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### About IATP

Institute for Agriculture and Trade Policy works locally and globally at the intersection of policy and practice to ensure fair and sustainable food, farm and trade systems. IATP is headquartered in Minneapolis, Minnesota with an office in Washington D.C..

# The TPP SPS chapter: not a “model for the rest of the world”

## KEY FINDINGS

- “Trade in products of modern biotechnology” has been located in Chapter 2, “National Treatment and Access for Market Goods,” so that controversies over GMOs or synthetic biology would be judged based on criteria of market access rather than risk assessments of their safety for human health or the environment.
- Provisions establishing an SPS consultative committee led by trade officials will further weaken and possibly conflict with global standards setting bodies on food and plant safety.
- Weakness in the U.S. regulatory agencies to provide the “appropriate level of sanitary and phytosanitary protection” required in the Chapter will be exacerbated by the confidentiality requirements that already hobble U.S. scientific peer review of food and agricultural products.

## Overview

**MINNEAPOLIS, NOVEMBER 12, 2015** — Proponents of the Trans-Pacific Partnership (TPP) Agreement, and particularly the White House, have insisted that the TPP is a “high standards” agreement. The Sanitary and Phytosanitary (SPS) “measures” affecting food safety and animal and plant health of agricultural trade are part of these “high standards.” Indeed, the TPP and the Transatlantic Trade and Investment Partnership (TTIP) are characterized as a “model for the rest of the world” by U.S. Trade Representative Michael Froman.<sup>1</sup> Far beyond any changes in tariffs, the most important U.S. export in the TPP is the making and enforcement of rules by which all TPP members, and any other countries that wish to export to the United States, must abide.

If the U.S. regulatory system and its scientific underpinnings had not been captured by the regulated industries,<sup>2</sup> it might be credible to claim that repeating the mantra of “high standards” might help lead to improvements in public and environmental

health and worker safety. TPP proponent support for Congressional regulatory “reform” and lawsuits for “regulatory overreach”<sup>3</sup> indicates to us that what is being exported is a framework for regulatory capture that will be legitimated by reference to binding trade commitments and, in the case of the TPP SPS chapter, by “science.”

The TPP chapter on SPS measures is a mere 18 pages of the total 6,194.<sup>4</sup> Following the Obama administration’s November 5 release of the TPP text<sup>5</sup>, the U.S. Congress and the public have 90 calendar days to review the text before President Barack Obama can sign the TPP. Then the clock begins to tick on implementing legislation to accept or reject the 6,194 pages, perhaps as early as May 2016.<sup>6</sup> No amendments are allowed to U.S. trade agreements, according to the Trade Promotion Authority (TPA) that Congress granted to the Obama administration on June 29.<sup>7</sup>

What follows is a critical interpretation of parts of the SPS chapter in the context of how the U.S. regulatory structure operates. Like the confidential USTR-industry dialogue and the intergovernmental negotiations that produced the chapter, the text alone reveals very little about how governments will provide the “appropriate level of sanitary or phytosanitary protection” promised in the World Trade Organization SPS Agreement (Article 5.3). The TPP chapter promises to “build upon and reinforce” (Article 7.2b) that Agreement and the thousands of pages of SPS texts and numerical standards of international organizations referenced in the appendices to the WTO SPS Agreement. But textual explication alone reveals nothing of the capacity of U.S. regulatory agencies to implement and enforce the text to protect public, animal, plant and environmental health and life, per their obligations under U.S. law.

In addition, the negotiators decided to locate provisions on “Trade in Products of Modern Biotechnology” for agricultural trade (Article 2.29) in Chapter 2, “National Treatment and Market Access for Goods,” apparently believing that “modern biotechnology” does not pose SPS issues about which there might be controversy. Since the text neglects to reference the relationship of Article 2.29 to the SPS chapter, we are obliged to explain the reference in this short analysis.

