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### About IATP

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# Food Import Re-Inspection and the “High Standards” of 21<sup>st</sup> Century Trade Agreements

**MINNEAPOLIS, OCTOBER 6, 2015** — Proponents of the Trans-Pacific Partnership (TPP) and Transatlantic Trade and Investment Partnership (TTIP) agreements often refer to the “high standards” that are reportedly contained in the draft negotiating texts.<sup>1</sup> There is no way to verify U.S. proponent claims about any of the “high standards” because access to the negotiating proposals of the U.S. Trade Representative are very restricted, with threats of severe penalties for disclosure in the ‘fast track’ Trade Promotion Authority bill signed on June 29 by President Barack Obama.<sup>2</sup> While Wiki-Leaks has published several draft TPP texts,<sup>3</sup> the chapter concerning **Sanitary and Phytosanitary Measures (SPS)**, covering food safety and the health of traded plants and animals and their byproducts, is not among them.

Fortunately, however, the European Commission, following the leaking of several proposed TTIP chapters, decided in January 2015 to publish most of its TTIP draft negotiations texts, including its SPS proposal.<sup>4</sup> Under this version of the SPS chapter, food and agriculture product re-inspection and testing at the port of entry would be considered “redundant” and banned (Article 8), except in “exceptional cases” (Article 13).<sup>5</sup> Inspection for invasive species would be allowed. The **inspection** status of “new trade” in **food** and **agricultural** products is not clear from the draft.

Trade agreements are designed to facilitate trade and, as a result, presume SPS measures to be potential trade barriers until and unless they are proven “necessary” to achieve a specific **regulatory goal**. To judge by the European Commission’s TTIP proposal to ban food re-inspection as a “redundant control,” re-inspection is no longer “necessary” to achieve the “appropriate level of Sanitary or Phytosanitary protection” as determined by the authorities of the importing jurisdiction (World Trade Organization SPS Agreement, Article 5). How does the attempt to balance the market entry objectives and the “appropriate level of protection” objectives work in practice?

## Why re-inspection? Why has it become controversial?

Import **re-inspection** is a traditional step in food safety management. Under current rules, the USDA and FDA can inspect both export facilities in the originating country and food as it arrives at U.S. ports. If re-inspection rates, fees, personnel and infrastructure are adequate, re-inspection can prevent contaminated, mislabeled, unlabeled and/or fraudulent food from entering into the food supply of the importing jurisdiction.<sup>6</sup> Re-inspection regimes can also expedite food and agriculture product traceability in the event that a contaminated or mislabeled consignment of products eludes the re-inspection system. Port of entry re-inspection provides an additional food safety control, which is particularly important if the inspection system of the exporting country is substantively weak, even if that system is characterized, according to bilateral negotiations in trade agreements, to be “equivalent” to that of the importing country. In practice, inspection and testing systems are often understaffed and underfunded at both the point of export and in U.S. ports, so the re-inspections are far from a redundant measure.

Re-inspection and inspection of food export facilities has become a political pawn in the TPP negotiations. A U.S. Department of Agriculture rule on catfish inspection and catfish export facilities inspection may be held up by the Office of Management and Budget, at the request of the U.S. Trade Representative, following lobbying by Vietnam, a major catfish exporter and a prospective TPP member. The USTR is concerned that adopting an export facilities rule and/or import rule with which Vietnam could not comply would imperil the tradeoffs required to complete the TPP negotiations. For example, an inability to satisfy a U.S. Maximum Residue Level of a veterinary drug used in catfish production could result in import rejection or, in the case of chronic infraction, an import ban. Vietnam has threatened to keep its ban on U.S. beef imports, if market access for its catfish exports is restricted due to inspection and other SPS rules.<sup>7</sup> The Food and Drug Administration has authority over all other seafood; the Congressional grant of authority to the USDA over catfish is, of course, not a science-based decision, but one originating in Congressional committee politics.

## Difficulty in estimating the impact of no food reinspection on consumer protection

It is difficult even to estimate quantitatively what the food specific impact of a ban on or even limitation in the rate of food import re-inspection would mean in terms of the consumer risk of acquiring foodborne illness. Despite the severe and long term health consequences triggered by specific pathogens, in the United States “outbreak illnesses are linked to a suspect/confirmed food on only 0.05 percent of the estimated 47.8 million U.S. annual foodborne illnesses,” according to a 2013 study by retired USDA economist Tanya Roberts.<sup>8</sup>

Dr. Roberts does not analyze why the U.S. government’s outbreak illness data is so poorly linked to specific foods, but her proposed solutions to the poverty of U.S. food safety data imply a lack of food industry cooperation with regulatory agencies concerning timely food recalls and trace-back of contaminated food, due to industry liability concerns. She proposes “to create a new farm-to-table database to trace types of pathogens to specific farms, food companies, and products, hopefully with the cooperation of industry and inclusion of company data.”<sup>9</sup> To secure that cooperation, the data would be anonymized to make it useful for government regulators trying to target food safety measures at certain foods, while preventing trial lawyers from using such data to prosecute companies for negligence or even strict liability for specific foodborne illness incidents.

