Much Ado About Nothing: Does the Death of the Trans-Pacific Partnership Affect Global Food Safety?

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Summary

With continued globalization of the food system and the increasing number of agricultural products traded on the world market, concerns regarding food safety standards in other countries led Congress to pass the Food Safety Modernization Act (FSMA) to better guard against outbreaks of foodborne illnesses. As the Food and Drug Administration (FDA) finalized the FSMA rules just last year, food safety experts began to fear that those new regulations could be undone if Congress ratified the Trans-Pacific Partnership (TPP). This may seem a moot issue now that President Donald J. Trump has withdrawn the United States from the TPP, but the question is still relevant. This Article argues that the controversy has largely been much ado about nothing because the General Agreement on Tariffs and Trade (GATT)—the trade agreement in effect among all 12 former TPP signatories, which will continue operating in the TPP's absence—provides adequate protection of the United States' ability to regulate its food supply through the implementation of domestic laws, such as the new FSMA rules.

> Food safety involves everybody in the food chain.
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> —*former U.S. Senator Michael Johanns*

> There is no sincerer love than the love of food.
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> —*George Bernard Shaw*

Lisa arrives home after a 12-hour workday, having resisted the lure of the drive-thru. With her stomach gurgling, she begins rummaging around her freezer's contents. She settles on tilapia. Lisa recalls her grandmother's voice at the kitchen table of her youth declaring that Lisa could not be excused from dinner until she ate all her vegetables. She takes out a package of frozen spinach as well. As her dinner defrosts, she pours a glass of apple juice, turns on the evening news, and prepares a salad. From the depths of the flat screen, a panel of experts debate whether trade deals such as the proposed Trans-Pacific Partnership (TPP) will boost global food safety standards or erode U.S. safety regulations. Lisa vaguely recalls this news program when, two days later, gut-wrenching cramps seize her stomach and she is homebound—more specifically, bathroom-bound—for the next two days. A subsequent doctor's visit reveals that Lisa was struck by listeriosis—a case of food poisoning caused, in this instance, from consuming contaminated spinach.

Listeria is a deadly bacterium, sickening 1,600 people each year by causing vomiting, diarrhea, fever, and muscle aches.[1] Listeria resides in animals' digestive tracts, and when fruit or vegetable crops are contaminated with animal waste, the bacteria can be transferred to humans.[2]

While leafy greens are vital for health and contain a wealth of nutritive properties, they are also responsible for nearly a quarter of the 9.6 million cases of foodborne illness that occur each year.[3] Leafy greens, such as spinach, that become contaminated with listeria are particularly problematic because the bacteria can be difficult to wash off the fresh leaves.[4] Moreover, in the case of frozen spinach, listeria can survive after cooking if the food is not heated thoroughly, and can even continue reproducing in the freezer.[5]

The news is replete with stories of food contamination, poisonings, and pathogen outbreaks. In the past decade, U.S. consumers have experienced severe illnesses after consuming contaminated peanut butter, spinach, canta-

1. *See* Sydney Lupkin, *Amy's Kitchen Recall: What to Know About Spinach Listeria Outbreak*, ABC News, Mar. 25, 2015, http://abcnews.go.com/Health/amys-kitchen-recall-spinach-listeria-outbreak/story?id=29894726.
2. *See id.*
3. *See* Bill Tomson, *Vegetables Big Culprit in Food Illness*, Wall St. J., Jan. 29, 2013, https://www.wsj.com/articles/SB10001424127887324329204578271970675684826.
4. *See* Lupkin, *supra* note 1.
5. *See id.*

loupe, eggs, seafood, and a variety of other domestically produced staple foods.[6] Imported products have also caused illness and shaken consumer confidence, especially imports from China—including deadly pet food,[7] antibiotic-laced honey,[8] contaminated baby formula, tofu fermented with sewer water, and gutter oil posing as vegetable oil.[9]

Since 2008, Chinese "food fiascoes included watermelons exploding from too much growth chemical, borax in beef, bleach in mushrooms, soy sauce made with arsenic and from human hair, and 'eggs' created using chemicals, gelatin and paraffin."[10] Such stories demonstrate the need for strong food safety regulations, such as those in the recently finalized Food Safety Modernization Act (FSMA) rules. They also underscore the importance of protecting the rights and abilities of countries on the global market to continue implementing measures for the health and safety of their citizens. Without food safety regulatory mechanisms at both the point of production and the port of entry, "[t]he regulatory, political, and economic pitfalls of one nation can become the burden of an importing nation."[11]

With the continued globalization of the food system and the increasing number of agricultural products traded on the world market, concerns regarding the food safety standards in other countries led the U.S. Congress to pass the FSMA to better secure domestic and foreign markets against outbreaks of foodborne illnesses. As the U.S. Food and Drug Administration (FDA) finalized the FSMA rules just last year, food safety experts began to fear that those new regulations could be undone if Congress ratified the TPP. While a myriad of other controversies surrounded the TPP, food advocates were asking, "What effect could the TPP, if implemented, have on food safety, for better or for worse?"

At first blush, this question may seem a moot issue now that President Donald J. Trump has withdrawn U.S. participation from the deal, but the question is still relevant. If the TPP would have had little to no effect on global food safety, then the debate raging around the trade deal in this respect has largely been much ado about nothing. If the TPP would have weakened food safety standards, as some experts feared, then so much the better for its death and swift burial under the new Administration. But if the TPP would have strengthened global food safety standards, then those more laudable aspects of the deal should be incorporated into future trade deals in the event the Trump Administration attempts to negotiate one.

This Article argues that the controversy surrounding the TPP's potential impact on food safety has largely been much ado about nothing, because the General Agreement on Tariffs and Trade (GATT)—the current trade agreement in effect among all 12 former TPP signatories and the deal that will continue operating in the TPP's absence—provides adequate protection of the United States' ability to regulate its food supply through the implementation of domestic laws, such as the new FSMA rules.

Accordingly, the Article unfolds as follows: Part I provides a discussion of the newly finalized domestic U.S. legislation (the FSMA rules), particularly the Foreign Supplier Verification Programs (FSVP) rule as the one most relevant to the safety of imported food products. Part II provides an overview of GATT and related World Trade Organization (WTO) agreements, namely the Sanitary and Phytosanitary (SPS) Agreement and the Technical Barriers to Trade (TBT) Agreement, and examines possible challenges to the implementation of the FSVP under those agreements. This part analyzes the likelihood of success if a country chose to assert before the WTO that the new FSMA rules violated certain trade obligations contained within GATT, and ultimately concludes that such a challenge is not likely to succeed. Part III discusses some of the provisions in the proposed TPP that were relevant to food safety, explores advocates' criticisms that those provisions would have eroded the United States' ability to insist on basic food safety standards, and considers how, if at all, the provisions of the TPP would have changed the rules of the game. Part IV concludes.