## **The “economic feasibility” of protecting consumers and plant and animal health and life**

Although the *Washington Post* has made the TPP keyword searchable<sup>8</sup>, there are almost no controversial SPS issues in the chapter—or anywhere else in the agreement—that a keyword search reveals. *Growth hormones, food and agricultural nanotechnology, endocrine disrupting chemicals, antimicrobial resistance to anti-biotics, plant synthetic biology* and so many others. Nothing about them—among other controversial food safety, and animal, plant and environmental health issues or technologies—appears in the SPS chapter. Instead, the chapter describes administrative procedures and consultative arrangements for resolving SPS “issues” insofar as they might impede agricultural trade. “Science,” or “scientific principles” or “science-based” rules (Article 7.9), provided they are “economically feasible,” are to transcend any one controversy over any one food or agricultural technology or over any one SPS rule.

However, it is crucial to understand how scientific evidence is subordinated and occulted as Confidential Business Information to realizing trade objectives through the regulatory process. Under the TPP rules and trade policy more generally, what trade and regulatory officials deem to be “appropriate” levels of protection are judged on whether SPS measures to provide that protection are potential or “disguised” trade barriers. Such judgments require a use and understanding of “science” that is filtered through confidentiality requirements, which are antithetical to the peer review that scientific consensus methodologically requires. TPP SPS Committee consultations about the science underlying SPS measures “shall be kept confidential unless the consulting Parties agree otherwise” (Article 7.17.6). The applicability of “science” to SPS measures is further qualified according to whether trade and regulatory officials decide the SPS measures are economically feasible.

The “economic feasibility” of the science-based SPS measures to provide the appropriate level of protection is formulated in this provision: “Each Party shall . . . select a risk management option that is not more trade restrictive than necessary to achieve the sanitary or phytosanitary objective, taking into account technical and economic feasibility” (Article 7.6c). “Economic feasibility” provides TPP members with a crucial loophole against providing SPS measures that are science-based.

For example, since the Congress refuses to fund the Food Safety Modernization Act (FSMA), including its import provisions, inadequately funded and staffed SPS measures of the FSMA are not “economically feasible” to implement and enforce. Because the food and agribusiness industry does not want to pay the fees to expedite trade under the FSMA, they appeal to the presidential Office of Management and Budget to do a “cost-benefit” analysis to delay levying of fees.<sup>9</sup> In the meantime, “science” cools its heels, waiting for lawyers and economists to decide which SPS measures are “necessary” and to what extent, according to cost-benefit analysis, to provide the appropriate level of protection.<sup>10</sup> Cost benefit analysis routinely underestimates the benefits of regulation and overstates the costs.<sup>11</sup>

## **What the chapter says it aims to do**

The chief objective of the chapter is to “protect human, animal and plant life or health in the territories of the Parties while facilitating and expanding trade by a variety of means to seek to address and resolve sanitary and phytosanitary issues” (Article 7.2a). Contrast this objective with the objective of the principles of risk analysis of the Codex Alimentarius, to which the SPS chapter is, in theory at least, legally bound:

While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.<sup>12</sup>

While the Codex advises its member governments to avoid “unjustified differences in the level of consumer health protection,” the primary emphasis in the Codex principles of risk analysis remains consumer health protection, not trade facilitation or expansion.

However, the objective of the TPP chapter is not to improve the “protection of human, animal and plant life or health” itself. Rather, such protection only applies insofar as SPS measures facilitate and expand cross-border trade of food and agricultural goods. So the issues to be resolved are not how best to protect, but how to eliminate or modify any SPS measures (laws, rule-making processes, rules, implementation and enforcement practices, even judicial rulings) that impede food and agricultural trade, if those measures cannot be justified in terms of the trade negotiators’ peculiar understanding and use of “science.”

