INSTITUTE FOR AGRICULTURE AND TRADE POLICY

Analysis of the draft Transatlantic Trade and Investment Partnership (TTIP) chapter on food safety, and animal and plant health issues (proposed by the European Commission, as of June 27, 2014)

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Trade agreements have a profound influence on how regulations to protect public health and how we produce food are developed, implemented and enforced or not enforced. U.S. and EU food safety regulations in the U.S. and the EU often set the bar for such standards around the world. There is much at stake in the wording of trade agreements, but remarkably, draft negotiations texts remained undisclosed to the public affected by the trade related food safety chapters in those texts. Instead of a public debate about appropriate protections for health and the type of agriculture we want, these negotiations are taking place behind closed doors, and heavily influenced by corporate trade advisors whose employers are the main beneficiaries of the trade agreements. This is a perverse approach to trade negotiations, forcing the public to read between the lines of leaked, partial texts. This leaked draft TTIP chapter doesn't tell us everything about where negotiations are headed on food safety, but it tells us enough to raise serious concerns.

IATP is one of more than 250 organizations that signed a letter to the European Commissioner of Trade, Karel De Gucht, demanding that the European Commission increase the transparency of TTIP negotiations, by among other measures, releasing for comment draft texts of the TTIP chapters following the conclusion of each round of negotiations.[1] IATP reiterates that demand and expands it to include the Office of the U.S. Trade Representative, which has held minimal public consultations on TTIP but has refused to release draft negotiating texts. Trade policy, because it requires that all national regulations protecting public health, the environment and worker safety, be subject to a "least trade restrictive" requirement, is simply too important to be left to government officials of the executive branch and corporate advisors.

TTIP language and consumer food safety concerns

The language of trade agreements is not consumer friendly. Concrete concerns about food safety are rendered abstract in the recently leaked draft TTIP chapter on Sanitary and Phytosanitary (SPS) issues. For example, consumer questions, raised at the July 14-18 round- of TTIP negotiations in Brussels, about the effect on European 'farm to fork" food safety programs, if the EU were to allow U.S. exports of chemically rinsed poultry are nowhere answered in the draft.[2] Consumers who expect to discover in the draft SPS chapter where the negotiations stand on specific consumer concerns, such as the non-therapeutic use of veterinary drugs like antibiotics allowed in U.S. meat and poultry production, or the import and labeling of food containing genetically modified organisms, will be disappointed.

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Instead, trade agreement SPS language about food safety, animal health and plant health outlines the general terms for enabling trade while complying with "the importing Party's appropriate level of protection." So, for example, unless the European negotiators object to the use of Maximum Residue Level (MRL) of a specific pesticide on imported grain or a specific veterinary drug in the production of imported meat, without creating "unjustified barriers to trade" (Article 2, paragraph 2), the TTIP regards that product as having an "appropriate level of protection" to enable importation and consumption of the product. Determination of MRLs and other metrics of what is "appropriate" happens in a domestic regulatory process, in which, at least in the U.S., much of the relevant data is classified as Confidential Business Information. Additionally or alternatively, those metrics can be set by international standard setting bodies, such as the Codex Alimentarius Commission, referenced in the TTIP draft. And given significant industry presence in Codex—these standards are often at the low end of consumer protection.

The draft SPS chapter requires TTIP Parties to adopt Codex standards "[within 12 months] (the brackets signify disagreement) "unless the importing party signals a reservation" (Article 8, paragraph 3). The European Commission uses the "unless" proviso, so that European Union members states would not be obliged to import U.S. meat grown with ractopamine, a veterinary drug banned in the EU but approved by the U.S. Food and Drug Administration (FDA) for use in the United States. Codex adopted a ractopamine MRL by an extraordinary and controversial vote on the basis of a risk assessment involving a half dozen 20 year old studies.[3] The U.S. meat industry, on the other hand, has made it clear that the EU ban on ractopamine has to be removed as a concrete outcome of the negotiations and thus this "carveout" will be subject to further controversy from the U.S. side.[4]