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6. *See* Josh Funk, *Peanut Butter Recalled Over Salmonella*, Wash. Post, Feb. 15, 2007, http://www.washingtonpost.com/wp-dyn/content/article/2007/02/15/AR2007021500597.html; *Multistate Outbreak of* E. coli *0157:H7 Infections Linked to Fresh Spinach (Final Update)*, Centers for Disease Control & Prevention, Oct. 6, 2006, https://www.cdc.gov/ecoli/2006/spinach-10-2006.html; Christina Caron, *CDC: Cantaloupe Listeria Outbreak Deadliest in a Decade*, ABC News, Sept. 28, 2011, http://abcnews.go.com/Health/cdc-listeria-outbreak-deadliest-decade/story?id=14622507; *Recall Expands to More Than Half a Billion Eggs*, NBC News, Aug. 20, 2010, http://www.nbcnews.com/id/38741401/ns/health-food_safety/t/recall-expands-more-half-billion-eggs/#.WJxgATvrWI0; Marc Santora, *Fish Toxin Cited as Cause of Poisonings in '10 and '11*, N.Y. Times, Jan. 31, 2013, http://www.nytimes.com/2013/02/01/nyregion/toxic-fish-caused-food-poisoning-outbreaks-report-says.html; Drew Falkenstein, *2010's Major Food Recalls and Outbreaks*, Food Poison J., Dec. 13, 2010, http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/2010s-major-food-recalls-and-outbreaks/#.WJxipzvrWI0.
7. Bryan Walsh, *China's Food Safety Problems Go Deeper Than Pet Treats*, Time, May 21, 2014, http://time.com/107922/china-pet-food-contamination-recall-video/.
8. *Honey Tainted by Antibiotics*, BBC News, Feb. 19, 2002, http://news.bbc.co.uk/2/hi/health/1829926.stm; Andrew Schneider, *Asian Honey, Banned in Europe, Is Flooding U.S. Grocery Shelves*, Food Safety News, Aug. 15, 2011, http://www.foodsafetynews.com/2011/08/honey-laundering/#.WFyAd8frWI0; Helena Bottemiller, *"Honeygate" Sting Leads to Charges for Illegal Chinese Honey Importation*, Food Safety News, Feb. 26, 2013, http://www.foodsafetynews.com/2013/02/honeygate-sting-leads-to-charges-for-illegal-chinese-honey-importation/#.WFyAusfrWI0; Andrew Amelinckx, *Feds Seize $2 Million Worth of Illegal Chinese Honey*, Mod. Farmer, Feb. 3, 2015, http://modernfarmer.com/2015/02/feds-seize-2-million-worth-illegal-chinese-honey/; News Release, U.S. Immigration and Customs Enforcement, HIS Chicago Seizes Nearly 60 Tons of Honey Illegally Imported From China (May 5, 2016), https://www.ice.gov/news/releases/hsi-chicago-seizes-nearly-60-tons-honey-illegally-imported-china.
9. Christina Rice, *What's in Your Food? A Look at Food Fraud*, Food Safety News, Apr. 14, 2015, http://www.foodsafetynews.com/2015/04/whats-in-your-food-a-look-at-food-fraud/#.WFyCq8frWI0.
10. Andrew Porterfield, "Chemical Free" Organic Industry's Unacknowledged "Pesticide Problem," Genetic Literacy Project, Feb. 20, 2017, https://www.geneticliteracyproject.org/2017/02/20/chemical-free-organic-industrys-unacknowledged-pesticide-problem/.
11. Jason J. Czarnezki et al., *Global Environmental Law: Food Safety & China*, 25 Geo. Int'l Envtl. L. Rev. 261 (2013), *available at* http://digitalcommons.pace.edu/lawfaculty/924/.

I. A Need for Reform: Enter the FSMA

"There's only one sure-fire way to guarantee you'll never get a foodborne illness: just don't eat ever again."[12]

The Centers for Disease Control and Prevention (CDC) estimates that 48 million people in the United States suffer from foodborne illnesses each year, 128,000 of whom are hospitalized and 3,000 of whom die.[13] The physical and economic costs of known and unknown pathogens in the food supply are staggering, with some estimates suggesting that foodborne illnesses cost the United States $77.7 billion per year.[14] Moreover, several "millions of food products enter the U.S. food system every year, with approximately 15 percent of the U.S. food supply originating outside of the country."[15] Nearly 60% of all fruits and vegetables and 80% of all seafood consumed in the United States is imported.[16]

In particular, a growing percentage of imported food in the United States arrives from China. In the decade preceding the FSMA, imports from China to the United States more than tripled between 2001 and 2008.[17] Nevertheless, the United States rejects more import shipments from China than any other country.[18] Such imports are routinely rejected because the food is determined to contain illegal chemicals or because it contains hazardous levels of drug residues.[19]

A. *The Genesis of the FSMA*

The domestic statistics regarding food poisoning, coupled with ever-increasing percentages of food imported from other countries with less regulatory oversight, led both Congress and then-President Barack Obama to conclude there was a need for enhanced food safety regulations for both domestically produced and imported food.[20] On January 4, 2011, President Obama signed into law the FSMA—a law FDA hails as "the most sweeping reform of our food safety laws in more than 70 years."[21] According to food safety experts, the promise of the FSMA is found in how the law shifts the focus of food safety to prevention, rather than reacting to contamination after the fact.[22]

There are five major elements to the FSMA: (1) preventive controls, (2) inspection and compliance, (3) imported food safety, (4) response, and (5) enhanced partnerships.[23] In terms of preventive controls, Congress mandated that FDA draft rules requiring the use of comprehensive, prevention-based controls throughout the entire food supply to minimize the likelihood of contamination and outbreaks.[24] The FSMA legislation also requires FDA to draft rules related to risk-based inspection and compliance measures to ensure industry is held accountable for producing food that is not adulterated or contaminated.[25]

As will be discussed in greater detail, the FSMA has also required FDA to adopt new measures—such as the FSVP—that allow FDA to ensure that imported foods meet the same safety standards that are applied to domestically produced food products in the United States.[26] As a means of securing the safety of imported food products, the FSMA allows FDA to accredit qualified third-party auditors for the purpose of certifying that foreign food facilities comply with U.S. food safety standards.[27] The FSMA also grants FDA mandatory food recall authority for the first time in history.[28] Finally, the FSMA directs FDA to improve its training of various safety officials (at the state, local, territorial, and tribal levels) for enhanced coordination of safety efforts.[29]

Although the FSMA was signed into law in 2011, it took FDA another five years to draft the final rules for implementing the law and fulfilling Congress' legislative mandates. Just last year, FDA finished publishing the seven final FSMA rules: (1) Mitigation Strategies to Protect Food Against Intentional Adulteration,[30] (2) Sanitary Transportation of Human and Animal Food,[31] (3) Standards for the Growing, Harvesting, Packing, and Holding of Produce for

12. David Knowles, *From Raw Milk to Sprouts to Imported Fish: Food Safety Experts Dish on What Grocery Store Items They Avoid*, N.Y. Daily News, Mar. 5, 2013, http://www.nydailynews.com/news/national/foods-safety-experts-avoid-article-1.1280331.
13. CDC, *Estimates of Foodborne Illness in the United States*, https://www.cdc.gov/foodborneburden/ (last updated Aug. 19, 2016).
14. *See generally* Robert L. Scharf, *Economic Burden From Health Losses Due to Foodborne Illness in the United States*, 75 J. Food Protection 123-31 (2012).
15. Reba A. Carruth, *Federal Rulemaking and the US Food and Drug Administration: International Regulatory Policy Cooperation in the 21st Century*, 20 Geo. Pub. Pol'y Rev. 61, 62 (2015).
16. *See id*. at 67.
17. *See* Fred Gale & Jean C. Buzby, U.S. Department of Agriculture, Imports From China and Food Safety Issues, A Report From the Economic Research Service (2009) (Economic Information Bulletin No. 52), *available at* http://ageconsearch.umn.edu/bitstream/58620/2/EIB52.pdf.
18. *See* Bryan Lohmar et al., U.S. Department of Agriculture, China's Ongoing Agricultural Modernization: Challenges Remain After 30 Years of Reform 1 (2009) (Economic Information Bulletin No. 51).
19. Food & Water Watch, A Decade of Dangerous Food Imports From China 6-7 (2011), *available at* https://www.foodandwaterwatch.org/sites/default/files/Dangerous%20Food%20Imports%20China%20Report%20Jun%202011.pdf.
20. *See* Alberto Jerardo, *Americans Have Growing Appetites for Imported Foods*, U.S. Dep't of Agric. Econ. Res. Service, Apr. 1, 2005, https://www.ers.usda.gov/amber-waves/2005/april/americans-have-growing-appetites-for-imported-foods.
21. *See* FSMA, amending the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.); *see also* FDA, *FDA Food Safety Modernization Act (FSMA)*, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ (last updated Feb. 27, 2017).
22. *See id*.
23. *See* FDA, *Frequently Asked Questions on FSMA*, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm (last updated July 13, 2016).
24. *See id*. at G.2, Preventive Controls.
25. *See id*. at G.2, Inspection and Compliance.
26. *See id*. at G.2, Imported Food Safety.
27. *See id*.
28. *See id*. at G.2, Response.
29. *See id*. at G.2, Enhanced Partnerships.
30. Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. 34165 (May 27, 2016) (to be codified at 21 C.F.R. §121) (requiring domestic and foreign food facilities to implement practices to prevent acts intended to cause wide-scale harm, such as bioterrorism).
31. Sanitary Transportation of Human and Animal Food, 81 Fed. Reg. 20091 (Apr. 6, 2016) (to be codified at 21 C.F.R. §11) (establishing requirements for shippers, loaders, and motor and rail vehicle carriers of food to use sanitary transportation practices).

Human Consumption,[32] (4) FSVP for Importers of Food for Humans and Animals,[33] (5) Accredited Third-Party Certification,[34] (6) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,[35] and (7) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.[36] While each rule brings much to bear on global food safety, the scope of this Article is largely dedicated to the FSVP, because the requirements in this rule are most likely to affect imports and to be challenged as potentially inconsistent with WTO obligations.