## **“Scientific principles” in the TPP: a practical U.S. regulatory application**

Even when the use of scientific principles in determining appropriate standards is discussed in the TPP, the integrity of the science behind the standards is subordinated to the goal of facilitating and expanding trade. The TPP SPS chapter would have citizens, who have been denied access for more than five years to the texts negotiated between the USTR, its industry advisors and foreign trade officials, rely on “scientific principles” and “risk analysis” to protect public and environmental health from whatever application of whichever technology that has products being traded. So, for example, “The Parties recognize the importance of ensuring that their respective sanitary and phytosanitary measures are based on scientific principles” (Article 7.9.1) But there is no definition of “scientific principles.” And to judge by current U.S. regulatory practice, the “science” referred to in the text could be the kind of the unpublished corporate science studies that frequently justify U.S. rulemaking and commercial approvals and yet remain “Confidential Business Information.”<sup>13</sup>

For example, in June, the U.S. Environmental Protection Agency (EPA) relied on 27 studies by Monsanto, most of them unpublished, to renew the commercial approval for Monsanto’s RoundUp, the trademark for glyphosate.<sup>14</sup> There is a long history of U.S. regulatory approval of genetically modified organisms and their accompanying pesticides, using the applicant’s unpublished research or a summary thereof without test data and experimental design.<sup>15</sup> Some of the Monsanto studies on glyphosate reviewed by the EPA were from the 1970s, before scientists discovered that glyphosate was an endocrine disrupting chemical that damaged normal human development. (Five independently funded studies were also considered.) In July, the International Agency for Research on Cancer (IARC) released its full report that characterized glyphosate as a “probable human carcinogen,”<sup>16</sup> after having vigorously debated whether the globally used herbicide should be classified as a “known human carcinogen.”<sup>17</sup>

The EPA, using Monsanto's unpublished "science" authorized a continuation of U.S. commercialization, and yet just in time to ignore the full IARC findings and without referring to the preliminary IARC summary released in March. The EPA will be able to claim, without fear of a TPP legal challenge, that its risk assessment was based on "scientific principles," whatever they are. But the EPA is far from the only agency battered into submission by members of Congress at the behest of industry.<sup>18</sup> Indeed, White House risk managers will ignore scientific evidence in risk assessments, if industry concerns about "economic feasibility" of both SPS and non-SPS regulatory measures are brought to their attention with sufficient persistence.<sup>19</sup>

## **Agricultural biotechnology in the TPP**

Perhaps because of the negative international publicity over Monsanto's genetically modified seeds, RoundUp and other EPA approved pesticides,<sup>20</sup> the USTR negotiators decided not to include an annex to the SPS chapter on the biotechnology plant varieties that are modified to withstand multiple applications of RoundUp and other herbicides. Instead, "Modern biotechnology" appears in the "National Treatment and Market Access for Goods" chapter, with a definition that limits the application of "modern biotechnology" to agricultural goods (Article 2.21). Article 2.29, "Trade in Products of Modern Biotechnology," is displaced from the SPS chapter, as if there were no SPS issues involved in the genetic modifications of agricultural crops, whether or not they are modified to withstand ever more toxic pesticides.

However, the terms of Article 2.29 indicate that "modern biotechnology" should be logically located within the SPS chapter, e.g. the reference to the Annex 3 of the "Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)" (Article 2.29.6b)iii and footnote 13). This reference concerns how TPP parties are to prevent the import of the undefined, "inadvertent low level presence" of GMOs unauthorized for import. Logically, TPP's SPS "competent authorities" would agree to the definitions, sampling and testing methods and numerical amount of "inadvertent low level presence" during negotiations for bilateral SPS "equivalency" negotiations among TPP members (Article 7.8).

For example, the USDA's grain inspection service would inform the "competent authorities" for grain and oilseed imports that the Grain Inspection and Stockyards and Packers Administration (GIPSA)

does not assess the effectiveness of different detection methods for biotechnology-derived traits nor does it determine the characteristics of fortified samples to a particular degree of accuracy, such as what is performed in the preparation of certified reference materials.<sup>21</sup>

Importing authorities would have to decide whether the GIPSA standards for detecting unauthorized GMOs for import would be adequate to provide the appropriate level of protection for their citizens.

