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

Introduction

On 2 May 2016, Greenpeace Netherlands leaked 13 chapters of the proposed TTIP, including the chapters on Sanitary and Phytosanitary Measures (SPS)[1] and Regulatory Cooperation, with text proposed both by the U.S. Trade Representative (USTR) and European Commission (EC) negotiating teams. The documents probably represent the state of negotiations as of April 2016.[2] TACD had published its Resolution on the EC proposed SPS chapter on 21 January 2016 without access to the USTR proposed text.[3] For the Resolution we used the Trans-Pacific Partnership Agreement (TPP) SPS chapter as a proxy for the USTR position for the TTIP SPS chapter. As a result of the Greenpeace Netherlands leak, TACD is able to respond to the USTR SPS chapter proposal, and thus update our 21 January Resolution.

According to an EC "Tactical State of Play Note" from March 2016 leaked by Greenpeace Netherlands, "Discussions on SPS were cumbersome, partly due to the fact that the US proposals were based on the TPP agreement most of the time."[4] The new USTR TTIP lead SPS negotiator, Sharon Borner, is a former employee of the Biotechnology Industry Organization (BIO).[5] Long-time BIO positions, reflected in the TPP SPS chapter and in the Market Access and National Treatment article on "Trade in Products of Modern Biotechnology," have now been imported with slight modifications, into the U.S. TTIP proposal.

In response to the leaked texts, the chief EU TTIP negotiator Ignacio Garcia Bercero said that the EU would not agree to any changes to EU biotechnology law resulting from the U.S. proposal.[6] However, there is already substantial evidence to show that U.S. diplomatic and industry lobbying, with the usual warning about "unjustified" disruptions to trade, have delayed the publication of an EU legal opinion about whether to regulate New Breeding Techniques (NBTs) for food plants and animals as Genetically Modified Organisms.[7] Furthermore, there is evidence of interference by the EU's Secretariat General in the regulatory process for evaluating endocrine disrupting chemicals, to conform to U.S. TTIP related demands.[8] TACD is concerned that EU law is being circumvented by regulatory and political pre-harmonization towards a final TTIP agreement.

The consolidated USTR and EC SPS proposals show that there is much yet to negotiate. For example, the United States has proposed an article on "modern agricultural technologies" without defining the term. The European Union's proposal to include an article on animal welfare has not been reciprocated by the USTR. Annexes referred to in the draft text remain to be specified. On the basis of TACD's analysis of these incomplete and yet to be agreed texts, we present this Update for discussion with U.S. and EC officials, particularly the competent authorities with legal responsibilities for providing the "appropriate level of sanitary and phytosanitary protection" according to the terms of World Trade Organization SPS agreement that is the common underlying basis for the proposed SPS chapter. Each recommendation is followed by a brief background justification.

SPS equivalence (Article X.4)

Recommendation: SPS equivalence determinations, whether applied to a single SPS measure or to whole SPS systems, must remain the sole and unqualified prerogative of the importing TTIP Party.

Background: The determination by competent authorities that the SPS measures of exporting countries are "equivalent" to those of the importing country, even when they differ, in providing the "appropriate level of sanitary and phytosanitary protection," is a crucial trade facilitation measure. To take a simple example, jurisdictions may require different Sanitary Operating Procedures to achieve the "appropriate level" of protection from pathogens in meat products. The EU proposal for SPS equivalence determinations (Article X.4.3) is the traditional one derived from the WTO SPS Agreement (Article 4.1): the importing Party has total discretion in granting equivalence to individual SPS measures and/or to whole SPS systems. The U.S. proposal for equivalence does not imply total discretion, because it additionally would require, among other measures, that the EU and U.S. "shall take into account, where relevant . . . WTO SPS Committee decisions" (Article X.4.2) in equivalence determinations. It is not clear what these "decisions" are, unless the U.S. means to apply WTO dispute settlement rulings involving the WTO SPS chapter to the implementation and enforcement of the TTIP SPS chapter, e.g. a ruling on India's measures against avian influenza.[9] TACD opposes applying dispute settlement rulings or other WTO SPS decisions of non-TTIP members to TTIP equivalence determinations.