Many food safety experts opine that the new FSMA rules, especially the FSVP, will ultimately reduce the risks associated with food imports.[37] While FDA was drafting the FSVP implementation rules, the United States imported 4.1 billion pounds of food products from China,[38] including nearly 40 million pounds of frozen spinach in 2012.[39] By the time the FSVP was finalized at the end of 2015, more than 20% of all frozen spinach consumed in the United States was imported from China.[40] Chinese products in the form of fruit juices, processed fruit products, prepared/frozen vegetables/fruits, onions/garlic, and preserved mushrooms accounted for 6% of all imports last year in the United States.[41] If your dinner has ever sounded anything like the one Lisa prepared, there is a 3 in 4 chance your fish arrived from China, a 2 out of 3 chance the apple juice you just poured was pressed in China, and a 1 in 5 chance that the spinach was grown and processed in China as well.[42]

B. *Food Safety and Imports: The FSVP*

Prior to the implementation of the FSMA, FDA did not have authority to regulate food safety standards for global food products other than at the port of entry.[43] FDA's only regulatory authority with respect to imports was the ability to refuse an article of food if, upon inspection at the border, a shipment appeared adulterated or misbranded in violation of the Federal Food, Drug, and Cosmetic Act.[44] Moreover, FDA was only able to physically inspect a fraction of food import shipments—just 1.9% of all imported food products in 2012.[45]

With the passage of the FSMA—and particularly the FSVP—FDA now has greater regulatory authority over food imports at the point of production, as opposed to simply inspecting at the point of entry. The final FSMA rule on the FSVP was published on November 27, 2015.[46] Under the FSVP, countries wishing to import food products to the United States must verify that their food safety programs, systems, and standards are adequate to ensure that the food is as safe as if it were produced, processed, or packed within the United States.[47] Specifically, importers must verify that their products are produced in compliance with 21 U.S.C. §350g (hazard analysis and risk-based preventive controls for processed foods) or 21 U.S.C. §350h (standards for produce safety for raw foods) and that their products are not adulterated or misbranded.[48]

Pursuant to 21 U.S.C. §350g(a), owners, operators, or agents in charge of food processing facilities must "evaluate the hazards that could affect food manufactured, processed, packed, or held by such facilities, [and] identify and implement preventive controls to significantly minimize or

32. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 21 C.F.R. §§112.1-112.213 (2016) (issuing regulations to minimize risk of consuming contaminated produce and foodborne illness by establishing science-based minimum standards).
33. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 21 C.F.R. §§1.500-1.514 (2016) (aiming to ensure the safety of imported food by requiring verification that food imported to the United States is produced in compliance with U.S. hazard analysis and risk-based preventive controls and standards for food safety under the Federal Food, Drug, and Cosmetic Act (i.e., food is not adulterated or misbranded with respect to allergen labels)).
34. Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 21 C.F.R. §§1.600-1.695 (2016) (adopting regulations for accrediting third-party certification bodies to conduct food safety audits of foreign food entities).
35. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, 21 C.F.R. §§110.3-110.110 (2016) (amending old good manufacturing practices to incorporate modern risk and science-based preventive controls across the food system).
36. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 21 C.F.R. §§507.1-507.215 (2016) (establishing food manufacturing practices for animal feed).
37. *See* Alexia Brunet Marks, *The Risks We Are Willing to Eat: Food Imports and Safety*, 52 Harv. J. on Legis. 125, 127 (2015). *See also* FDA, *5 Ways New FDA Rules Will Make Your Foods Safer*, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm459072.htm (last updated Nov. 3, 2015).
38. *See* Rice, *supra* note 9.
39. *See Testimony Before the House Committee on Foreign Affairs: Hearing on the Threat of China's Unsafe Consumables*, at 4, 11, app. 1 (2013) (statement of Patty Lovera, Assistant Director, Food & Water Watch), http://docs.house.gov/meetings/FA/FA14/20130508/100807/HHRG-113-FA14-Wstate-LoveraP-20130508.pdf.
40. *Where Does Our Food Come From?*, Tex. A&M Today, Jan. 30, 2014, https://today.tamu.edu/2014/01/30/where-does-our-food-come-from-research-reveals-unsavory-truths-about-global-food-supply-chain/, quoting Burlington Industries Distinguished Professor in Supply Chain Management at Clemson University and visiting Faculty Fellow of the Texas A&M University Institute for Advanced Study Aleda Roth. In addition, China "has a virtual monopoly as a supplier of vitamins, food supplements and many ingredients in pharmaceuticals" (*id.*).
41. *See* Renée Johnson, Congressional Research Service, The U.S. Trade Situation for Fruit and Vegetable Products tbl. 2, at 4 (2016), *available at* https://fas.org/sgp/crs/misc/RL34468.pdf.
42. *See* Food & Water Watch, A Decade of Dangerous Food Imports, *supra* note 19, app. 1, at 12.
43. *See* 21 U.S.C. §381(a).
44. *See id.* Food may be deemed adulterated if it bears a poisonous or deleterious substance (*see* 21 U.S.C. §342(a)(1)); contains an unsafe food additive (*see* 21 U.S.C. §342(a)(2)(C)); is filthy, putrid, or decomposed or is otherwise unfit for food (*see* 21 U.S.C. §342(a)(3)); or if it is prepared in insanitary conditions whereby it becomes contaminated with filth (*see* 21 U.S.C. §342(a)(4)). Food may be misbranded if it purports to be a food item for which a standard of identity has been prescribed and it fails to conform to that definition and standard (*see* 21 U.S.C. §343(g)); *see also* Libby, McNeill & Libby v. United States, 148 F.2d 71 (2d Cir. 1945) (condemning catsup as misbranded where it contained sodium benzoate as an ingredient, in contravention of the standard of identity of catsup disallowing such an ingredient). Food may also be deemed misbranded if it bears a false or misleading label, per 21 U.S.C. §321(n). FDA could also refuse imported food products under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 if the products arrived from an unregistered foreign facility (*see* 21 U.S.C. §305).
45. *See* FDA, *2013 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices*, http://www.fda.gov/food/guidanceregulation/fsma/ucm376478.htm (last updated Dec. 5, 2016).
46. *See* FDA, *Frequently Asked Questions on FSMA*, *supra* note 23, at G.3 How Will FDA Implement FSMA?
47. *See* 21 U.S.C. §381(q)(1), (7).
48. *See* 21 U.S.C. §384a(a)(1)(A)-(B), (c)(3).

prevent the occurrence of such hazards and provide assurances that such food is not adulterated . . . or misbranded" and must "monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice." In developing the aforementioned hazard analysis, such owners are required to "identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility," which include hazards arising from "biological, chemical, physical, and radiological" sources, as well as those that could result from "natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives."[49]

The hazard analysis contemplates only those hazards arising from naturally or unintentionally introduced situations.[50] After the hazard analysis is complete, owners/operators/agents are required to identify and implement preventive controls, especially at "critical control points" for the purpose of assuring that any identifiable hazards are "significantly minimized or prevented."[51] This implementation of preventative controls is known as creating and following a hazard analysis critical control point (HACCP) plan.

An HACCP plan also requires monitoring and prompt corrective action where appropriate.[52] The FSVP further requires all owners, operators, and agents to verify that the preventive controls they implement are adequate to control the identified hazards.[53] The FSVP also contains extensive recordkeeping requirements for owners to demonstrate adequate monitoring of such preventive controls and to maintain evidence of corrective actions when taken.[54]

Unless importers establish such a verification program, their products will not be permitted entry to the United States.[55] Such verification activities can include, but are not limited to, "onsite auditing, sampling and testing of a food, [and] review of the foreign supplier's relevant food safety records."[56] Verification activities can also include "monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments."[57]

C. *Brief Overview of the Other FSMA Final Rules as They Relate to Imports*

The FSVP is just one of the final seven FSMA rules FDA finished drafting last year. Another FSMA rule that works in concert with the FSVP to ensure the safety of imported food products is the Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits, issued on November 27, 2015.[58] This rule allows foreign governments or agencies, or other third parties, to seek accreditation from FDA (or other recognized accreditation bodies where appropriate) to conduct food safety audits to issue food and facility certifications demonstrating that the facilities meet U.S. requirements.[59] Importers can rely on third-party audits to demonstrate that the foreign food complies with U.S. laws and standards.[60] Scholars note that third-party audits and certifications can provide many different benefits, including "(1) gatekeeping and monitoring expertise, (2) enhanced credibility and information sharing, (3) cost savings, (4) food safety gains, and (5) gaining industry cooperation and reducing the regulatory burden."[61]