Tensions among trade promotion officials and SPS regulators

The draft SPS chapter, dated June 27, 2014, both reveals and obscures how food safety and animal and plant health regulation will fare under the TTIP, if it becomes binding trade law. Much of the obscurity resides in at least nine Annexes alluded to the SPS chapter, which have not been leaked and/or not yet negotiated. There are also fundamental contradictions inherent in mandating **"least trade restrictive"** norms to the implementation and enforcement of SPS regulations that otherwise would seek to optimize public health.

The tension between TTIP negotiators seeking to maximize trade and SPS regulators with statutory duties to protect human, plant and animal health have escalated to the point where the FDA is trying to remove transatlantic SPS regulatory cooperation and harmonization provisions from TTIP. According to a July 16 article in *Inside U.S. Trade*, industry sources ascribe the FDA initiative to traditional regulatory turf wars with the presidential Office of the U.S. Trade Representative (USTR).[5] The most proximate causes of the FDA resistance to trade policy imperatives appear to concern transatlantic audits on good manufacturing practices for medicines and Grade A dairy classification.

EU objectives for the TTIP SPS chapter

Provisions in the leaked draft SPS chapter suggest that there are other reasons for TTIP negotiators to remove SPS harmonization and cooperation provisions from trade negotiations. A prefatory note to the chapter states, "The main objectives of this draft SPS chapter, which reflect the comments provided by [EU] Member States, industry and other associations during the preparatory phase" include "Respect of the Right to Regulate"; "Systems Recognition under the [U.S.] Food Safety

Modernization Act" (FSMA); "Prominent coverage of animal welfare"; "A paradigm change on the plant health import regime of the U.S." and "Transparency." The draft offers varying degrees of clarification on each of these objectives and related matters.

The "Respect of the Right to Regulate" is the first objective listed in the brief cover note, prefacing the draft chapter, from European Commission negotiators to members of the Trade Policy Committee. However, an unqualified Right to Regulate is stipulated nowhere in the draft itself. Instead, the first objective in Article 2 is to"[f]acilitate trade between the Parties to the greatest extent possible." This objective is then immediately qualified by the proviso of "preserving each Party's right to protect animal or plant life or health in its territory and respecting each Party's regulatory systems, risk assessment, risk management and policy development processes." How this right is preserved under pressure, for example, to maximize U.S. poultry exports to Europe, is subject to details contained in the yet to be agreed Annexes, which presumably will go beyond the WTO SPS chapter and annex terms for recognizing the "equivalency" of SPS laws, regulations and enforcement measures.

"Systems recognition" under the FSMA: Removing port of entry re-inspection and testing from food safety management requirements

The European Commission has raised questions about the import requirements of the U.S. Food Safety Modernization Act (FSMA) since President Obama signed the law in January 2011. In 2013, the FDA issued its rule to ensure foreign supplier verification of compliance with FDA food import requirements. FSMA implementation in general and of imported foods in particular has been stymied by transnational corporate refusal to pay for the food facilities inspection fees for supplier verification proposed by the Obama administration.[6] Entailed in the FDA rule is "Systems recognition" under the FSMA, which, in a TTIP context, refers to mutual recognition of U.S. and EU food safety management systems as equivalent.

As IATP began to report in 2008, industry has long sought to replace verification of food safety management performance by port of entry inspection of products with export food facility certification, by governments or third parties, verified by audits of facilities.[7] The terms of certification and auditing to verify SPS system equivalence are outlined in Article 12 of the draft. In Article 9, paragraph 1, industry, and particularly the Grocery Manufacturers Association, has gotten its wish to eliminate port of entry inspection and testing results as a factor in the SPS systems equivalence determination.[8] According to the draft text, recognition of SPS systems as "equivalent" by TTIP Parties will occur **"without a need for individual re-inspection [of products] or other additional guarantees.** (our emphasis) Nevertheless, Parties are allowed to inspect for the "interception of regulated pests," such as plant diseases and invasive species (Article 14, paragraph 3).

