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Investigation No. TPA-105-001: Trans-Pacific Partnership Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors (and Consumer Interests)

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Summary

The U.S. agricultural trade performance of so called “Free Trade Agreements” (FTAs) since 1994 has been anemic. A recent review of six FTAs puts their collective agricultural trade deficit at $1.6 billion.¹ U.S. agricultural exports have not delivered prosperity to farmers and ranchers. Instead, they depend Farm Bill subsidies to survive, e.g. a Congressional Budget Office FY 2017 projected $3.37 billion to compensate corn and soybean farmers for market price failure.²

The Commission should not discount agricultural trade data that lead to a negative evaluation of the Trans-Pacific Partnership Agreement (TPP).³ TPP agribusiness advocates extol projected export increases while asking the Commission to model tariff-line specific import impacts.⁴ The Institute for Agriculture and Trade Policy (IATP)⁵ requests the Commission to use current methodologies for evaluating the agri-environmental, social and labor cost impacts of trade liberalization in the TPP.⁶ We urge the Commission not to externalize TPP agriculture input and food trade-related costs, particularly in sectors such as dairy where imports are redundant to the huge surplus in U.S. and global dairy production.⁷

The Commission also should also evaluate U.S. regulatory capacity and resources to safely manage agricultural trade derived not just from current technologies, but from emerging technologies, such as agri-nanotechnology and synthetic biology. The terms of the TPP chapter on Sanitary and Phytosanitary Measures (SPS), weak U.S. capacity to manage TPP trade safely and the consequences of that diminished capacity is the focus of the following analysis.

Building on or weakening the WTO SPS Agreement?
Like the confidential U.S. Trade Representative industry dialogues and the intergovernmental negotiations that produced the TPP SPS chapter and revealed nothing substantive about it to the public, the text of the TPP 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.

U.S. environmental, health and safety regulatory agencies are under a Congressional budgetary and agency mandate siege to eliminate “unnecessary” regulations and expedite commercial approval of a broad array of products and to incentivize innovation, which is assumed, wrongly, to be thwarted by regulation.8 One result of the failure to adequately fund the Food Safety Modernization Act (FSMA) is that the Food and Drug Administration conducted less than a third of the foreign food facilities inspections required under the FSMA.9 Part of the food safety “modernization” demanded by the Grocery Manufacturers Association and other industry groups is to replace port of entry product inspection and testing with the auditing of foreign food export facilities to determine their compliance with FDA requirements. Under the FSMA’s Voluntary Qualified Importer Program (VQIP), export facilities deemed to comply could pass through ports of entry with reduced inspection and testing intensity.10

It is therefore alarming that the FDA is unable to complete even the initial audits required from 2011–2017 by the FSMA (Section 308 c). Furthermore, the food and agribusiness industry lobbied the Office of Management and Budget to strike regulatory service fees, including those of the VQIP, from the FY 2017 budget.11 The food industry rejected regulatory user fees in President Obama’s proposed FY 2017 budget increase for the FDA’s food safety program, including $25 million to implement the FSMA, a tenth of what Representative Rosa DeLauro said would be the cost of full implementation.12

If U.S. food and agriculture imports were not projected to increase under the TPP—20 percent for dairy imports by 202513—and if the FDA’s food inspection rate were not “appallingly low” due to successive budget cuts over 35 years, according to its Science Board,14 then there might be less cause for regulatory concern about the TPP. However, “[I]n 2012, about one-third of all fish and seafood imports came from TPP countries”5 and that portion is expected to rise dramatically under the TPP.16 Ninety federal inspectors conducted physical inspections but did laboratory testing on far less than one percent of 5.2 billion pounds of imported fish in 2011.17 The Centers for Disease Control identified imported foods as the source of 18 of 120 foodborne illness outbreaks in 2015, but also estimated that only three percent of U.S. food-borne illness was reported to authorities, usually that which required hospitalization.18
Despite this massive under-reporting of U.S. foodborne illness, health related costs of. Acute foodborne illnesses in the U.S. have been estimated at $93.2 billion annually.\textsuperscript{19} Expediting increased agricultural imports from TPP countries almost certainly will increase that cost, whether or not FDA requires U.S. food importers to strengthen their notoriously weak food traceability systems to identify the source of foodborne illness or food mislabeling.\textsuperscript{20} Only about one half of a percent of pathogen-caused foodborne illness can be traced back to a specific food,\textsuperscript{21} due in part to the weakness of U.S. traceability.