The final FSMA rule for produce safety was also issued on November 27, 2015.[62] The FSVP requires that importers verify that the imported food was produced in accordance with the U.S. standards for produce safety.[63] Raw agricultural products that are imported to the United States must comply with the standards for produce safety contained within 21 U.S.C. §350h.[64] The final FSMA rule on produce safety exempts foods that are not raw agricultural commodities.[65]

49. 21 U.S.C. §350g(b)(1)(A).
50. *See* 21 U.S.C. §350g(b)(1)(B). Hazards arising from intentional acts of adulteration evincing an intent to cause wide-scale public harm are addressed in the FSMA's Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration, which applies to both domestic and foreign facilities that process, manufacture, or pack food for consumption in the United States (*see* 21 C.F.R. §§121.1, 121.3). The final FSMA rule on intentional adulteration was issued on May 27, 2016 (*see* Mitigation Strategies to Protect Food Against Intentional Adulteration, 81 Fed. Reg. 34166 (May 27, 2016) (to be codified at 21 C.F.R. pts. 11 and 121), https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-12373.pdf.
51. 21 U.S.C. §350g(c)(1).
52. *See* 21 U.S.C. §350g(d) and (e), respectively.
53. *See* 21 U.S.C. §350g(f).
54. *See* 21 U.S.C. §350g(g).
55. *See* 21 U.S.C. §384a; *see also* 21 U.S.C. §301(zz).
56. Final Rule, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 80 Fed. Reg. 74226, 74227 (Nov. 27, 2015), http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm [hereinafter FSVP Final Rule].
57. 21 U.S.C. §384a(c)(4).
58. *See* Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 80 Fed. Reg. 74570 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 1, 11, and 16), https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28160.pdf.
59. *See* 21 C.F.R. §1.640. *See* 21 U.S.C. §381(q)(2)(C) (requiring that certifications be supported by scientific, risk-based evidence demonstrating that the food safety systems in another country adequately ensure that the article of imported food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States).
60. *See* 21 U.S.C. §384d. Third-party auditors can include foreign governments or agencies that conduct food safety audits and may be accredited by established accreditation bodies that ensure auditors adhere to model standards and requirements for regulatory audit reports (*see id.*).
61. Alexia Brunet Marks, *A New Governance Recipe for Food Safety Regulation*, 47 Loy. U. Chi. L.J. 907, 945-46 (2016).
62. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015) (to be codified at 21 C.F.R. pts. 11, 16, and 112), https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf.
63. *See* 21 U.S.C. §384a(a)(1)(A).
64. 21 U.S.C. §350h(a)(1)(A). The standards for produce safety requires FDA "to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables . . . that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death." Moreover, the rules are required to address science-based minimum standards related to "soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water" with respect to the growing, harvesting, sorting, packing, and storage operations of raw agricultural commodities" (*id.* §350h(a)(3)(B)).
65. *See* 21 C.F.R. §112.2(a)(3). Raw agricultural commodities are foods that are in their raw or natural state without any processing (*see id.*).

The final FSMA rules for preventive controls for human food[66] and for preventive controls for animal food were both issued on September 17, 2015.[67] The final rules for preventive controls for human food apply to domestic and foreign facilities that produce, pack, process, or manufacture food intended for consumption in the United States.[68] Among other things, the rules are intended to ensure that such food is not adulterated or contaminated "whereby it may have been rendered injurious to health."[69]

To that end, the rules require the use of preventive controls to address hazards such as environmental pathogens and to minimize or prevent the hazard (such as monitoring, corrective action, verification, and recordkeeping).[70] An environmental pathogen, such as listeria, is defined as one "capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen."[71] Similar to the final rule for human food, the final FSMA rule for animal food applies to both domestic and foreign facilities and requires registration of all facilities with FDA.[72]

Lastly, the final FSMA rule for sanitary transportation was issued on April 5, 2016.[73] This rule does not apply to transportation by ship or air and therefore would only cover imports entering the country by land from Mexico or Canada.[74]

II. The History of GATT

The base agreement of the WTO (created in 1995) is GATT, drafted in 1947 and revisited through a series of successive trade negotiation rounds.[75] The intended effect of GATT is achieving liberalized trade by eliminating the taxes imposed at customs on imported products (tariffs), spurring innovation and creating market competition, eliminating other trade barriers such as technical standards that could unfairly impede the free flow of goods, and eliminating discrimination against products produced in other countries in favor of national producers.[76] The reason liberalized trade has become so important in the international community is rooted in the economic theory of comparative advantage, which espouses the idea that every country should produce that which it is most efficient at producing and then trade to acquire the set of goods and services it wishes to consume.[77] Economists have demonstrated time and again that such a trade scheme results in both countries maintaining stronger economies, hence the name of the theory because each country achieves a comparative advantage.[78]

A. *How GATT Reduces Protectionist Trade Policies*

The strength of GATT as a tool to liberalize trade lies in the Agreement's "most favored nation" (MFN) clause, which provides that if country A agrees to reduce tariffs for country B, then country A must also provide that same tariff reduction for every other WTO Member country.[79] Thus, the MFN principle articulates "the obligation to offer imports from (and exports to) any WTO Member the best-available treatment offered to any other country."[80] The complete MFN clause provides:

> With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all matters referred to in paragraphs 2 and 4 of Article III, any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.[81]

In addition to the MFN principle, another key strength of GATT lies in Article III, which requires that all Member States afford "national treatment" to imported goods.[82] Article III requires that Member States treat imported products no less favorably than domestically produced like products.[83] Put another way, GATT does not permit Member States to treat imported products "less favorably" than domestic products.[84] In order to demonstrate that

66. *See* Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908 (Sept. 17, 2015) (to be codified at 21 C.F.R. pts. 1, 11, 16, 106, 114, 117, 120, 123, 129, 179, and 211), https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf.
67. *See* Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56170 (Sept. 17, 2015) (to be codified at 21 C.F.R. pts. 11, 16, 117, 500, 507, and 579), https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf.
68. *See* 21 C.F.R. §117.1(b).
69. *Id.* §117.1(a)(1)(ii).
70. *See id.* §117.3.
71. *Id.*
72. *See id.* §507.3; 21 U.S.C. §350d.
73. *See* Sanitary Transportation of Human and Animal Food, 81 Fed. Reg. 20092 (Apr. 6, 2016) (to be codified at 21 C.F.R. pts. 1 and 11), https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf.
74. *See* FDA, *FSMA Final Rule on Sanitary Transportation of Human and Animal Food*, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm (last updated Dec. 5, 2016); *see also* 21 C.F.R. §1.902(a).
75. *See* WTO, *Understanding the WTO*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/tif_e.htm (last visited Mar. 2, 2017).
76. *See* Ari Afilalo & Sheila Foster, *The World Trade Organization's Anti-Discrimination Jurisprudence: Free Trade, National Sovereignty, and Environmental Health in the Balance*, 15 Geo. Int'l Envtl. L. Rev. 633 (2003).
77. *See id.*
78. *See id.*
79. *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, art. I, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]. However, if the countries meet certain conditions (e.g., the tariffs between country A and country B are reduced to zero), then country A does not need to provide MFN treatment to all the other WTO countries (GATT art. XXIV).
80. Joost H.B. Pauwelyn et al., International Trade Law 323 (Rachel E. Barkow et al. eds., 3d ed. 2016).
81. GATT *supra* note 79, art. I:1.
82. *Id.* art. III.
83. *Id.*
84. *Id.* art. III:4.

a measure accords less favorable treatment to imports, a Member State must show that the "measure has a detrimental impact on the conditions of competition for like imported products" and once such a "detrimental impact" on the like imported products has been established, there is de facto impermissible discrimination.[85] However, Article XX of GATT allows countries to carve out exceptions to this "like products" requirement in order to preserve the health and life of humans, plants, and animals.