But if the foreign suppler verification program is poorly implemented, whether due to budget cuts or personnel failings, but TTIP "systems recognition" of SPS equivalence is determined to exist diplomatically , well, food, food ingredient or feed buyer beware. Import re-inspection and testing at port of entry, traditionally the last step in food safety management to verify that other programs are working, will disappear under this draft of the SPS chapter.

The elimination of port of entry re-inspection and testing will not cause much change to U.S. import food policy, since, there is little port of entry re-inspection and testing. For example, according to a 2007 Food and Water Watch report, the FDA tests only about .6 percent of seafood shipments, a relatively high risk for contamination food.[9] In 2012, the European Commission required physical inspection of 20 percent of seafood import shipments for exporting countries determined to have

SPS equivalence for seafood.[10] In sum, the elimination of a port of entry re-inspection and testing requirement for TTIP equivalence determinations represents a sea change in EU SPS policy, one that is not likely to be popular with European consumers.

Rationales for eliminating food re-inspection and testing in TTIP

The industry rationale for eliminating re-inspection and testing is not just to expedite more food trade more quickly. Detaching re-inspection and testing from SPS systems equivalence determination provides a layer of government verified and certified food safety management insulation from liability for exporting or importing contaminated products. Under the draft chapter, exporting and importing companies may be less vulnerable to loss of brand value, sales and reputation, due to discovery of contaminated or adulterated food or agricultural products resulting from port of entry product inspection or testing. If the government of the importing Party to TTIP has verified that food facilities of an exporting Party meet government requirements for importing safe and wholesome food, food ingredients and feed, the non-inspection and non-testing of food and feed products is irrelevant in this version of the TTIP.

It may be possible to trace back contaminated or unwholesome food back to an import expedited but uninspected consignment of products that are subsequently distributed throughout the territory of the TTIP Parties. According to an April 18 article in *Food Chemical News*, Mike Taylor, FDA's deputy commission for foods and veterinary medicine, has told industry stakeholders not to depend on FDA regulation to enable food traceability programs.[11] The traceback of contaminated or unwholesome food will be lead by industry or not.

It will be very difficult for individual consumers or consumer organizations to hold governments legally liable for food exporting facilities certification, verification and auditing failures. Because of inspection and testing results, there is evidence that can be used to sue a company for producing and exporting contaminated food, although many such cases are settled out of court under terms that prevent disclosure of much food contamination outbreak information. But, in the U.S., a "doctrine of deference" to regulatory authorities prevails in federal courts, unless a regulatory action is judged to be an arbitrary and capricious violation of statutory or constitutional law.[12] If the regulatory action is to rely on certification and auditing of foreign food facilities, without inspection or testing at port of entry to demonstrate they comply with U.S. SPS requirements, the failure of a certification and auditing program may result in a new regulation or even new legislation. However, TTIP mandated food facilities certification without product inspection will not require consumer redress for government actions or decisions not to act that resulted in the exporting of contaminated food products.

Article 14 on "Import checks/fees" does not refer to fees for inspection check of products but fees for administrative checks to see that documentation about whole consignments of products conforms to the terms of the certification of export facilities as having equivalent SPS management systems. Annex IX "sets out the principles and guidelines for import checks and fees." The rates and terms for payment of fees for such checks will be a contentious issue, insofar as U.S. industry has rejected all FDA proposals that it should pay for the certification of export food facilities.

As IATP has reported in its *Global Food Safety Monitor*, U.S. industry has long refused to pay for the trade expediting export facilities certification/ no food inspection system that it wants, calling such fees a "general tax" on the food industry.[13] Evidently U.S. industry will have to change its "no new taxes"

mantra, if it is to satisfy the conditions outlined in draft Article 14 and Annex IX. The only guidance for setting fee rates in draft Article 14 is "Any fees imposed for the procedures on imported products from the exporting Party shall not be higher than the actual cost of the service" (paragraph 5).