But by putting "modern biotechnology" within the chapter on "National Treatment and Market Access for Goods," the TPP negotiators are able to discuss issues about "trade in products of modern biotechnology" without any reference to the SPS chapter requirements. Instead, any SPS concerns about these products will be discussed in the "Committee on Agriculture Trade (Working Group)," which has no requirement for experts to discuss or demonstrate risk assessment or risk analysis for GMOs. What is particularly remarkable about this Trans-Pacific regulatory evasion is that Article 2.29 will apply to products derived from synthetic biology, the next generation of "trade in products of modern biotechnology." The techniques of synthetic biology are of an order of magnitude more complex than the transgenic plant varieties engineered to withstand multiple applications of a pesticide.

For example, the plant synthetic biology varieties that have received USDA field trial permits do not yet have a reliable safeguard against Horizontal Gene Transfer of DNA or RNA sequences foreign to agricultural or wild plants. According to one research team

Synthetic biology and other new genetic engineering techniques will likely lead to an increase in the number of genetically engineered plants that will not be subject to review by USDA [U.S. Department of Agriculture], potentially resulting in the cultivation of genetically engineered plants for field trials and commercial production without prior regulatory review for possible environmental or safety concerns.<sup>22</sup>

Three scientific committees reported to the European Commission in early 2015 that

[c]urrently available safety locks used in genetic engineering such as genetic safeguards (e.g. auxotrophy and kill switches) are not yet sufficiently reliable for SynBio. Notably, SynBio approaches that provide additional safety levels, such as the genetic firewalls, may improve containment compared with classical genetic engineering. However, no single technology solves all biosafety risks and many new approaches will be necessary.<sup>23</sup>

TPP negotiators, such as former Biotechnology Industry Organization vice president Sharon Bomer Lauritsen, likely do not care that NGOs or academics point out the logical incoherency of excluding “modern biotechnology” from the purview of the SPS chapter and hence from that of the WTO SPS Agreement. No matter how logically inconsistent it is to put “modern biotechnology” and its synthetic biology successors outside of the SPS chapter, doing so means that trade disputes over the products of “modern biotechnology” will have to be filed with reference to the non-scientific framework of the “National Treatment and Market Access for Goods” chapter.

The most disingenuous provision within Article 2.29 is this: “Nothing in this Article shall require a Party to adopt or modify its laws, regulations, and policies for the control of products of modern biotechnology within its territory.” (Article 2.29.3) This provision will certainly be invoked ad nauseam to try to make “modern biotechnology” less controversial among the TPP countries’ civil society. However, the passage should come with a footnote, perhaps something such as:

Expect a visit from the U.S. State Department officer for biotechnology and/or the Foreign Agricultural Service representative in your Embassy to discuss how you can adopt our regulations or modify your laws and regulations to better expedite the import of our agricultural products of modern biotechnology. If you refuse the visit, either expect to look for a new job or expect market entry problems for your country’s exports.

The likelihood of the realization of this footnote is documented in about 900 Wiki-leaked State Department cables from 2005-2009 analyzed by Food and Water Watch.<sup>24</sup> In these cables, the power of the State Department to cause “voluntary” changes in laws and import regulations to increase trade in agricultural biotechnology products is on full display.

In the current low price environment for agricultural commodities, Monsanto and other biotechnology companies are laying off thousands of employees, cutting research and development budgets and buying back the shares of their equity stock to keep share prices high enough to enable share price-based bonuses.<sup>25</sup> It is only a slight exaggeration to say that without U.S. government intervention share prices would be tanking.

