

## **Resolution on the proposed chapter on Sanitary and Phytosanitary Measures in the Transatlantic Trade and Investment Partnership (TTIP) Agreement**

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### **Introduction**

In October 2013, the Transatlantic Consumers Dialogue (TACD) sent to the European Commission (EC) and the U.S. State Department a “Resolution on the approach to food and nutrition related issues in the Transatlantic Trade and Investment Partnership.”<sup>i</sup> That Resolution covered a number of food and nutrition topics represented in past TACD resolutions. The Resolution could only refer to an “approach” to TTIP negotiations, since in 2013, neither TACD—nor indeed, anyone other than government officials and security-cleared industry trade policy advisors— had access to draft negotiating proposals, for the purpose of doing a text-based analysis.

Following the unauthorized disclosure of EC negotiating proposals, including a July 2014 proposal for the chapter on Sanitary and Phytosanitary measures<sup>ii</sup>, in January 2015, the Commission decided to make many of its TTIP negotiating proposals public, including that for the SPS chapter, following discussion of the proposals with the Office of the U.S. Trade Representative (USTR) negotiators. TACD is grateful to the Commission for the release of these negotiating texts, which have enabled TACD make to recommendations in the following Resolution.

Regrettably, and despite several TACD letters to the USTR and in June 2015, to President Barack Obama<sup>iii</sup>, requesting that the United State publish its draft TTIP negotiating texts, the U.S. TTIP positions remain unavailable to the public whose interests are purportedly represented in them. However, on November 5, the United States, together with other prospective members of the proposed Trans-Pacific Partnership Agreement (TPP), published the TPP negotiating texts and annexes.

TACD assumes that the US will push for a high degree of legal and substantive consistency between the TPP SPS chapter and the TTIP SPS chapter. The EU, however, might be more inclined to accept provisions broadly similar to those in the already published CETA SPS Chapter and to its own textual position. The recommendations in this Resolution are drawn from our analysis of the latest publicly available European Commission proposed SPS chapter<sup>iv</sup> and the TPP SPS proxy for the U.S. position, in the searchable WikiLeaks version.<sup>v</sup> The analysis and the resulting recommendations are by no means exhaustive.

### **Definitions: “competent authority” and “primary representative”**

#### *Recommendation:*

While TACD supports the proposed TTIP definition of a “competent authority” in SPS issues, TACD opposes adding a “primary representative” definition to the TTIP SPS chapter, such as that in the TPP SPS chapter. The inclusion of such a “primary representative” could result in the inclusion of officials

in the TTIP Joint Management Committee for SPS issues from an agency without SPS competency or statutory SPS authority.

*Background:*

Definitions are crucial for realizing and operationalizing the binding TTIP commitment to providing the “appropriate level of sanitary and phytosanitary protection.” Article 5 of the Commission’s proposal requires that relevant SPS agencies corresponding to its definition of “competent authority” (Article 2b) be defined in an appendix. TACD agrees with this orthodox definition of “competent authority.”

The TPP SPS chapter defines “competent authority” as “a government body of each Party responsible for measures and matters referred to in this Chapter.” (Article 7.1.2) That same chapter defines “primary representative” as “the government body of a Party that is responsible for the implementation of this Chapter and the coordination of that Party’s participation in Committee activities under Article 7.5 (Committee on Sanitary and Phytosanitary Measures)” (Article 7.1.2) The addition of a “primary representative” to the TTIP Joint Management Committee for SPS issues could result in the subordination of the relevant competent authority to a “primary representative” without SPS competency or authority.

**Implementing and providing adequate resources to implement the right to regulate and the “appropriate level of sanitary and phytosanitary protection”**

*Recommendation*

TACD recommends that an Article 3a be added to the Commission’s SPS proposed text, to stipulate that Parties must resort to State to State dispute settlement, if either Party fails to comply with Article 3, whether the resources availed to implement the Chapter are from governments or from the for profit sector. Absent an enforcement mechanism to ensure that sufficient resources are made available to implement all provisions in the SPS Chapter, governments might discriminate economically against SPS measures that effectively “preserve the right to protect” in favor of paying preferentially for those SPS measures that facilitate trade “to the greatest extent possible.”