Agricultural animal welfare issues

"Prominent coverage of animal welfare" refers to "best endeavor" (we will try), not binding ("shall") measures to prevent trade in livestock products from animals that have been abused. For example, Article 11, paragraph 1, states "The Parties recognize that animals are sentient beings. They undertake to respect trade conditions for live animals and animal products that are aimed to protect their welfare." So, while this aspirational language is perhaps new in a trade agreement, it is designed to be unenforceable. There will be no requirements that Parties mandate compliance with animal welfare laws as a condition of being able to trade in animal agriculture products.

In the United States, where a proposed and controversial "Right to Farm" amendment to a state (sub-federal) constitution would pre-empt enforcement of U.S. animal welfare laws, a TTIP requirement to protect animal welfare for livestock products in order to trade is a nearly politically impossible TTIP outcome.[14] A U.S. state or EU member state could pass mandatory laws or rules on agriculture animal welfare, but such mandatory measures could not be used to prevent import of products from abused animals under the non-binding language of Article 11, paragraph 1.

Article 1 terminates the U.S.-EU cooperative agreement on animal health and veterinary practices, once TTIP becomes binding law. Instead, the draft would direct the governments to eliminate existing enforceable bilateral cooperation and instead focus on new language in international fora. "Parties undertake to collaborate in international fora [above all, the World Animal Health Organization] with the aim to promote the further development of good animal welfare practices and their implementation" (Article 11, paragraph 4). This provision reflects the status quo in the World Trade Organization SPS agreement.

Plant health issues: a "paradigm change?"

On the basis of the leaked draft text, it is difficult to discern the "paradigm change on the plant health import regime of the U.S." that EU trade negotiators see as an objective achieved in the draft the SPS chapter. There is, of course, mutual recognition of plant health sanitary measures for traded products, subject to five qualifying sub-paragraphs. These provisos have in common the mutual recognition by the Parties of the concepts of "Pest Free Areas, Pest Free Places of Production, Pest Free Production Sites . . . areas of low pest prevalence, as well as protected zones established by the exporting Party" (Article 10, paragraph 7). The overall import of these sub-paragraphs is to ensure that if a plant disease, e.g. soy rust, is established in one part of the U.S. or in an EU Member State, that it will not prevent exports of soy from areas of low or no incidence of soy rust.

The mutual recognition of plant health regulatory systems is in accord with the prevailing standards of the International Plant Protection Convention (Article 7a), whose work is presumed to be authoritative and binding in the WTO SPS agreement. Importing Parties have "[within 90 days]" (the brackets signify disagreement among the negotiators) to object to an exporting Party's regulatory

decision about what areas are pest free or of low pest incidence (Article 7c). Given this conformity with IPPC plant health standards, save for the short amount of time to object to plant regulatory decisions, it is difficult to detect the aforementioned "paradigm shift" in the U.S. plant health regime.

Enabling trade of animal agriculture products from countries with animal diseases

Trade in agricultural "animals, animal products and animal by-products," such as meat, hides, milk and aquaculture products, such as "farmed" fish, is also subject to a principle of recognition by TTIP governments that the incidence of an animal disease, such as swine fever or Mad Cow disease, in one area of a country cannot be used to ban or otherwise qualify trade from another area that is deemed to be disease free. In the WTO SPS chapter, this principle of "regionalization" of trade in animal agriculture products is governed by the standards of the World Animal Health Organization (OIE in its French acronym). However, according to the draft chapter, "The importing Party shall recognize for trade the health status of zones, as determined by the exporting Party, with respect to the animal and aquaculture diseases specific in [Annex II]" (Article 10, paragraph 2).