Remarkably, the USDA can only recommend, but not require, manufacturers of contaminated poultry, meat and egg products to recall those products from retail outlets. Following an outbreak of Salmonella-contaminated chicken, during which the USDA did not recommend recall for more than a year, because it does not consider *Salmonella* to be an adulterant, legislation was introduced in May to grant the USDA mandatory recall authority for meat, poultry and egg products contaminated by any pathogen.<sup>10</sup>

USDA’s Food Safety Inspection Service, in rejecting a Center for Science in the Public Interest petition to declare Salmonella in ground beef and poultry to be an adulterant, responded, “FSIS does not consider raw meat and raw poultry products, including ground meat and poultry, to be adulterated when they contain *Salmonella* because ordinary methods of cooking and preparing food kill *Salmonella*.”<sup>11</sup> Pathogenic bacteria, such as *E coli*, in food that cannot be killed by “ordinary methods of cooking and preparing” are considered adulterants and subject to **FSIS** regulation.

One USDA researcher considers a policy of zero tolerance for Salmonella to be “the expression of a regulatory preference for the precautionary principle but has little to do with food safety and human health.”<sup>12</sup> If the USDA continues to insist that Salmonella is not an adulterant because declaring it an adulterant would result in an economically unsustainable amount of product recalls, then an equivalence determination on meat hygiene standards under TTIP will have determine what is an “appropriate level” of protection for European Union member state consumers.<sup>13</sup>

Getting product-specific evidence of food contamination for legal redress is difficult in the U.S. civil justice system, according to a September report by the American Association for Justice.<sup>14</sup> For internationally traded food that is contaminated and results in foodborne illness, the process of obtaining probative evidence to hold exporters liable for harm caused by their products will be that much more difficult. The food industry is eager to make to make SPS rules in the 21<sup>st</sup> century trade agreements, which would minimize re-inspection and testing of food products in the port of entry, “fully enforceable” beyond enforcement through the WTO’s government-to-government dispute settlement system. By “fully enforceable” beyond the WTO dispute settlement system, we understand TTIP and TPP proponents to mean subjecting SPS rules to the Investor State Dispute Settlement (ISDS) chapter of the TTIP and TPP. Under the ISDS, private investors could demand both compensation and changes to or elimination of rules that industry claims do not fulfill a legitimate regulatory objective or that discriminate against foreign investors to “nullify or impair” the value of their investment.<sup>15</sup>

## **U.S. poultry inspection and poultry hygiene: a case study in the challenges of harmonizing trade related SPS rules in TTIP or TPP**

According to a Food and Water Watch blog, the USDA’s New Poultry Inspection System (NPIS) allows poultry processors to inspect their own products with a near absence of federal government oversight.<sup>16</sup> Just one USDA inspector would be stationed at the end of the production line to inspect 2.33 chicken carcasses and one turkey carcass per second. Another federal inspector would perform unspecified “food safety activities” not on the production line, including checking on the compliance of plant paperwork with FSIS rules.

It is not clear how the near privatization of poultry inspection and the proposed ban on port of entry re-inspection would be made consistent with food inspection rules of governments that require government employees only to inspect meat, poultry and other food products, to avoid the conflicts of interest inherent in industry self-regulation. However, the non-compliant microbiological testing results of the plants that are being awarded NPIS status raises the question of whether contaminated poultry parts will be exported to TTIP countries banned from re-inspecting them at the port of entry.

The National Chicken Council has demanded that the TTIP negotiations result in an end to European Union member state bans on importing chlorine-rinsed U.S. chicken exports.<sup>17</sup> Decontamination of poultry carcasses by anti-microbial rinses can reduce pathogens, but such rinses are far from a failsafe method. In 2014, the European Food Safety Authority (EFSA) issued a Scientific Opinion on the safety and efficacy of one such rinse, based on data and studies including eight peer-reviewed studies, submitted by the applicant.<sup>18</sup> U.S. poultry exporters are seeking EFSA approval for a poultry rinse that would enable them to export rinsed poultry to EU member states.