The genetic resources that modern biotechnology modify receive a mention only in the TPP chapter on Exceptions. “Article 29.8: Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources Subject to each Party’s international obligations, each Party may establish appropriate measures to respect, preserve and promote traditional knowledge and traditional cultural expressions.” It is fitting that the TPP ignore the genetic resource base of modern biotechnology, since the U.S., together with the EU and Japan, have resisted all efforts, to amend the WTO intellectual property agreement on genetic resources and traditional knowledge, to require patent holders of modern biotechnology, both medical and agricultural to disclose the origin of the genetic resources used in their products.<sup>26</sup>

## **Building on the WTO SPS Agreement or building a TPP Caucus to lobby the WTO SPS Committee?**

The Foreign Agriculture Service of the U.S. Department of Agriculture reviews hundreds of foreign SPS measures to determine whether and how they might be inhibiting an expansion of U.S. agricultural exports.<sup>27</sup> In 2012, the World Trade Organization’s SPS Committee reported 16 “SPS-specific trade concerns,” i.e. SPS measures enacted by WTO members that appeared to violate the WTO SPS agreement.<sup>28</sup> U.S. food and agriculture exporters and importers are unhappy that the putative SPS violations they report to U.S. officials are not resolved more quickly in the WTO process. As a result, the agribusiness lobby has advocated a “WTO plus” SPS agreement that would emulate the U.S. regulatory process, in which their products are invariably approved for commerce.<sup>29</sup>

The “appropriate level of sanitary and phytosanitary protection” in the WTO SPS agreement, adopted in the TPP (Article 7.1 et passim) will be determined by the “competent authorities” in U.S. regulatory agencies. However, in the TPP, the “primary representative” (Article 7.1.2) for the implementation of TPP will not be the “competent authorities,” much less the scientists, but in the case of the United States, the Office of U.S. Trade Representative, which has no scientific competence.

The TPP SPS Chapter, purported to “reinforce and build on the SPS Agreement,” (Article 7.2b) in fact, may well detract from the use of the WTO SPS Committee to inform WTO members about SPS issues that may result in trade barriers. TPP members will be obliged to participate in the TPP Committee on Sanitary and Phytosanitary Measures “to improve the Parties’ understanding of sanitary and phytosanitary issues that relate to the implementation of the [WTO] SPS Agreement and this Chapter” (Article 7.5.3a). The TPP SPS Committee may also develop positions for “meetings held under the auspices of the Codex Alimentarius Commission, the World Organisation for Animal Health and the International Plant Protection Convention” (Article 7.5.3g). This latter provision is ostensibly optional (“may consult”) but in a Chapter with so many “shalls” and opportunities for cooperation, it would be a brave, even foolhardy, “competent authority” who did not obey the orders of the TPP “primary representative” (i.e. the trade minister) to not consult.

The status of the WTO SPS Committee and the WTO recognized international standards setting organizations (which are already subject to considerable political pressure by commercial interests) is further weakened in the TPP SPS chapter. The TPP Parties will merely “take into account” the “standards, guidelines and recommendations” of the World Animal Health Organization and International Plant Protection Convention concerning plant and agricultural animal diseases in the TPP territories. (Article 7.7.2) “The [TPP] Parties may cooperate on the recognition of pest- or disease-free areas” (Article 7.7.3). Or they may not, if doing so would harm the trade or investment of a U.S. firm. The relationship of the TPP SPS Chapter to the WTO SPS Agreement and to the international organizations referenced in the Agreement is opportunistic, like that of a parasite.

## Dispute Settlement in the TPP SPS Chapter

U.S. agribusiness lobbyists have long complained to their Members of Congress that the WTO dispute settlement system was too slow and does not “fully enforce” SPS related rulings. Members of Congress, in turn, pressed the U.S. Trade Representative for a TTP (and TTIP) SPS chapter that would be “fully enforceable.”<sup>30</sup> Did they get their wish fulfilled?