How does this grim numerical recitation of FDA’s capacity, or lack thereof, ensure the safety of imported food apply to the provisions of the TPP? Members of Congress, at the behest of their agribusiness and food industry constituents have demanded that the USTR negotiate “fully enforceable” TPP (and the Trans-Atlantic Trade and Investment Partnership) SPS measures, to the point of applying private arbitration investor tribunals under TPP’s Investment Chapter to SPS disputes.\textsuperscript{22} However, short of the “nuclear option” of launching or threatening to launch an Investor State Dispute Settlement lawsuit against a TPP member, the TPP provides many measures to pressure importing country authorities to accept exports.

For example, U.S. agribusiness exporters believe that TPP’s Rapid Response Mechanism (Article 7.11 paras. 6–8) “is a win for U.S. agriculture,’’ because it “requires faster, more structured notifications for SPS incidents as well as a tighter timeframe for reaching resolutions” \textsuperscript{23} e.g. concerning an unquantified “low level presence” of unauthorized Genetically Modified Organisms. (“Trade in Products of Modern Biotechnology,” is located in the National Treatment and Market Access chapter, Article 2.27, to be discussed in the next section of this short comment.) However, there is good cause to believe that the Rapid Response Mechanism can and will be used challenge U.S. inspection and testing of perishable agricultural goods, particularly seafood and produce.\textsuperscript{24} Furthermore, the huge increase in food additives and related chemicals will not be limited to U.S. produced food. FDA’s deputy commissioner for food Michael Taylor declared “We simply don’t have the information to vouch for the safety of these chemicals” that the food industry adds to food without FDA knowledge, much less regulation.\textsuperscript{25} TPP member use of national treatment and market access requirements will pressure U.S. officials to allow imports of food products with food additives about which FDA has little to no knowledge.

\textit{Low Standard of Scientific Data in TTP Risk Assessment}\textsuperscript{26}

In the TPP SPS chapter, there is an Article that encapsulates the U.S. 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, judged 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 were a trade dispute that centered on the Maximum Residue Level for glyphosate, a globally traded herbicide product. Evidence in such a dispute would include glyphosate’s regulatory history relative to the “reasonably available and relevant scientific data” standard. In 1985, the U.S. Environmental Protection Agency (EPA) had “classified glyphosate as a possible carcinogen,” but reclassified glyphosate as non-carcinogenic in 1991 following the submission of new data by Monsanto, the herbicide’s manufacturer. The EPA has not done a full risk assessment of glyphosate since 1993. Fast forward to the EPA’s June 29, 2015 weight of evidence report on whether glyphosate harms hormonal development, including that of humans, i.e. whether or not it is an endocrine disruptor. Endocrine disorders include diabetes, sexual dysfunction, growth disorders and thyroid disease. Some endocrine tumors are cancerous.

The EPA relied largely on 27 studies submitted by Monsanto, half of them unpublished, to conclude that the agency had sufficient evidence to determine that Monsanto’s RoundUp, the trademark for glyphosate, is not an endocrine disruptor. A crucial element in this determination was the 2014 cut-off date for reviewing scientific literature, one of nine criteria for excluding evidence from the weight of evidence report.

In July, the International Agency for Research on Cancer (IARC) released its full report that characterized glyphosate as “probably [a] human carcinogen,” after having vigorously debated whether the herbicide should be classified as a “known human carcinogen.” The EPA has said that it will take the IARC findings into consideration when it issues a “Proposed Interim Decision” at least seven years after it began its reassessment of glyphosate in 2009. If the decision is adverse to Monsanto and other glyphosate manufacturers, they can submit new studies, including Confidential Business Information, to reverse the adverse risk assessment, as they succeeded doing 25 years earlier.

The very low TPP standard for the use of scientific data in risk assessment will pose growing costs of import rejections for exporters and greater risks to consumers of imports under that standard as the scientific complexity of food and agriculture products increases. 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 risks not contemplated in the SPS chapter or in Article 2.27 on “Trade in Products of Modern Biotechnology” in the Market Access and National Treatment Chapter. 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. If the TPP were to enable trade in products of synthetic biology, following the Article 2.27 approach to facilitate trade of “low level presence” of products of modern biotechnology unapproved in the importing TPP member, it is doubtful that the competent authorities of the prospective TPP members 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 (HGT) of synthetically modified organisms (SMOs).38 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. The same lack of bio-safety containment will apply to fish and animals modified by gene drives and other techniques.