The criteria for such recognition are stipulated in a yet to be negotiated Annex III. Paragraph 4 stipulates language about information the importing Party may demand of the exporter. Paragraph 5 references OIE standards in the context of "additional guarantees" of trade acceptable animal health status for diseases not in the Annex II list. However, the burden of proof is clearly on the importing country's authorities to demonstrate why they cannot accept the animal "health status" of a region in the exporting country, as determined by authorities in that country. Depending on the disease in question, that demonstration may be difficult to sustain without causing a trade dispute if the disease is not easily transmissible, particularly from animals to humans.

Administering the SPS chapter and resolving SPS disputes under TTIP

Once trade negotiations are completed, the resulting agreements are overseen by standing Committees that meet on a regular basis to help the regulators of Parties to the agreement to interpret and implement it. Perhaps the most important function of such Committees is to hear and attempt to mediate complaints, in this case about trade related SPS issues, before those complaints become the subject of formal trade disputes. (The victors in dispute settlements are entitled to demand compensation form the loser, although such compensation may be slow in coming or not at all, as in the latest $147 million in annual payments due from the United States to Brazil, as a result of the U.S. Upland Cotton Subsidies dispute.[15])

The implementation of the TTIP SPS chapter is to be overseen by a Joint Management Committee (Article 18). The functions of the Committee are similar to those of the WTO SPS Committee, which is composed of member government SPS and trade officials. Although the WTO SPS Committee meetings are closed to the public, the WTO secretariat does publish meeting minutes and annual reports of Committee member trade concerns about the SPS regulations in member countries. There is no mention of transparency measures in draft Article 18.

The TTIP SPS Committee is to review the as yet un-negotiated or at least undisclosed Annexes to the draft chapter (Article 18, paragraph 2d). To judge by the paragraphs in brackets, the most contentious issue for the Joint Management Committee will be its relation with the TTIP Oversight Body, once the terms for that Body are agreed in an Institutional Chapter (paragraph 9). If the Committee is unable to resolve a trade related SPS complaint "expeditiously, the Committee shall, upon request of

a Party report promptly to the [TTIP Oversight Body]" (paragraph 6). The brackets appear to indicate that the Commission is willing to negotiate about to whom the Committee should report, if it cannot resolve a trade related SPS complaint.

It is also unclear from this text what link the SPS chapter will have to a broad and comprehensive Regulatory Cooperation Chapter under TTIP—the latter with likely more sweeping ramifications with the way new rules and legislations related to various issues, including food safety, are vetted under TTIP. An EU position paper on the chapter suggests that its scope would also apply to rules and legislations of EU member-states and U.S. states with a Regulatory Cooperation Council set up as part of its implementation process.

Prospects for Investor State Dispute Settlement (ISDS)

The SPS chapter says nothing about what the Oversight Body would do to resolve a SPS related dispute nor whether such adispute would be subject to the extremely controversial Investor State Dispute Settlement (ISDS) mechanism. Under the ISDS, the SPS "measure" (regulation, law, court ruling, manner of implementation and enforcement) of a Party could be charged by a private "investor" to have "impaired" the investors' anticipated TTIP benefits. A private tribunal, not a public court, would evaluate the investor's complaint and decide whether a TTIP Party would have to compensate the investor for loss of the anticipated benefit and/or change the investor offending "measure" to conform to TTIP. ISDS is so controversial in the EU that Germany announced in May its opposition to including an ISDS chapter in TTIP[16] and the Commission itself has just completed an online consultation on the issue[17] which received an unprecedented response—a total of 149,399 submissions.[18]

The US Trade Representative has thus far resisted industry lobbying and Congressional pressure to make TTIP SPS measures "fully enforceable" by making them explicitly subject to the ISDS. Alternatively, TTIP dispute settlement could require that the TTIP Parties themselves commit to making SPS measures "fully enforceable" in domestic courts of law. However, demands for industry specific exemptions ("carve-outs") from ISDS, e.g. tobacco advertising restrictions to protect public health have been resisted in other Free Trade Agreements, so the negotiations to agree on ISDS carve-outs, will be highly contentious.[19]