*Background*

Among the objectives of the Commission’s SPS proposal is to “Facilitate trade between the Parties to the greatest extent possible while preserving each Party’s right to protect human, animal or plant life and health in its territory . . .” (EU proposed Article 2.1). The “right to protect,” as well as trade facilitation, however, requires human, budgetary and infrastructural regulatory resources to realize that right. The Commission proposed SPS text states, “The Parties shall avail themselves of the necessary resources to effectively implement this Chapter” (EU proposed Article 3). The TPP SPS has no such binding requirement.

TACD does not believe that either the United States or the European Commission will use the State to State Dispute Settlement chapter to litigate against the other for failure to comply with Article 3, in the unlikely case that the U.S. would agree to it.<sup>vi</sup> Each Party must ensure that its export facilities and consignments comply with the other Party’s food safety requirements. However, insufficient funding of food controls would jeopardize the proper implementation of the SPS Chapter. For example, the budget and staffing of the Food and Drug Administration does not enable it to inspect even a third of foreign food exporting facilities mandated by the Food Safety Modernization Act of

2010.<sup>vii</sup> An insufficient funding of food controls similarly is an issue in the European Union, where mandatory fees levied on business operators have been proposed to pay the costs of the control system. However, the European Council and Parliament rejected mandatory fees for these regulatory services.

In the current Commission SPS chapter proposal, there is no cause of action that would compel the European Commission to sue the United States for failing to avail itself of the resources to verify EU member state compliance with U.S. import requirements, much less for failing to provide the regulatory means to ensure the “appropriate level of sanitary and phytosanitary protection” for U.S. consumers. TACD calls on the US and the EU to ensure that sufficient budget and staffing are allocated to food official controls on both sides of the Atlantic. Requiring Parties to undertake State to State dispute settlement to implement proposed Article 3, for example, would be one way to ensure adequate resources to realize the “right to protect.”

### **Including “Trade in Products of Modern Biotechnology” in the TTIP**

#### *Recommendation*

TACD neither supports nor sees the need to include any specific provision dealing with agricultural biotechnology in the TTIP – be it placed within the SPS chapter or outside, as is the case in the TPP text, where the biotechnology provision is subsumed under the market access chapter. Under the CETA agreement, the EU and Canada have agreed to “*cooperate internationally on issues related to biotechnology such as low level presence of genetically modified organisms*”.<sup>1</sup> TACD does not support the inclusion of similar language in the TTIP, since such “cooperation” could require the EU to abandon its zero tolerance policy regarding unauthorized GMOs in food.

Trade concerns or disputes over products of agricultural biotechnology should be discussed by competent authorities from the relevant agencies. Putting trade in products derived from “modern biotechnology” in a national treatment and market access for goods chapter is a bad legal precedent that ignores the far greater scientific complexity of the future products to be regulated and if approved by regulators, traded. Furthermore, investor lawsuits against governments, provided for in the Investment Chapter, frequently cited alleged failure to provide a “minimum standard of national treatment” as a cause of action for Investor State Dispute Settlement lawsuits.<sup>viii</sup>

#### *Background*

In the TPP, “Trade in products of modern biotechnology” (Article 2.29) has been located in Chapter 2, “National Treatment and Access for Market Goods,” so that controversies over the “low level presence” of GMOs unauthorized for import would be judged based on criteria of market access<sup>ix</sup> rather than risk assessments of their safety for human health or the environment. The quantity of “low level presence” is not defined in the TPP, and will be presumably negotiated bilaterally through the TPP Committee on Agricultural Goods. In the CETA text, the issue of a “low level presence” of GMOs and a cooperation in the field of biotechnology is addressed in chapter 29 on “dialogues and bilateral cooperation” (Art. X.03)

It is not improbable that the future deregulation of food and agricultural products derived from the far more powerful and complex gene editing techniques of synthetic biology will raise human and environmental health issues.<sup>x</sup> 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>xi</sup> In the European Union, meanwhile, the question whether or not these new techniques fall under the relevant GMO-Regulation is still heatedly debated. If the TTIP were to enable trade in products of synthetic biology, following the Article 2.29 approach, it is questionable whether the competent authorities of the EU Commission and United States could provide “the appropriate level of sanitary and phytosanitary protection.”