The TPP would entrench the voluntary consultation with industry commercialization applicant approach of the 1986 U.S. Coordinated Framework for the Regulation of Biotechnology (CF). Currently, Federal agencies do not ensure the safety of the products of biotechnology under the guidance provided by the CF.39 For example, the Food and Drug Administration (FDA) does not vouch for the safety of the products of biotechnology. Rather, the agency informs the commercial applicant that it has reviewed such data and summaries of applicant studies as the applicant voluntarily submits. Then it writes to the applicant, for example: “Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different in composition, safety, and other relevant parameters from corn currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. ... as you are aware, it is Monsanto’s responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements” (FDA Letter, 1996).40 The product, or more precisely, the transgenic “event,” is then deregulated without any post-approval monitoring of how the “event” performs when it or a similar “event” is reproduced as a transgenic seed. FDA and other U.S. agencies delegate to the applicants the responsibility for ensuring the safety of products derived from biotechnology.

However, applicant claims about the safety of their products41 are not based on science, at least not on peer-reviewed science that is validated in post-market safety assessments of products of biotechnology. For example, in 2002, the National Research Council concluded, “claims concerning the lack of effects from the tens of millions of hectares of transgenic crops that have been planted in the United States during the last three years...
are nonscientific. There has been no environmental monitoring of these transgenic crops, so any effects that might have occurred could not have been detected.” The regulatory decision to not monitor transgenic crops is likewise not the result of a positive determination of the safety of transgenic crops by Federal scientists on the basis of review of mandatory submissions of applicant data and information as specified by the relevant agencies.

Conclusion
It would be tragic for U.S. farmers and consumers if the TPP were approved by a Congressional majority hell bent on weakening environmental, health and safety regulators through a thousand budget cuts and policy riders. The parameters of the Commission’s analysis may not allow for a full analysis of the costs of deregulation and non-regulation of the food and agribusiness industry under the TPP. IATP hopes, nevertheless, that the analysis and sources presented in this short comment will aid the Commission in doing a full cost analysis of the TPP SPS chapter.


5 The Institute for Agriculture and Trade Policy (IATP) is a nonprofit, 501(c)(3) nongovernmental organization, headquartered in Minneapolis, Minn., with an office in Washington, D.C. Our mission states, “The 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.”

The budgets and mandates of U.S. agencies with statutory SPS obligations are under sustained attack, often by TPP proponents, such as the U.S. Chamber of Commerce. 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


11 Joan Murphy, “Food industry urges OMB, HHS not to revert to FSMA user fees in FY 2017 FDA budget plan,” Food Chemical News, August 28, 2015.


16 Ibid.


19 “High Cost of Food-Borne Illness: New Study Provides State-by-State Breakdown.” Ohio State University press release, June 3, 2015. http://cfaes.osu.edu/news/articles/high-cost-foodborne-illness-new-study-provides-state-by-state-breakdown This study, by former Food and Drug Administration economist Robert Scharff, employs FDA’s methodology, which includes Quality of Adjusted Life Years (QALYs). The U.S. Department of Agriculture methodology for estimating the cost of foodborne illness does not include QALYs, and so estimated medical costs of non-fatal food-borne illness at $14.1 billion in 2012. See


26 The first four paragraphs of this section are taken from the TransAtlantic Consumers Dialogue resolution on the TTIP SPS chapter, for which I was a co-author. http://tacd.org/wp-content/uploads/2015/01/TACD-Resolution-TTIP-SPS -GREEN_rev0216.pdf


29 http://www.webmd.com/diabetes/endocrine-system-disorders

30 http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Endocrine/Endocrinetumours.aspx


33 http://www.globalresearch.ca/international-agency-for-research-on-cancers-full-report-on-glyphosate-monsantos-roundup/5465798


41 E.g. David Schultz’s interview with Phil Miller, Monsanto’s vice president for global and regulatory affairs, Chemical Regulation Reporter, Bloomberg BNA, November 9, 2015.