Transparency in a non-transparent negotiation

Last but not least among EU negotiator objectives, the draft TTIP SPS chapter strives for "transparency" among regulators about SPS measures (Article 15). One Party "shall notify the other Party without delay" of a broad array of "significant changes" in SPS measures and in the status of plant and animal diseases related to products traded among the Parties (paragraph 1). However, when TTIP Parties implement SPS controls to prevent, contain or eradicate animal or plant health disease or food borne illness, they are required only to "endeavor to exchange information" (paragraph 2 a).

The difference between these two paragraphs is striking. SPS regulatory and legislative measures which could impede trade must be reported without delay. Information about the implementation and enforcement of SPS control measures may or may not be exchanged. How, under the terms of this

draft, are the Parties to judge whether the SPS measures on paper are effective when implemented and enforced as SPS controls? One of the "significant changes" that Parties are not required to report are changes in SPS agency budgets and staff levels to enable implementation and enforcement.

Conclusion: the high public health cost of food safety regulatory failure

Trade-related SPS measures are proto-typically about standards, not about whether or not those standards are implemented and enforced. Failure to implement and enforce SPS rules, whether for imported or domestic foods, comes at a very high cost, even just in monetary terms. In 2012, the U.S. Centers for Disease Control estimated that foodborne illness caused by 14 major pathogens cost the United States $33 billion annually in hospital costs, loss of life, loss of qualify of life, and loss of workers' hours.[20] Also in 2012, the Obama administration proposed that the food and agriculture industry pay $220 million in food export facility inspection and certification fees to facilitate trade in $49 billion of FDA regulated food import products and $417 billion of domestic food products.[21] The industry has refused and continues to refuse to pay the food facilities inspection fee, claiming that the fees for trade facilitation service are an unfair general tax. Food facilities inspection verifies the export and import certification systems to enable trade facilitation. Even if U.S. and EU SPS rules were not subject to "least trade restrictive" criteria, failure to pay for the facilities inspection that replaces port of entry inspection and testing requirements in TTIP, ensures that TTIP will not work to protect consumer, animal and plant health.

The draft leaked TTIP SPS chapter, incomplete as it is without annexes, gives much cause for concern about the subordination of SPS measures to trade maximization objectives stated explicitly in the draft (Article 2, paragraph 1). The concern grows to anxiety when put in the larger context of the lack of requirements in the TTIP to implement and enforce SPS measures with budgets and personnel adequate to protect human, plant and animal health. The FDA's aforementioned attempt to strip regulatory harmonization and cooperation provisions out of the TTIP is surely a sign of that anxiety. Industry dogma that consumer demands are irrational, while its demands are rational and justified by "science" whose data is subject to extensive Confidential Business Information claims, will not allay that anxiety. As long as industry and government make TTIP SPS law whose content is only revealed in the occasional leaked text, there will be little opportunity for the citizens affected by trade related SPS measures to improve public health outcomes of traded food products.

Disclosure of draft TTIP negotiating texts is not a panacea for protecting health, environment or worker safety. The texts are not easy to analyze, and their likely modes of implementation, in concert with international standard setting bodies, provides further interpretive problems. Furthermore, influencing the development, implementation and enforcement of SPS standards, laws and regulations, whether U.S., EU or international, is a technical and expensive business. Even with disclosure of negotiating texts, industry lobbies remain vastly better resourced and connected to the government officials who may have worked and/or will work in the regulated industries. But no trade negotiations process can have public support when trade policy officials limit, as they do now, the non-corporate public to "listening sessions" and other forms of non-reciprocal input. The opportunity for the non-corporate public to influence the terms of the trade policy that affects their lives begins with timely and full disclosure of the draft negotiating texts and preparatory documents.

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