The mention of the TPP state to state dispute settlement chapter is fairly short in the SPS chapter, just two paragraphs. TPP parties to an SPS disagreement are supposed to first resolve their differences through Cooperative Technical Consultations (CTC) with “the appropriate involvement of relevant trade and regulatory agencies” (Article 7.17.5). A note from U.S. horticulture industry advisors to the USTR concerning the U.S.-Chile Free Trade Agreement gives some insight into how the CTC might use “science” to resolve horticulture SPS disputes:

U.S. negotiators must recognize this factor [the need for U.S. export access to Chilean markets] and seek SPS agreements that are flexible enough to ensure phytosanitary mitigation while at the same time being commercially sound. Simply basing SPS agreements on sound science is not enough.<sup>31</sup>

“Flexibility” will presumably include resolving disputes by “various means” that are not simply invocations of “science,” though confidential to be sure.

In keeping with the spirit of Confidential Business Information, “All communications between the course of CTC, as well as all documents generated for the CTC, shall be kept confidential unless the consulting Parties agree otherwise” (Article 7.17.6). Thus the “science” to justify an SPS measure, even if it bears directly on public, animal, plant or environmental health, will remain disclosed only to the “relevant trade and regulatory officials.” The disputing Parties cannot proceed to use of the dispute settlement chapter without first having attempt to resolve their differences through CTC meetings (Article 7.17.8). Thus far, it is difficult to see how this dispute settlement procedure is different from that of the application of WTO dispute settlement to SPS disputes.

However, the SPS chapter exempts certain paragraphs and subparagraphs from application of the dispute settlement process (Article 7.18), e.g. as outlined in footnotes two, concerning equivalence of SPS measures and four, concerning risk analysis. There is no clear logic as to why these paragraphs, and not others, are not subject to dispute settlement. Nor is it clear as to whether SPS measures could be subject to the Investor State Dispute Settlement (ISDS) chapter, given the extremely broad definition of what comprises an “investment” in the Investment Chapter.<sup>32</sup>

Parties to a TPP dispute get to choose the forum in which they may settle the dispute, just as they would for an ISDS settlement. (Article 28.4) Perhaps U.S. agribusiness lobbyists and Members of Congress will have their wish for “fully enforceable” fulfilled on the assumption that the World Bank forum, just down the road, will be more attentive to their concerns than a WTO dispute panel in Geneva.

However, because the TPP does include an appellate body (as does the WTO dispute settlement process), to double check that the dispute panelists have correctly interpreted the dispute settlement procedures, the TPP process will be quicker—just 15 months from the panel hearing to its final report (Article 28.18). Furthermore, compensation under the TPP dispute settlement chapter will be more rapid. (Article 28.19 and 28.20). No more malingering or legislative refusal to pay WTO authorized retaliation, as in the U.S. Upland Cotton Subsidies case!<sup>33</sup> So if the dispute settlement cases are decided in favor of U.S. agribusiness and compensation is paid in full and/or offending SPS measures are modified or eliminated, perhaps the agribusiness lobby will consider SPS measures, finally, to be “fully enforceable.”

## Conclusion

The complexity of the SPS text, as well as its relationship to other provisions in the agreement on Regulatory Cooperation, Investment and Dispute Settlement, to name just a few issues, will require additional analysis. For example, the status of “import checks” and inspection and testing is not treated here, though I have discussed inspection and testing bans proposed by the European Commission in the TTIP SPS chapter.<sup>34</sup> The weakened capacity of the Food and Drug Administration to inspect foreign food facilities, in lieu of port of entry import inspection and testing,<sup>35</sup> surely calls into question the contribution of “import checks” to the “appropriate level of sanitary and phytosanitary measures.”

Likewise the “transparency” measures and the relation of the SPS chapter to the Regulatory Cooperation and Technical Barriers to Trade chapters certainly will require additional study. Will “transparency” requirements burden smaller governments with endless industry demands for comments to revise and delay regulations until regulations are so riddled with exemptions, exclusions, waivers and postponements as to be ineffective? These and other issues in the TPP deserve a fuller public debate in the next few weeks, before President Obama can sign what he hopes will be a “legacy making” trade deal that is largely about removing regulatory “irritants” to trade.

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