The EFSA panel found that the rinse was less effective in killing pathogens when sprayed on the carcasses, the most common form of application in U.S. poultry processing. Given the aforementioned production line speeds, spraying an antimicrobial rinse is the decontamination method that is most compatible with U.S. production speed. Because the commercialization applicant did not present data on pathogen reduction resulting from the slower production methods of dipping carcasses in the chemical rinse, EFSA noted “There were few data on reduction of pathogens for this treatment.”

Spraying the rinse does not reach the inside of the carcass, where remaining fecal matter and viscera host pathogens. The USDA has a pathogenic reduction standard for Salmonella on whole carcasses but not yet on chicken parts. The USDA has just begun to develop a Salmonella standard to apply to chicken parts. A USDA advisory committee claims that *Salmonella* presence in meat, egg and poultry products has declined 20 percent since 1995.<sup>19</sup>

However, consumers usually buy poultry parts, such as chicken breasts, rather than whole carcasses, so the anti-microbial spray may not reach the inside to those parts. The foodborne illness risks of contaminated poultry are such that the USDA advises consumers not to wash poultry parts with water, lest washing spread pathogens, e.g. to vegetables prepared on the same cutting board.<sup>20</sup> Consumer surveys indicate that perhaps 80-90 percent of consumers wash poultry before cooking it.<sup>21</sup> The USDA also advises preparation of meat and non-meat product with separate utensils and cutting boards, to prevent cross contamination of foods by pathogens.

The USDA has good cause to warn about the risk to consumers of washing the already chemically rinsed poultry. In 2013, *Consumer Reports* tested for six pathogens on 316 chicken breasts purchased in 26 states, including chicken from four major chicken processing companies. According to the report, “Enterococcus was the most common bacterium we found, occurring in 79.8 percent of our samples. Next was E. coli, in 65.2 percent of them; campylobacter, 43 percent; klebsiella pneumoniae, 13.6 percent; salmonella, 10.8 percent, and staphylococcus aureus, 9.2 percent.” About half of the sampled breasts “tested positive for at least one multi-drug resistant bacterium.”<sup>22</sup> Given this prevalence of pathogenic bacteria on chicken and the severity of foodborne illness resulting from the consumption of such bacteria, you might assume that U.S. poultry hygiene rules, including inspection rules, would be strengthened and stringently enforced. But you would be wrong.

## **“Modernizing” inspection with computer modeling of pathogen detection data**

In lieu of robust federal inspection and testing of poultry for pathogens and visible defects, the USDA believes that computer modeling of microbiological testing rates derived from its Public Health Information System (PHIS) data will “modernize” the inspection process. However, a USDA Office of the Inspector General’s audit of PHIS in August found that four years after the beginning of PHIS implementation, “FSIS [Food Safety Inspection Service] did not proactively create sufficient internal controls to monitor and evaluate the performance of PHIS, nor did the agency ensure that the system was accessible, operating as designed, and that its data were complete and accurate”.<sup>23</sup> This and other Inspector General criticisms of PHIS may lead even the most fervent believers in privatized inspection for exported as well as domestic food products to question whether the new data system has improved public health outcomes of poultry inspection.

Given the aforementioned production line speeds, the poultry inspectors, both federal and plant, cannot enter inspection data in the PHIS database in near real time, so data is reconstructed at the end of the inspector’s shift. The data entry requirements make it very unlikely that production lines will be stopped during a work shift, even if the two federal inspectors were to find that there were sufficient physical defects in the carcasses and non-compliance with pathogen testing standards to warrant production stoppage.

USDA and Food and Drug Administration product recalls of contaminated foods that threaten public health (Class I recalls) have been increasing since at least 2000. FDA recalls nearly doubled between 2002 and 2012, which might be expected given the increase in ready-to-eat foods, the most frequent source of recalls.<sup>24</sup> Neither the USDA nor the FDA publicize what portion of the food recalls are of imported food. However, industrious data mining and use of the Freedom of Information Act (FOIA) by Food and Water Watch have discovered that imported meat recalls have increased since the Bush administration and that the consignments of recalled meat products had not passed through port of entry import inspection.<sup>25</sup>

Food and Water Watch has likewise discovered that port of entry rejections of imported seafood products, even under the FDA’s mere one percent of shipment re-inspection rate, had increased. (Since European Union member states, pre-TTIP, inspect 20-50 percent of seafood imports, depending on seafood species, it is difficult to imagine how the U.S. and EU inspection rates will be “harmonized” or determined to be equivalent in TTIP.) About 90 percent of seafood consumed in the U.S. is imported and about a third of that comes from prospective TPP countries.<sup>26,27</sup> As slight as is the FDA’s rate of import re-inspection is, given the dominance of imported seafood in the U.S. seafood diet, it is hard to imagine that the USTR would assent to or propose a ban on food import re-inspection in the TPP.