Regarding the issue of “low level presence,” three scientific committees have already informed the European Commission that there are no reliable biological containment barriers against Horizontal Gene Transfer of synthetically modified organisms (SMOs).<sup>xii</sup> As a result, HGT of novel DNA and RNA sequences to agricultural and wild plants from deregulated products of plant synthetic biology is a certainty in the foreseeable future, as is the presence of “low level” SMOs in deregulated products. If the SMOs were to become an invasive species, the Article on “Emergency Measures” (Article 16) could be applied by the importing party, but at that point regulatory action would take place only after harm had occurred, the very antithesis of how the Precautionary Principle should be operationalized.

### **Audits, verification, facilities certification and import checks: overlapping SPS measures are to protect consumers**

#### *Recommendation*

Each Party shall be free to verify, through regular audits, including unannounced facilities audits and import checks, that food exported by the other Party effectively meets its import requirements (EU proposed Article 11 and 13). As frequency rates for import checks are to be set in an Annex to the SPS Chapter, such Annexes must be made available to the public, including to civil society organizations, to verify that import checks and facilities audits are adequate to realize governments’ “right to protect” its consumers.

TACD recommends that the TTIP SPS chapter include an Article that would stipulate the criteria for granting pre-clearance status and for revoking that status. Products deemed by competent authorities to present high risk of microbiological contamination, such as meat and seafood products, would not be eligible for preclearance status. Article 7 on trade facilitation should include a provision that would allow competent authorities to apply permanent control measures for products approved to enter into commerce on the basis of non-public and unpublished studies and data submitted by commercialization applicants. Article 11.9 should be modified to read, “Both Parties will publish the results and conclusions of their verification procedures,” in order to increase transparency in the auditing of government control systems and of programs in which governments have delegated their authorities to operators of food and agriculture facilities, whether in law or in fact.

#### *Background*

The realization of the “appropriate level of sanitary and phytosanitary protection” requires multiple and overlapping layers of SPS measures from farm to fork. The application of SPS measures would be reduced in “pre-clearance” programs, where port of entry re-inspection and testing of food and agriculture products would be allowed only “in exceptional cases” (EU proposed Article 7.12 a). U.S.

consumer groups have been critical of U.S. Department of Agriculture pre-clearance programs for meat imports, which preclude port of entry re-inspection and testing, a traditional food safety management tool.<sup>xiii</sup>

Inspections of food and agricultural products from the authorized export facilities qualified for “pre-clearance” to expedite trade (proposed Article 7.12a) may be carried out only “in exceptional cases” (Article 13.7), according to the article on Import Checks and Fees. SPS control activities “should not be applied as a permanent import measure and only foreseen to facilitate **new** trade” (proposed Article 7.12a, with boldface in the original text). Even for “new trade”, a notion not defined in the proposed text, but which relates to yet to be regulated food and agricultural products, such as those containing nanomaterials or those derived from synthetic biology, SPS controls must be temporary. However, there are no criteria concerning which products and export facilities will be eligible the “pre-clearance” program in which inspection and testing of products is deemed by competent authorities to be unnecessary for achieving the “appropriate level of sanitary and phyto-sanitary protection.”

### **Science, Risk Assessment and Risk Management**

#### *Recommendation*

TACD believes that the TPP SPS standard of allowing only “reasonably available and relevant scientific data” (Article 7.9.5) to be used in risk assessment gives commercial applicants, risk assessors and managers too much discretion to decide which scientific studies and data will be used in determining a risk assessment, which in turn, will affect the scientific integrity underlying the risk management decision. TACD recommends that the TTIP SPS chapter stipulate that the scientific data and studies used in risk assessment must be publicly accessible for peer review and comment. Scientific data and studies that have to do with public, animal, plant and environmental health must not be classified as Confidential Business Information or otherwise deemed to be not “reasonably available and relevant.”