In the event that a Member State believes that "any benefit accruing to it directly or indirectly" under GATT "is being nullified or impaired" or that one of GATT's objectives is being impeded as a result of the actions of another Member State, the complaining Member State may seek redress through the WTO's dispute settlement mechanism.[86] A system of rule enforcement, encapsulated in the WTO's Dispute Settlement Understanding (DSU), sets forth the procedures aggrieved Member States must follow in order to resolve trade disputes.[87] A complaining Member State must first make a request for consultations with the alleged offending Member[88]: "The goal of the consultation stage is to enable the disputing parties to understand better the factual situation and the legal claims in respect of the dispute and to resolve the matter without further proceedings."[89] However, if this goal is not achieved, then a panel, composed of three individuals (either current or former government officials, former Secretariat officials, or trade academics/lawyers), will be convened to act in a fact-finding capacity, hear evidence, and render a decision on the matter.[90] In the event of an unfavorable decision, both parties have the option of appealing the decision to the Appellate Body—a group of individuals serving four-year terms and appointed by the DSU.[91]

1. GATT Side Agreement: The SPS Agreement

The SPS Agreement, which includes all 164 WTO Member States, was negotiated during the Uruguay Round discussions in 1995 and aims to prevent countries from implementing food safety measures that unfairly restrict trade.[92] The SPS Agreement specifically recognizes that all WTO Member States have the right to regulate food safety to protect "human, animal or plant life or health," but requires that such regulations be based on the available scientific evidence and applied only to the "extent necessary to protect human, animal, or plant life or health."[93]

A sanitary or phytosanitary measure is defined as any measure applied "to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, disease-carrying organisms or disease-causing organisms."[94] Article 2 of the SPS Agreement sets forth the basic rights and obligations of the Member States, including that Members ensure that "their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."[95]

Notably, the Agreement relies on the Codex Alimentarius Commission as the global food safety standard for international trade, and encourages countries to harmonize their food safety standards with the Codex as a means of facilitating trade.[96] The Codex was created in 1963 as the result of a partnership between the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) and consists of Member States who set international food safety standards.[97]

FDA took care to craft the FSVP in accordance with the standards set forth in the Codex so as not to run afoul of the SPS Agreement:

> The proposed FSVP regulations recognize the relevance of the work of Codex in establishing international food safety standards, guidelines, and recommendations. Codex was formed in 1963 by the Food and Agriculture Organization and the World Health Organization of the United Nations to develop food standards, guidelines, and related texts such as codes of practice, and is recognized by the WTO as the international standards organization for food safety. In describing the general characteristics of food import control systems, the Guidelines for Food Import Control Systems (CAC/GL 47-2003) (Ref. 6) developed by the Codex Committee on Food Import and Export Inspection and Certification Systems recognize several related concepts, including: that countries can set their own appropriate levels of protection (para. 1); that standards should be based on risk and, as far as possible, applied equally to imported and domestic food (paras. 2, 4, 5); that there is a potential need for different approaches to compliance monitoring of domestic and imported food to ensure consistent levels of protection (e.g., para. 15); and that

85. Pauwelyn et al., *supra* note 80, at 314, quoting WTO Panel, *European Communities—Measures Prohibiting the Importation and Marketing of Seal Products*, WT/DS400/R/WT/DS401/R and Add. 1 (adopted June 18, 2014).
86. GATT *supra* note 79, art. XXIII:1.
87. *Id*. art. XXIII.
88. Pauwelyn et al., *supra* note 80, at 131.
89. *See id*.
90. *See id*. at 132-35.
91. *See id*. at 135-36.
92. *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm [hereinafter SPS Agreement]; *see also* WTO, *Members and Observers*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Mar. 2, 2017).
93. SPS Agreement, *supra* note 92, art. 5.
94. *Id*. Annex A(1).
95. *Id*. art 2.
96. *Id*.
97. David A. Wirth, Geographical Indications, Food Safety, and Sustainability: Conflicts and Synergies, Boston College Law School Legal Studies Research Paper Series, Research Paper 359, at 16 (2015), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2587539.

> there is utility in conducting audits, along with using other tools, in addition to assessing importer controls to ensure that imported foods are safe, including importers' use of supplier verification systems.[98]

Although the FSVP regulations "recognize the relevance" of the Codex standards,[99] this is not the same as harmonizing the FSMA rules with the Codex. Thus, the United States was required to (and did) complete risk assessments to justify the measures contained in the FSMA.[100]

2. GATT Side Agreement: The TBT Agreement

The TBT Agreement was also reached during the Uruguay Round and is similar in structure to the SPS Agreement. Whereas the SPS Agreement is narrowly focused on protecting the health and life of animals, plants, and humans from certain types of risks (diseases, pests, etc.), the TBT Agreement is broader in scope. The TBT Agreement regulates environmental and public health concerns for goods, including food products, specifically those relating to "packaging, marking or labeling requirements."[101] The TBT applies to any regulations that relate to product characteristics or their related processes and production methods.[102] Such regulations are not permitted to create unnecessary obstacles to international trade.[103]

The regulations of Member States that conform to the standards adopted by an international standardizing body such as the Codex are presumptively valid as not running afoul of the TBT Agreement.[104] Thus, "those national measures that conform to international standards are effectively insulated from challenge."[105] Notably, the SPS and TBT Agreements are mutually exclusive and, as related to the FMA rules, only the SPS Agreement applies.[106]

B. The FSVP Is Consistent With Member Countries' WTO Obligations Under GATT

Whether the requirements of the new FSMA rules, especially the FSVP, might be challenged under relevant existing international treaties (i.e., GATT, SPS, TBT) as inconsistent with those treaty agreements remains an open question. To date, there have not been any WTO Member States claiming impairment or seeking to avail themselves of the DSU because of any perceived unfavorable treatment afforded to their products when compared with U.S. domestic products under the FSMA rules. However, it is important to note that the compliance date for the FSVP is not until May 2017, so the lack of WTO challenges thus far may not be surprising.[107]

Moreover, while a country exporting food products to the United States could assert such a challenge because it is an admittedly costly and significant investment of time to comply with the FSMA rules such that the FSMA possibly constitutes a barrier to free trade, it seems unlikely that a challenge would survive. GATT specifically recognizes the ability of Member States to regulate to protect the public health of their populace.[108] Specifically, Member States implementing food safety regulations must comply with the requirements set forth in the SPS Agreement, which require national legislation be (1) science-based, (2) risk-based, and (3) not more restrictive than necessary.[109] Moreover, national measures that are equivalent to international standards such as the Codex are presumptively valid.[110] Thus, in the event of a WTO Member State asserting a challenge against the United States on the grounds that the FSMA—specifically the FSVP final rule—constituted an unfair barrier to trade in violation of GATT, the United States would need to demonstrate that the FSVP is in fact rooted in science, takes a preventive approach to risk, and is not more restrictive than necessary to achieve its public health aims.[111]

Moreover, the FSVP does not seem to run afoul of GATT's national treatment standard, which states:

> The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.[112]

The goal of the FSVP is to ensure that food produced outside of the country meets applicable U.S. food safety standards. Thus, the FSMA seeks to ensure that the production of imported food meets the safety standards governing domestic food production. Because both imported food products and domestic food products are subject to the same safety standards, it seems unlikely that a Member State could successfully allege that an imported product was accorded less favorable treatment.

98. Proposed Rule, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45730, 45741 (proposed July 29, 2013) (codified at 21 C.F.R. pt. 1), http://www.registrarcorp.com/fda-guidance/fsvp.jsp.
99. *Id.*
100. *See* SPS Agreement, *supra* note 92, art. 3(3) (providing that if a measure or standard "conforms" to an international standard in every respect, then performing a risk assessment is not necessary).
101. Agreement on Technical Barriers to Trade, Apr. 15, 1994, pmbl. para 5 & Annex 1 paras. 1 and 2, 1868 U.N.T.S. 120 (1995) [hereinafter TBT Agreement].
102. *See id.* Annex 1.
103. *See id.* art. 2.2.
104. *Id.* art. 2.5.
105. Wirth, *supra* note 97, at 359.
106. *See* TBT Agreement, *supra* note 101, art. 1.5, stating that the TBT Agreement does "not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the application of Sanitary and Phytosanitary Measures."
107. *See* FSVP Final Rule, *supra* note 56, at 74332 (stating that, as a general matter, most importers would be required to comply with the FSVP regulations within 18 months following the publication date of the rule).
108. *See* GATT, *supra* note 79, art. XX.
109. SPS Agreement, *supra* note 92, art. 5.
110. *Id.* art. 2.
111. *See id.* art. 5.
112. GATT, *supra* note 79, art. III:4.

A concrete example helps illustrate the point. Consider that the FSVP requires each importer to perform risk-based foreign supplier verification activities to verify that the food imported is not adulterated or misbranded.[113] Consider further that the FSMA amends the Federal Food, Drug, and Cosmetic Act by prohibiting "the importation or offering for importation of a food if the importer . . . does not have in place an FSVP."[114] Assume that China does not implement an FSVP because it is costly and burdensome, and a shipment of frozen spinach intended for export to the United States is therefore subsequently refused entry due to the lack of an FSVP verifying that the frozen spinach complied with U.S. safety standards and was not adulterated or misbranded. Assume further that U.S. safety standards reduce the risk of pathogen contamination by implementing preventive controls throughout the supply chain to reduce the reasonably foreseeable hazards likely to cause illness due to the growing, fertilizing, harvesting, washing, packing, and shipping of leafy greens. Such preventive controls would be based on experience, illness data, scientific reports, etc., to reduce as much as possible the risk of contamination.