## Cost benefit analyses and trade impact analyses in TTIP and TPP: consequences for SPS measures to prevent foodborne illness

The European Commission proposal for the TTIP regulatory cooperation chapter would require trade impact assessments for each “regulatory action” before the implementation of a rule: “the findings of impact assessments shall be published no later than the proposed or final regulatory acts at the central level” (Article 7.3a).<sup>28</sup> Regulatory cooperation provisions would apply to all rules in all sectors, except in the financial services sector, where the United States is resisting Commission demands that regulatory cooperation be included in TTIP and subject to the Investor State Dispute Settlement chapter. Indeed, the application of regulatory cooperation to the SPS chapter is mentioned in the prefatory remarks to the regulatory cooperation chapter.

In a leaked TPP regulatory cooperation text from 2010, the proposed Regulatory Impact Assessment would require a demonstration of the “net benefits” of a rule, with a footnote explaining the term as “the differences between a planned regulatory actions benefits and costs” (Article X.3 a3).<sup>29</sup> Requiring *ex ante* trade impact assessment or cost-benefit analysis before the implementation of a rule is a speculative exercise in econometric estimates that quantify factors in policy scenarios. In trade policy, quantification of costs and benefits that concern the already quantifiable tariffs, import quotas and export subsidies is less difficult than quantifying the costs and benefits of non-tariff barriers to trade, such as SPS rules. There is an extensive literature that critiques the econometric modeling of *ex ante* cost-benefit analysis.<sup>30</sup> Rather than try to summarize this literature, for the purpose of this short analysis, we propose that any cost-benefit analysis of SPS rules be conducted after the implementation of a rule, as is done customarily in U.S. regulation. Then, both industry and government will have more experience and historical data on whether the rule has achieved its regulatory objective, and with what costs and benefits. *Ex post* cost-benefit analysis reduces reliance on econometric projections

If standards in trade agreements are to be more than rhetorically “high,” they must be implemented, enforced and enabled by SPS budgets targeted at the foods generally considered to be of highest risk of microbial contamination, particularly animal and seafood products. The U.S. House of Representatives has rejected five Obama administration proposals to fund implementation<sup>31</sup> of the Food Safety Modernization Act, which the President signed into law in 2011.<sup>32</sup> A successful lawsuit by the non-governmental Center for Food Safety forced the FDA to issue implementing rules at the end of August.<sup>33</sup>

Public health economists estimate the cost of foodborne illness on a per pathogen basis, in part to target SPS interventions to prevent foodborne illness originating with that pathogen. For example, according to Robert Scharff, a former FDA economist, acute (requiring hospitalization) foodborne illness in the United States cost an estimated \$78 billion in 2010.<sup>34</sup> How much should the government budget to implement the Food Safety Modernization Act (FSMA) and the Meat and Poultry Inspection Act to reduce this very high cost to public health from foodborne illness?

Sixty-five food trade associations wrote to the Department of Health and Human Services on August 26, urging the FDA not to propose food industry user fees again, having already been rejected by the House of Representatives, to supplement the \$109 million House proposed budget for implementing the FSMA.<sup>35</sup> But the FDA, at the end of July, had already released its proposed Fiscal Year 2016 food facilities inspection fees of \$221 an hour, if U.S. travel was involved, and \$315 an hour if foreign travel was involved.

Evidently, the FDA does not believe that it can implement the FSMA with the budget appropriated by Congress, and will require the food industry to pay fees for regulatory services, including those needed for food exporter certification and the expedited no import inspection program demanded by the industry. The budgetary standoff for food safety and the projected increase in food exports and imports under TPP and TTIP leave SPS regulators in an excruciating predicament. They are under constant pressure to make their SPS rules less trade restrictive and yet must provide an “appropriate level of protection,” while food safety budgets remain inadequate to carry out the legal obligations of the SPS agencies.

## Conclusion

The European Commission SPS chapter proposal stipulates audits and verifications of the U.S. and EU Party’s SPS controls (Article 11), certification of export facilities (Article 12) as compliant with importing country requirements, and import checks that will include product inspections “in exceptional cases” (Article 13). None of these proposals is objectionable on its face. But given the well documented failing of the U.S. food safety system, illustrated here in the case of poultry, banning food product re-inspection as a redundant food safety control invites consumer exposure to unreasonable risk of foodborne illness.

# Endnotes

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