TACD recommends adding to the objectives of Article 2.1 “respecting each Party’s regulatory systems, risk assessment, risk management and policy development processes, such as the application of the precautionary principle and the use of other legitimate factors than science in making risk management decisions.” Just as even the definition of risk assessment in the WTO SPS Agreement includes economic factors (Annex 8, paragraph 4), and the application of SPS measures includes their “economic feasibility” (TPP, Article 7.6 c), so must risk managers be able to use other legitimate factors, e.g. economic, social, ethical, in making risk management decisions. As such, the definition of “risk management” modelled on the one included under the TPP SPS Chapter would not be acceptable, as it would prevent risk management decisions based on other factors than the results of risk assessment alone.

#### *Background*

In the TPP SPS chapter, there is an Article that encapsulates the use of science in risk assessment to approve products for domestic commercialization and via trade agreements, for international trade. “Each Party shall ensure that each risk assessment it conducts is appropriate to the circumstances of the risk at issue and takes into account reasonably available and relevant scientific data, including qualitative and quantitative information” (Article 7.9.5). Regulatory approvals are not based on the basis of a weight of evidence in publicly available and peer-reviewed science but on the basis of

what risk managers and assessors, in response to Confidential Business Information claims, judge to be “reasonably available and relevant scientific data.”

What is “reasonably available and relevant scientific data?” An answer to this question presumably would be proposed during the course of a dispute about whether an SPS measure had been based on “science.” Imagine, for example, that there was a dispute that centered on the Maximum Residue Level for glyphosate, a globally traded herbicide product. 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>xiv</sup> Similarly, in the European Union, the re-approval of glyphosate has been widely criticized, due to the choice of scientific evidence reviewed by the European Food Safety Authority (EFSA). According to toxicologist Jennifer Sass, “The dramatic inconsistency between the EFSA and IARC [International Agency for Research on Cancer] cancer reports spurred 96 prominent scientists from 25 countries to voice strong opposition to the EFSA report.”<sup>xv</sup>

In July, the IARC released its full report that characterized glyphosate as a “probably human carcinogen,”<sup>xvi</sup> after having vigorously debated whether the herbicide should be classified as a “known human carcinogen.”<sup>xvii</sup> Contrary to the IARC’s findings and without referring to its report, the EPA, using Monsanto’s partly unpublished scientific data, reauthorized U.S. commercialization of RoundUp. The EPA concluded that the Monsanto studies, including the unpublished ones, were “reasonably available and relevant scientific data” whereas the IARC report was not. While the EPA risk assessment of glyphosate is controversial in public health terms, it conforms to the TPP requirement regarding use of “scientific data” in risk assessment. Such commercial authorizations often are controversial, because much of the data supporting them is characterized as Confidential Business Information<sup>xviii</sup> and therefore not “reasonably available” for the peer review characteristic of scientific method. Therefore, competent authorities must have the right to take precautionary measures even when SPS measures have conformed to trade agreement requirements of broadly being “based on scientific principles,” however much scientific data and studies are not deemed to be “reasonably available.”

### **Animal welfare provisions advancing standards in both regions**

#### *Recommendation*

TACD supports strengthening animal welfare legislation in the EU and the US and opposes a race to the bottom in animal welfare issues. It is essential that the path for future legislative reforms is not impeded, further intensification of animal farming is avoided, animal welfare rules are not weakened and the two parties agree on binding protections in animal welfare. TACD also proposes that the United States and the European Commission collaborate to lead the development of a World Animal Health Organization Code of Ethics in Animal Welfare as a crucial step towards progress in trade-related animal welfare.