The effect of the final FSMA FSVP rule is a ban of certain foods, unless verification of equivalent food safety practices is demonstrated. In assessing whether the FSVP regulation constitutes a ban that affords less favorable treatment to imports that do not comply with U.S. food safety standards, the relevant inquiry would be whether products are like products (e.g., spinach grown in the United States versus spinach grown in China) when one variant of the product could pose a significant health risk. Case law suggests that significant health risks can be considered in determining whether products are like or not for the purposes of assessing violations of GATT Article III:4.

In the 2001 *EC-Asbestos* case, the WTO Appellate Body considered whether the European Union's (EU's) ban on cement containing asbestos from Canada was a like product comparable to EU cement produced with noncarcinogenic polyvinyl alcohol, cellulose, and glass (PCG) fibers such that Article III:4 of GATT was triggered.[115] If cement containing asbestos and cement not containing asbestos were considered like products, then the EU regulatory ban would violate GATT Article III:4. However, if the two products were not considered "like products," then it could not be said that the EU ban was affording less favorable treatment to the Canadian cement and, thus, no violation of GATT would be found. Thus, the issue in *EC-Asbestos* was whether asbestos cement products and PCG fiber cement products were "like products" such that the EU ban on asbestos fibers constituted regulatory protectionism in violation of GATT.

The Appellate Body reasoned that in determining whether products are "like" or not, there must be a consideration of (1) the properties, nature, and quality of the products; (2) the end uses of the products; (3) consumer tastes, habits, perceptions, and behavior; and (4) the tariff classifications of the products.[116] In this instance, the Appellate Body determined that health risks must be contemplated when considering the first factor—the nature and quality of the products. Because cement made with asbestos was scientifically demonstrated to be a carcinogen and cement made with noncarcinogenic PCG fibers did not raise the same health concerns, the Appellate Body determined that the two products were not "like" and that therefore the EU regulatory ban on cement containing asbestos did not run afoul of GATT national treatment requirements in Article III:4.[117]

Here, a similar outcome would be achieved in the hypothetical spinach example. Suppose that, in enforcing the FSMA, border authorities rejected a shipment of frozen spinach from China for lack of an FSVP, and China wished to challenge the FSVP rule. A possible basis for a challenge under GATT and the SPS/TBT Agreements would include a claim by China that the U.S. rejection of its frozen spinach for failure to comply with the FSVP violated the national treatment requirement of GATT. The dispute settlement body would first need to consider whether U.S. spinach produced according to certain food safety handling standards and Chinese spinach not produced according to the same standards were "like products."

An additional wrinkle in this analysis—and a feature that distinguishes this hypothetical case from the scenario present in *EC-Asbestos*—is whether the Chinese-produced spinach is more likely to contain pathogens such as listeria, as opposed to the U.S. spinach. This is where the science-based and risk-based requirements of the SPS Agreement are applicable. The United States would need to justify the FSVP rule's requirement that all growers implement HACCP plans by demonstrating that—given the different handling, processing, and growing techniques—the Chinese spinach produced without an HACCP plan is more likely to contain a disease-causing pathogen than would be the case had China complied with U.S. food safety standards, which require the use of HACCP plans.

If the United States can show that U.S. spinach produced according to FSMA rules is not likely to contain listeria (or other pathogens) but Chinese-produced spinach not produced in accordance with FSMA rules is likely to contain listeria (or other pathogens), then the two products would not be considered like products. Thus, China would not be likely to prevail in claiming that the ban on imports for food products not in verified compliance with

113. *See* 21 U.S.C. §384a(a)(1)(B). An "importer" is defined as "the United States owner or consignee of the article of food at the time of entry of such article into the United States" (21 U.S.C. §384a(a)(2)(A)) or "the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States" (21 U.S.C. §384a(a)(2)(B)).

114. 21 U.S.C. §331(zz); FSVP Final Rule, *supra* note 56, at 74232 (codified at 21 C.F.R. pts. 1, 11, 111).

115. WTO Appellate Body, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R (adopted Apr. 5, 2001).

116. *See id.*

117. *See id.*

the FSMA (i.e., produced in accordance with an FSVP) constitutes regulatory protectionism in violation of GATT.

Applying the same analysis as the Appellate Body applied in *EC-Asbestos*, we would first need to consider whether Chinese spinach is a "like product" to U.S. listeria-free spinach. In this scenario, we would assume that Chinese production practices do not comply with U.S. food safety standards such that Chinese spinach is more likely to contain listeria or that Chinese spinach does in fact contain listeria. Under these circumstances, the properties, nature, and quality of these products are different insofar as one contains, or is likely to contain, listeria and the other does not. This situation is analogous to cement that contains a carcinogen (asbestos) and cement that does not (noncarcinogenic PCG fibers). While the end uses of the products are the same (consumption to meet nutritional requirements) and assuming the tariff classifications of U.S. spinach and Chinese spinach are the same, it still would be difficult to assert that the two products are in fact like products given the difference in their properties (one contains listeria and the other does not).[118]

What if, however, both products did not contain listeria? What if, even though the Chinese spinach was produced without the benefit of equivalent preventive controls, it tested negative for listeria, the same as the U.S. spinach? Interestingly, this is where the third factor in the *EC-Asbestos* case is likely to carry the most weight. Considering consumer tastes, habits, perceptions, and behavior, consumers might very well prefer to consume only spinach that was grown and processed pursuant to certain food safety standards with the goal of minimizing the likelihood of listeria contamination, as opposed to consuming spinach that, while free of pathogens, contains a higher risk of testing positive for listeria because the same preventive controls (or their equivalent) were not followed. Given consumers' perceptions and attitudes toward health risks—real or perceived—it seems that the FSVP rule of the FSMA is likely to survive any challenges alleging that the regulation constitutes unfair protectionism under the framework stated in *EC-Asbestos*.

Nevertheless, even if in our hypothetical spinach case a dispute settlement body deemed the application of the FSVP to be discriminatory in violation of GATT, the challenged measure could still survive under one of the exceptions contained within GATT Article XX. As relevant here, GATT Article XX provides:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (a) . . .
>
> (b) necessary to protect human, animal, or plant health.[119]

Determining whether the FSMA generally—and the FSVP in particular—would qualify as a permissible exception under GATT Article XX requires establishing the following elements:

> (1) that the policy in respect of the measures for which the provision was invoked fell within the range of policies designed to protect human, animal, or plant life or health;
>
> (2) that the inconsistent measures for which the exception was being invoked were necessary to fulfill the policy objective; and
>
> (3) that the measures were applied in conformity with the requirements of the introductory clause [the chapeau] of Article XX.[120]

Here, assuming again for the sake of argument that the FSVP violates GATT as a preliminary matter, it seems that the FSVP would qualify as a regulation that constitutes a valid exception to GATT. First, it seems likely that the policy for which the FSMA was enacted (food safety) falls squarely within the range of polices designed to protect human, animal, or plant life or health. FDA provided in the final FSVP rule that its purpose was to "better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation."[121]

The second element—that FSVP is *necessary* to fulfill this policy objective, is likely to be fulfilled depending on the specific facts at issue given different food products. Returning to the hypothetical Chinese spinach case, the United States would need to demonstrate that the FSVP requirements are not more burdensome on trade than necessary to protect public health. Given the reliance of FDA on the international standards contained in the Codex when creating the FSVP, the United States would be entitled to a strong presumption that its FSVP measure is valid and China would bear the burden of rebutting that strong showing.

Moreover, China would also bear the burden of demonstrating that it evaluated the availability of any alternatives and that other alternatives exist that are as effective at achieving the same level of protection that the FSVP measure is designed to afford.[122] China would need to demonstrate that other such alternatives are both less trade-restrictive than the FSVP and still just as effective at

118. *See* Pauwelyn et al., *supra* note 80, at 182-83 (explaining that the WTO maintains a classification schedule of tariff concessions from importing countries that all WTO Members agree to and submit to being bound by. These tariff concession rates are multilaterally agreed upon tariff ceilings for each country and product, called the "bound tariff rate," and apply on an MFN basis to all WTO Members).

119. GATT, *supra* note 79, art. XX (General Exceptions), at (b).

120. WTO Panel, *United States—Standards for Reformulated and Conventional Gasoline*, WT/DS2/R (adopted Jan. 29, 1996) (reasoning that justifying the application of GATT art. XX(b) requires fulfilling all the aforementioned elements).

