrimp farming.<sup>183</sup>

Today, both the USDA and the FDA are pursuing third-party certification policies for imported food to supplement government inspections and reduce the government oversight of imports. In 2014, the USDA established an electronic certification for imported meat, poultry and egg products to streamline import procedures.<sup>184</sup> The FDA has finalized a Foreign Supplier

<sup>178</sup> Moss and Martin (2009); Armour, Stephanie, John Lippert and Michael Smith. “Food sickens millions as industry-paid inspectors find it safe.” *Bloomberg News*. October 11, 2012.

<sup>179</sup> Booth and Brown (2011).

<sup>180</sup> Committee on Energy and Commerce. U.S. House of Representatives. Committee Staff Report on the Investigation of the Outbreak of *Listeria Monocytogenes* in Cantaloupe at Jenson Farms. January 10, 2012 at 1 to 4.

<sup>181</sup> Weise, Elizabeth. “Egg farm inspector linked to earlier salmonella outbreak.” *USA Today*. September 22, 2010; Neuman, William. “Egg farms violated safety rules.” *New York Times*. August 30, 2010; Armour, Lippert and Smith (2012).

<sup>182</sup> Moss and Martin (2009); Booth and Brown (2011).

<sup>183</sup> FDA CFSAN. “Assessment of the Third-Party Certification Pilot for Aquacultured Shrimp.” July 2011 at Phase 3.

<sup>184</sup> USDA FSIS. “Effective Date for Foreign Inspection Certificate Requirements.” 80 Fed. Reg. 129741.

Verification program that requires importers to provide food safety certifications for all FDA regulated foods except juice and seafood, in part holding the importers accountable for the safety of the imports but also reducing government inspection.<sup>185</sup> The FSV program was designed to further the WTO's equivalency requirements.<sup>186</sup> The FDA has also created a Voluntary Qualified Importer Program that allows certified importers to pay a fee to access expedited shipment entry into the United States.<sup>187</sup>

### ***TPP equivalency locks in the deregulatory trend, makes it difficult to rollback***

***deregulatory efforts:*** Domestic deregulation policies combined with the pressure to recognize equivalence and certification measures in the TPP establish a trend that replaces government inspection with a system where industry regulates itself. It will be difficult to reverse these private, third-party food safety verification schemes under the certification provisions of the TPP without risking a trade tribunal. Ultimately, this creates downwards pressure throughout the region to recognize and implement deregulatory food safety policies that weaken the oversight of food and expose consumers to foodborne hazards.

This cascade of deregulation mirrors the equivalency race-to-the-bottom effect on recognizing potentially weaker foreign food safety regulatory governance as comparable, or close enough to, U.S. food safety standards. The downward pressure on all food safety oversight is self-reinforcing: U.S. standards are weakened to meet foreign standards, which are turn are weakened to be a pale reflection of our weakened system, creating a cycle of food safety deregulation all over the world.

## **V. CONCLUSION**

The TPP threatens to undermine U.S. food safety standards, weaken the inspection of imported food and lock in deregulation of food safety oversight. Nations should be able to establish and implement food safety policies that provide the level of protection their citizens demand without interference from international trade tribunals. The TPP is significantly more aggressive than the language in previous trade deals governing import inspection, scientific justification and deregulatory equivalence.

The food safety language in the TPP essentially presumes that food safety measures that affect trade are effectively import barriers akin to tariffs. The TPP provide mores powerful avenues for the food and agribusiness industries to attack, weaken and eliminate food safety standards at foreign trade tribunals. American industry would aim at foreign food safety measures, but U.S. standards would be more vulnerable as well. A domestic food safety standard or law would be more likely to be successfully challenged in a TPP tribunal than under any other trade agreement.

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<sup>185</sup> FDA. "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals." 80 Fed. Reg. 74226 et seq.. November 27, 2015.

<sup>186</sup> *Ibid.* at 74262; Agriculture, Rural Development & FDA Subcommittee. Senate Appropriations Committee. Hearing on FDA Food Supply Safety Efforts. September 16, 2015.

<sup>187</sup> FDA Food Safety Modernization Act. Pub. L. No. 111-353. §302. January 4, 2011.