#### *Background*

The European Commission aims to further cooperate with the United States on issues related to animal welfare through TTIP (Art. 2.7). It proposes an entire article on the matter (Art. 17) which is aiming to increase information exchange, research collaboration and the set-up of a working group on animal welfare. While the EU does include in its proposal the recognition of animals as “sentient beings”, as in Article 13 of the Treaty for the Functioning of the European Union (TFEU)<sup>xix</sup>, the

proposed TTIP animal welfare provisions, are weak, non-binding and unenforceable. In addition, Article 17.2 includes a commitment to “exchange information, expertise and experiences in the field of animal welfare with the aim to align regulatory standards related to breeding, holding, handling, transportation and slaughter of animals”.

However, any alignment of standards creates a downward pressure on the party with the highest animal welfare standards, the EU in this case. The EU has a significant body of legislation on farm animals with species-specific Directives and a General Directive on the protection of farm animals, as well as detailed Regulations on Transport and Slaughter. The EU also has enacted bans on some of the worst confinement methods, has proposed a ban on cloning of animals for food production, and has banned the use of hormones and the use of antibiotics as growth promoters in animals.

In the U.S., no federal animal welfare legislation is in place, apart from the 1966 “Animal Welfare Act” which exempts farm animals. There is no federal legislation governing the welfare of animals while they are on the farm and the federal provisions on slaughter and transport are much less detailed than EU legislation (clauses on slaughter actually exempt poultry). A few U.S. federal states have implemented specific legislations relating to some production standards, such as a ban on battery eggs in California or the minimum size of barns in Oregon and Arizona.<sup>xx</sup> At the same time, two-thirds of US consumers regard animal welfare as an important aspect of their purchasing decision.<sup>xxi</sup> While legislative change is not likely to take place in the near future, recently, increasing public awareness about animal suffering and consumer demand for humane farming methods have resulted in market driven improvements in animal welfare standards adopted by a growing number of retailers.

Given the lack of U.S. interest in trade related animal welfare, as reflected in the absence of any clauses on animal welfare in the TPP, enacting higher and binding standards on animal welfare will be next to impossible. Trade agreements tend to favor large-scale intensive systems engaged in food production at a lower cost and with significant potential for animal suffering. It remains to be seen how the World Animal Health Organization (OIE) standards will affect EU and U.S. state animal welfare laws if OIE standards are used in a TTIP dispute to try to overturn those laws. It is therefore proposed that an OIE Code of Ethics in Animal Welfare be used in SPS management decisions, since OIE standards and codes of practice are binding on the EU and US, unless they file a reservation during their approval.

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<sup>i</sup> <http://tacd.org/wp-content/uploads/2013/09/TACD-FOOD-Resolution-on-the-approach-to-food-and-nutrition-related-issues-in-the-TTIP.pdf>

<sup>ii</sup> [http://www.iatp.org/files/2014.07\\_TTIP\\_SPS\\_Chapter\\_0.pdf](http://www.iatp.org/files/2014.07_TTIP_SPS_Chapter_0.pdf) An analysis of this leaked SPS chapter negotiating proposal is at [http://www.iatp.org/files/2014\\_09\\_02\\_TTIP\\_SPS\\_Analysis.pdf](http://www.iatp.org/files/2014_09_02_TTIP_SPS_Analysis.pdf)

<sup>iii</sup> <http://tacd.org/wp-content/uploads/2015/06/TACD-letter-to-President-Obama.pdf>

<sup>iv</sup> [http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc\\_153026.pdf](http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153026.pdf)

[http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc\\_153120.pdf](http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153120.pdf)

<sup>v</sup> <https://wikileaks.org/tpp-final/7-Sanitary-and-Phytosanitary-Measures-Chapter/7.%20Sanitary%20and%20Phytosanitary%20Measures%20Chapter.pdf>