121. FSVP Final Rule, *supra* note 56, at 74226.

122. *See* Pauwelyn et al., *supra* note 80, at 314.

preserving the Member State's right to achieve its desired level of protection regarding the right pursued (here, public health).[123] So long as the FSVP measures remain rooted in science-based and risk-based analysis, the FSVP should satisfy this element.

Finally, the FSVP would likely satisfy the chapeau insofar as the measure applies to all imports and requires that production of food products be done in conformance with food safety standards equivalent to the U.S. standards—which are based on the Codex. In this scenario, it seems difficult to determine how China could allege that the FSVP constitutes a "means of arbitrary or unjustifiable discrimination" since all domestic food and imported food must abide by the same minimum level of food safety prevention standards.[124] Thus, it seems that the FSVP should be safe from challenge.

The above analysis notwithstanding, in the event of a dispute settlement decision finding a failure of a Member State to carry out its obligations under GATT (i.e., affording national treatment no less favorable to imports)[125] or a finding that the FSVP as applied nullifies the competitive advantage or the negotiated economic benefits the countries agreed to even if the FSVP does not technically violate GATT,[126] then the United States would not have to repeal the FSVP rules and regulations. Rather, the Member State seeking redress would need to propose some level of suspended concessions to be applied to the United States, not to exceed the calculated lost sales resulting from the U.S. measure.[127] However, suspension of concessions is viewed as a measure of last resort and is extremely rare, having been implemented in only three cases to date.[128]

Although GATT does not require countries to change their regulations, there is clearly a preference "for the non-implementing Member to bring its measures into conformity with its obligations."[129] For this reason, global commentators have expressed concern that WTO trade rules such as those contained in GATT could potentially weaken food safety standards if countries with more lenient standards exert pressure on countries with stricter standards to harmonize their standards to facilitate the ease of trade.[130] However, given the slim likelihood of a successful challenge for the reasons stated above, the FSMA standards should operate as a floor, below which WTO Member countries cannot deviate if they wish to maintain their export markets to the United States.

123. *See* WTO Appellate Body, *Brazil—Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (adopted Dec. 17, 2007).
124. GATT, *supra* note 79, art. XX, chapeau.
125. *See id*. art. XXIII(1)(a).
126. *See id*. art. XIII(1)(b).
127. *See id*.
128. *See* Pauwelyn et al., *supra* note 80, at 136.
129. *See id*.
130. *See* Hilary Bambrick, National Centre for Epidemiology and Population Health, the Australian National University, Trading in Food Safety? The Impact of Trade Agreements on Quarantine in Australia (2004) (Discussion Paper Number 73), *available at* http://www.tai.org.au/sites/defualt/files/DP73_8.pdf.

III. The TPP and Its Critics

Given that President Trump withdrew the United States from the TPP upon assuming office, the GATT and FSMA rules will need to suffice in safeguarding global food safety. If President Trump begins negotiating a new trade deal to replace the TPP, the key question is whether the trade deal is likely to have a beneficial impact on food safety standards beyond the current situation that exists under GATT and the new FSMA regulations.

The TPP may have impacted global food safety, if only because the deal was expected to increase global trade, including food products. The U.S. International Trade Commission commenced an investigation regarding the projected economic impacts of the TPP on the U.S. economy and released its findings on November 17, 2015, which included a projected 0.5% gain for the U.S. agriculture and food industries.[131] Thus, to the extent that the TPP would have resulted in more food moving across borders, it was likely to have an effect on food safety, but the TPP did not seem likely to add any additional protection for food safety standards above what is currently provided for within the context of GATT and the FSMA.

A. *What Was the TPP?*

A discussion of the TPP is still relevant, even after the death knell for U.S. participation in the deal has finished sounding. For TPP opponents, an analysis of the TPP is relevant with respect to the adage that "those who do not know history are doomed to repeat it." Those who have no desire to revive the deal will want to ensure the aspects they found objectionable remain dead and buried. For those former TPP supporters who hope that negotiations will eventually ensue for a new deal, they will want to incorporate the less objectionable aspects of the former trade deal or revise some of its provisions to address the critics' concerns, thereby making any prospective deal more politically palatable.

Touted by some as "the most ambitious free trade deal of the postwar era," and a "landmark accord," the TPP had received its fair share of criticism and praise from the countries it concerned, as well as from other sovereign nations and advocacy groups across the globe.[132] The trade deal represented an agreement between the United States, Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam—whose combined forces amounted to nearly 40% of the global gross domestic product (GDP).[133] TPP supporters boasted of the advantages U.S. markets would have

131. Melissa Miller Proctor, *What the TransPacific Partnership Agreement Could Mean for U.S. Manufacturers, Retailers, and Distributors*, Nat'l L. Rev., Aug. 24, 2016, http://www.natlawreview.com/article/what-trans-pacific-partnership-agreement-could-mean-us-manufacturers-retailers-and.
132. Peterson Institute for International Economics, Assessing the Trans-Pacific Partnership, Volume 1: Market Access and Sectoral Issues 3, 6 (2016) (PIIE Briefing 16-1), *available at* https://piie.com/system/files/documents/piieb16-1.pdf.
133. *See id*.

received if the deal was implemented; economic projections estimated that the United States stood to experience an increase in annual incomes of $131 billion if the deal passed.[134] The goals of the Agreement included lowering the barriers to trade in goods and services in Asia, as well as negotiating new issues such as digital trade, treatment of state-owned enterprises, handling intellectual property rights, ensuring regulatory coherence across nations, and enacting enforceable commitments regarding labor and environmental welfare.[135]

In 2009, President Obama announced the United States' intention to begin participating in TPP negotiations, which commenced shortly thereafter.[136] In June 2015, both the U.S. House of Representatives and the U.S. Senate voted in favor of granting President Obama trade promotion authority—more commonly known as "fast track" authority—to continue the trade deal negotiations with foreign countries.[137] Fast track authority involves a delegation of authority from Congress to the president to facilitate and conclude trade agreements on behalf of the United States.[138] After the president signs a trade agreement, Congress must then ratify it and begin approving any implementing legislation in the event the trade agreement requires changes to U.S. statutory law.[139] When a treaty is fast-tracked, Congress is not permitted to amend the treaty; rather, it can only conduct a yes-or-no vote, with a simple majority determining ratification.[140]

Five-and-a-half years of negotiations finally concluded on February 4, 2016, when the United States and 11 other countries signed the TPP.[141] Following the signing, a two-year ratification period began, wherein at least six other countries accounting in total for at least 85% of the combined GDP that the deal contemplated (which necessarily had to include the United States and Japan due to their size) were required to approve the deal before it could take effect.[142]

B. Was an Additional Trade Deal Even Necessary?

Although many tariffs were eliminated with GATT and other WTO agreements, the TPP sought to further eliminate traditional barriers to trade (such as tariffs) while also updating "rules to meet business and social goals," including improved "mechanisms for setting food standards and technical barriers and for assessing the conformity of products with them."[143] An analysis of TPP tariffs yields that the negotiating countries were able to approach their target of eliminating tariffs for 99% of all agricultural products (including live animals, meat, dairy, vegetables, and beverages) in most instances.[144]

While GATT had already reduced or eliminated most tariffs, the TPP sought to further promote free trade by reducing other non-tariff barriers while also ensuring that countries adhered to safeguarding human rights and maintaining stewardship of the environment. For example, the TPP sought to address non-tariff trade barriers such as lengthy transit times for goods crossing international borders. Experts noted that "[a]s tariffs have come down and lean retailing and global supply chains have become the norm, delays at the border have arguably become the main impediment to goods trade. The [TPP] eases the movement of goods across borders by eliminating excessive delays and opaque rules."[145]

The costs of moving goods through customs and across borders vary from country to country.[146] According to the World Bank's 2016 Doing Business Indicators, complying with the documentary import requirements at the border takes 72 hours in Malaysia and Peru, 62 hours in Vietnam, 48 hours in Brunei Darussalam, 44 hours in Mexico, 40 hours in Japan, 39 hours in Australia, 36 hours in Chile, 35 hours in Singapore, 25 hours in New Zealand, and 2 hours in Canada and the United States.[147] Current estimates indicate that each day of delay at the border results in a 1% reduction in trade.[148] Experts also note that each day goods spend in transit equates to an ad valorem tariff of 0.6 to 2.1%.[149] Thus, a trade agreement that decreases time spent at the bor-