U.S. proposed article on "Science and Risk" (Article X.5)

Recommendation: TACD urges the EC not to agree to the USTR proposal that TTIP adopt the U.S. regulatory "notice & comment" process, which has prevented finalization of SPS and other rules to protect consumers. TACD recommends replacing the language cited in the U.S. proposal below with "Parties shall ensure that risk assessments are made only on the basis of publicly available scientific studies, data and information, with no classification of such evidence as Confidential Business Information." Regulatory data and information pertaining to consumer, food animal and environmental health and safety must not be considered unavailable to public review because of Confidential Business Information (CBI) classification.

Background: This proposed article does not have a corresponding article in the EC proposal. The second paragraph of the "Science and Risk" article purports to be based on Article 5.6 of the WTO SPS agreement, which is concerned with the "technical and economic feasibility" of SPS measures to provide the "appropriate level of sanitary and phytosanitary protection." Competent authorities would be forbidden from finalizing and enforcing a SPS regulation until and unless they have evaluated "any alternatives to achieve the appropriate level of protection being considered by the Party or identified through timely submitted public comments, including where raised, the alternative of not adopting any regulation." This paragraph would give "timely submitted public comments" regarding alternatives to regulation equivalent legal status to the regulations proposed by competent authorities.

In essence, the USTR proposes to export the ever higher evidentiary burden on U.S. agencies to justify SPS regulatory actions—which has resulted in "paralysis by analysis"[10]— to EU member states via TTIP. For example, the U.S. Food and Drug Administration proposed a ban in 1972 on certain anti-biotics in animal production but the industry has used the notice and comment process to delay regulation to this day.[11] This USTR proposal is an example of a binding form of regulatory "cooperation," which, if finalized in TTIP, would delay and dilute measures to provide consumers with the "appropriate level

of sanitary and phytosanitary protection."[12] No wonder the U.S. Chamber of Commerce says that "regulatory cooperation is the gift that keeps on giving"[13] – "gifts" for its members, of course!

According to the U.S. proposal, "each Party", to carry out risks assessments "shall ensure that it takes into account relevant available scientific evidence, including quantitative or qualitative data and information"(Article X.5.1). This is a near repetition of the standard of evidence that the USTR successfully included in the TPP SPS chapter (Article 7.9.5). The key regulatory loophole in this TTIP proposal lies in what scientific evidence is "available" for a risk assessment. Risk assessments would not be based on a weight of evidence from publicly available studies, data and information, but on the basis of what risk managers, in response to CBI claims by commercial applicants, judged to be "relevant available scientific evidence." CBI permitted exclusions of applicant data and information from public review greatly diminish the scientific robustness of risk assessments and the public's confidence in the scientific integrity of the regulatory system. [14]

"Regulatory Approvals for Products of Modern Agricultural Technology" (Article X.12)

Recommendation: TACD urges the EU and the U.S. to suspend negotiations on the proposed article until the competent agencies of each Party have demonstrated they have the authority and capacity to regulate food and agricultural products derived from techniques of modern biotechnology and food and agricultural products that incorporate nanomaterials. Legal strategies to deregulate such products on the basis of commercial applicant submitted studies, data and information must not displace the need for pre-market safety assessment and post-market monitoring by competent authorities of novel food and agricultural products.

Background: The USTR proposes an entire article on "modern agricultural technology", however, without defining the term. The TPP "Trade in the Products of Modern Biotechnology" article has been reduced to a TTIP paragraph which would require the EC to cooperate in a "Global Low Level Presence Initiative to develop an approach or set of approaches to manage low-level presence [of GMOs unapproved in the importing country] in order to reduce unnecessary disruptions affecting trade" (Article X.12.7). The substance and quantity of "low-level presence" remains undefined. TACD assumes that the USTR proposes to include in an eventual definition of "modern agricultural technology" more technologies than those of "modern biotechnology".