<sup>vi</sup> The budgets and mandates of U.S. agencies with statutory SPS obligations are under sustained attack, often by TTIP proponents. E.g. Ronald White, “Congress’ Latest Assault on the EPA,” Center for Effective Government, July 14, 2014. <http://www.foreffectivegov.org/blog/congresss-latest-assault-epa> Lydia Zuraw, “Congress Wants FDA to Drop Agency’s Push for FSMA User Fees,” *Food Safety News*, August 29, 2014. Lydia Wheeler, “House Dems ask agencies to request full funding for FDA,” *The Hill*, September 2, 2015. <http://thehill.com/regulation/252542-house-dems-ask-agencies-to-request-full-funding-for-fda>

- vii “Food Safety: Additional Actions Needed to Help FDA Ensure the Safety of Imported Food,” Highlights, General Accountability Office, February 27, 2015. <http://www.gao.gov/products/GAO-15-183>
- viii Cite the Public Citizen analysis of ISDS causes of action
- ix “Novel TPP Provisions Aim to Ag Biotech ‘LLP’ Rejections,” *Inside U.S. Trade*, November 17, 2015.
- x Doug Gurian Sherman, “The Next Phase of Genetic Engineering: A Flood of New Crops Evading Environmental Regulation,” *Civil Eats*, January 27, 2015. <http://civileats.com/2015/01/27/the-next-phase-of-genetic-engineering-a-flood-of-new-crops-evading-environmental-regulation/>
- xi Sarah R. Carter et al., “Synthetic Biology and the U.S. Biotechnology Regulatory System: Challenges and Options,” J. Craig Venter Institute, May 2014, 24. <http://www.icvi.org/cms/fileadmin/site/research/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf> .
- xii [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_048.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_048.pdf) at 6.
- xiii E.g. Helen Bottemiller, “Consumer Groups Ask USDA to Halt Pilot Program to Lessen Canadian Border Inspection,” *Food Safety News*, September 19, 2012. <http://www.foodsafetynews.com/2012/09/consumer-groups-as-usda-to-halt-pilot-program-to-lessen-canadian-border-inspection/#.VlvdE3arS1s>
- xiv Sharon Lerner, “EPA Uses Monsanto’s Research to Give RoundUp a Pass,” *The Intercept*, November 3, 2015. <https://theintercept.com/2015/11/03/epa-used-monsanto-funded-research/>
- xv Jennifer Sass, “Glyphosate—IARC Got It Right, EFSA Got It from Monsanto,” National Defense Resource Council, November 30, 2015. [http://switchboard.nrdc.org/blogs/jsass/glyphosate\\_-\\_iarc\\_got\\_it\\_right.html](http://switchboard.nrdc.org/blogs/jsass/glyphosate_-_iarc_got_it_right.html)
- xvi <http://www.globalresearch.ca/international-agency-for-research-on-cancers-full-report-on-glyphosate-monsantos-roundup/5465798>
- xvii Clare Robinson, “Monsanto’s RoundUp (glyphosate) Narrowly Missed Being Classified as Known Human Carcinogen,” *GM Watch*, August 13, 2015. <http://www.globalresearch.ca/monsantos-roundup-glyphosate-narrowly-missed-being-classed-as-known-human-carcinogen/5469093>
- xviii Kaare M Nielsen, “Biosafety Data as Confidential Business Information,” *PLOS Biology* 11(3) (March 2013), 1. <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1001499>
- xix Part of the “Lisbon Treaty” signed in 2009. This is a very important development, the recognition of animal sentience in the EU Treaty, we believe this will serve as a basis for future reform. Article 13 in TFEU says: “*In formulating and implementing the Union’s agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage.*” Trade is not mentioned as one of the categories, however agriculture and fisheries are mentioned, transport too, and they are all related to trade.
- xx <https://awic.nal.usda.gov/government-and-professional-resources/state-and-local-laws>
- xxi Animal Welfare Institute, 2014, Consumer Perceptions of Animal Welfare, Washington, [https://awionline.org/sites/default/files/uploads/documents/fa-consumer\\_perceptionsoffarmwelfare\\_-112511.pdf](https://awionline.org/sites/default/files/uploads/documents/fa-consumer_perceptionsoffarmwelfare_-112511.pdf)