This definition likely will include not only genetically-modified organisms and cloning techniques but also products of food and agri-nanotechnology, which are not regulated and therefore are not approved by competent authorities. For example, in 2006, TACD member the International Center for Technology Assessment and five other NGOs petitioned the Food and Drug Administration to regulate products under FDA authority that incorporated nanomaterials.[15] In 2014, the FDA issued voluntary guidance to industry concerning nanomaterials in FDA regulated products.[16] However, with the discovery by Friends of the Earth that infant formula with nanomaterials is now in the marketplace, the efficacy of FDA's voluntary guidance appears to be nil.[17] A vague trade rule on "products of modern agricultural technology" by a negotiating Party without the capacity to protect the smallest consumers will not provide the "appropriate level of sanitary and phytosanitary protection."

Regulatory Cooperation in SPS matters (Art. X.15 – X.17)

Recommendation: TACD reiterates the need to only assign officials from "competent authorities" to SPS committees instead of officials from trade or other ministries. Regulatory cooperation in SPS matters has to be based on voluntary cooperation and must not require "reaching mutually acceptable solutions" (Article X.15.2). Also the option to use a precautionary approach in risk assessment and risk management needs to be included as a fundamental principle of regulatory cooperation.

Background: As a so-called "living agreement," the aim of the TTIP is to further develop the agreement over time in order to harmonize or converge regulatory approaches. In this context, cooperation between regulatory authorities in SPS matters is a particular interest of the US administration and may be regarded as a subset of the requirements in the horizontal regulatory chapter. Therefore, TACD's more general critique of the regulatory cooperation chapter in TTIP equally applies to its SPS chapter.[18]

The demands of the US proposals again highlight the danger that has already been observed in the TPP that the respective competent authorities of the EU and USA could be sidelined by assigning "primary representatives" for the SPS Joint Management Committee that would represent the objectives of trade ministries and leave in an advisory role those authorities with legal obligations in SPS matters. The characterization of the implementation of those authorities, e.g. regarding Endocrine Disrupting Chemicals, as a 'trade irritant' by TTIP promoters,[19] signals to TACD that in the event of a conflict between the exercise of SPS legal authority and the achievement of TTIP's trade objectives, the "primary representatives" would cooperate to remove the trade "irritant."

In terms of the language used, the US proposals include a high number of undefined legal terms aimed at fostering cooperation between authorities, which most certainly can be interpreted as binding the two parties to finding joint positions. This is reflected in the demand that the Joint Committee should cooperate "with a view to reaching mutually acceptable solution" (Article X.15.2) or in demanding "cooperative technical consultations" (Article X.17).

Conclusion

It is regrettable that TACD must continue to rely on leaked documents in order to interpret the USTR's TTIP positions. Within the limitations of interpretation imposed by the USTR and, of course, of our own analytic limitations, TACD will continue to advise negotiators on how we believe that consumer interests can best be represented in TTIP. We look forward to a frank and full discussion of the TACD TTIP SPS resolution and this update to that resolution with U.S. and EU officials.

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[2] https://www.ttip-leaks.org/#docdoc11
[3] http://tacd.org/wp-content/uploads/2015/01/TACD-Resolution-TTIP-SPS_-GREEN_rev0216.pdf
[4] https://ttip-leaks.org/pandaros/doc16.pdf
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[14] 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
[15] http://www.centerforfoodsafety.org/files/nano-fda-petition-final-icta-2006_31048.pdf
[16] http://www.iatp.org/blog/201408/fda-to-industry-please-call-us-if-you-put-nanomaterials-in-food
[17] http://www.foe.org/projects/food-and-technology/nanotechnology/baby-formula
[18] http://tacd.org/wp-content/uploads/2015/02/TACD-TTIP-Resolution-on-Regulatory-Cooperation.pdf
[19] Erica Smith with Baskut Tuncak and David Azoulay, "Lowest Common Denominator: How the proposed EU-US Trade deal threatens to lower standards of protection from toxic pesticides," Center for International Environmental Law, January 2015, at 19. (Declaration of interest: IATP provided comments on a draft of this report.) http://ciel.org/Publications/LCD_TTIP_Jan2015.pdf.