134. *See id*. at 6.
135. *See id*. at 3, 6.
136. *Trans-Pacific Partnership Announcement*, Office of the United States Trade Representative Executive Office of the President, https://ustr.gov/tpp/overview-of-the-TPP, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2009/december/trans-pacific-partnership-announcement/.
137. Hunter Marston, *What the Trans-Pacific Partnership Means for Southeast Asia*, Diplomat, July 27, 2015, http://thediplomat.com/2015/07/what-the-trans-pacific-partnership-means-for-southeast-asia/. *See* U.S. Const. art. II, §2 (providing that the president "shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur").
138. Pauwelyn et al., *supra* note 80, at 57.
139. *See id*.
140. *See id*.
141. Peterson Institute for International Economics, Assessing the Trans-Pacific Partnership, Volume 2: Innovations in Trading Rules 3 (Jeffrey J. Schott & Cathleen Cimino-Isaacs eds. 2016) (PIIE Briefing 16-4), *available at* https://piie.com/system/files/documents/piieb16-4.pdf.
142. Rebecca Howard, *Trans-Pacific Partnership Trade Deal Signed, but Years of Negotiations Still to Come*, Reuters, Feb. 4, 2016, http://www.reuters.com/article/us-trade-tpp-idUSKCN0VD08S.
143. Peterson Institute, Assessing the TPP, Vol. 1, *supra* note 132, at 7-8.
144. *Id*. at 41. For example, Vietnam currently imposes a 40% tariff on rice, which will be eliminated immediately once the Agreement takes effect (*see id*.). Similarly, Mexico's 20% tariff on long grain rice will be phased out within a decade (*see id*.).
145. Peterson Institute, Assessing the TPP, Vol. 2, *supra* note 141, at 66.
146. *Id*. at 66-67.
147. World Bank, Doing Business, *Trading Across Borders*, http://www.doingbusiness.org/data/exploretopics/trading-across-borders (last visited Mar. 2, 2017).
148. Simeon Djankov (Ministry of Finance, Bulgaria), Caroline Freund (Research Department, World Bank) & Cong S. Pham (School of Accounting, Economics, and Finance, Deakin University), *Trading on Time*, 92 Rev. Econ. & Stat. 166-73 (2010).
149. David L. Hummels & Georg Schaur, *Time as a Trade Barrier*, 103 Am. Econ. Rev. 2935-59 (2013). Ad valorem tariffs are customs duties that are calculated and assessed based on the value of the imported product. For example, a 10% ad valorem tax on an imported $4.00 chocolate bar would result in a price of $4.40. In contrast, specific duties are customs duties assessed based on the weight, volume, or quantity of a product (i.e., a tax of 32.66 cents per kilogram of chocolate) (*see* Pauwelyn et al., *supra* note 80, at 183).

der can "have a meaningful effect on stimulating trade between the TPP countries."[150]

Nevertheless, there may be another pathway to decreasing the time goods spend at the border now that the TPP is a dead letter. The Trade Facilitation Agreement (TFA) was concluded at the WTO's Bali Ministerial Conference in 2013 and contains a variety of provisions to expedite moving and clearing goods across borders.[151] The TFA also provides measures for achieving greater cooperation between customs and other appropriate authorities to facilitate trade compliance issues and contains provisions for technical assistance in this area.[152] If implemented, economists anticipate the TFA will reduce Members' trade costs by 14.3% on average.[153] Canada recently became the 103rd WTO Member country to ratify the Agreement.[154] The Agreement requires the ratification of only seven more WTO Member States before it can come into force.[155] If the Agreement takes effect, it will be binding only on those WTO Member States who have ratified it and any new Member States who subsequently accept the Agreement's protocol.[156]

In addition to further reducing the costs of trade, the United States, as the former chief proponent of the TPP, recognized that it could also set the rules with respect to human rights, labor, food safety, and environmental issues that are largely not covered by GATT.[157] However, the TPP has been the recipient of rampant criticisms from food safety groups. The Center for Food Safety, Public Citizen, and Food & Water Watch have argued against implementing the TPP, expressing concern that U.S. ratification of this trade treaty could have the effect of jeopardizing the safety of the world's food supply, while also voicing their disagreement with numerous provisions related to jobs, the environment, and public health.[158]

In response to these and other similar criticisms, President Obama had asserted:

> If you don't want China to set the rules for the 21st century—and they're trying—the TPP makes sure we set the rules . . . [s]o it's simple: If you want to help China, then you shouldn't pass this trade deal we negotiated. If you want to help America, then you need to pass it.[159]

However, as evidenced by the heated controversy the TPP generated among members of the American public and in politics, an evaluation of the TPP and a determination of whether to implement the deal or not was far from simple.

C. How the TPP Could Have Changed the Rules of the Game

Despite all the TPP sought to achieve, there were two provisions—specifically with respect to food safety—that caused great concern: the Investor-State Dispute Settlement (ISDS) mechanism and the SPS provision. Many advocacy and consumer protection organizations viewed these two provisions as deal breakers, and the provisions will require substantial revision if a Trump Administration hopes to negotiate a new deal to successfully replace the TPP.

1. ISDS Mechanism

The ISDS mechanism in Chapter 28 of the TPP Agreement articulated "how the United States and the 11 other participating countries can lodge complaints over alleged failures to implement the agreement's provisions and outlines remedies available to aggrieved parties, including retaliation by raising tariffs."[160] This mechanism was intended to protect free trade from discrimination and expropriation without compensation.

This mechanism provided that, in the event a Member country passed a law or measure that a company or corporation deemed inconsistent with that country's obligations under the Agreement, the company/corporation could request consultations with the country allegedly violating the Agreement[161] and attempt to settle the matter through negotiation, mediation, or some other form of alternative dispute resolution.[162] In the event that the parties are unable to agree on a resolution, an independent panel of three members (who shall have expertise in international trade) may be convened, pursuant to the procedures set forth in the Agreement.[163]

150. Peterson Institute, Assessing the TPP, Vol. 2, *supra* note 141, at 66-67.
151. News Release, WTO, Canada Ratifies the Trade Facilitation Agreement (Dec. 16, 2016), https://www.wto.org/english/news_e/news16_e/fac_15dec16_e.htm.
152. *See id*.
153. WTO, World Trade Report 2015, Speeding Up Trade: Benefits and Challenges of Implementing the WTO Trade Facilitation Agreement 7, 73, 134 (2015), *available at* https://www.wto.org/english/res_e/booksp_e/world_trade_report15_e.pdf.
154. News Release, WTO, *supra* note 151.
155. *See id*. The TFA requires two-thirds of the WTO membership to formally ratify the Agreement before it takes effect (*see id*.). For a complete list of all the WTO Member countries who have accepted the TFA, *see id*.
156. WTO, *How to Accept the Protocol of Amendment to Insert the WTO Trade Facilitation Agreement Into Annex 1A of the WTO Agreement*, https://www.wto.org/english/tratop_e/tradfa_e/tradfa_agreement_e.htm (last visited Mar. 2, 2017).
157. *See* Office of the U.S. Trade Representative, The Trans-Pacific Partnership: Protecting Workers, *available at* https://ustr.gov/sites/default/files/TPP-Protecting-Workers-Fact-Sheet.pdf; Office of the U.S. Trade Representative, The Trans-Pacific Partnership: Strategic Importance of TPP, *available at* https://ustr.gov/sites/default/files/TPP-Strategic-Importance-of-TPP-Fact-Sheet.pdf.
158. Lydia Zuraw, *Food Safety Groups Oppose Trans-Pacific Trade Partnership*, Food Safety News, Nov. 10, 2015, http://www.foodsafetynews.com/2015/11/food-safety-groups-oppose-trans-pacific-trade-partnership/#.WD2Ic8efyI1.
159. Adam Behsudi, *Pharma Deal With or Without TTIP*, Politico, June 2, 2016, http://www.politico.com/tipsheets/morning-trade/2016/06/pharma-deal-with-or-without-ttip-cracks-show-at-tisa-meeting-ministers-eye-environmental-goods-deal-by-september-214607 (quoting President Obama).
160. Peterson Institute, Assessing the TPP, Vol. 2, *supra* note 141, at 101. *See* Trans-Pacific Partnership art. 28.3(1), at 28-2, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [hereinafter TPP].
161. *See* TPP, *supra* note 160, art. 28.5, at 28-3 to 28-4.
162. *See id*. art. 28.6, at 28-4.
163. *See id*. arts. 28.7-28.13, at 28-4 to 28-13.

After hearing the dispute, the panel must issue a report containing findings of fact, determinations regarding whether the measure at issue is inconsistent with the country's obligations under the TPP, reasoning for its legal and factual findings, and recommendations for the resolution of the dispute where the parties have requested such a recommendation.[164] In the event that the parties fail to cure any deficiencies the panel found, then the injured company/corporation may be entitled to compensation and to suspend benefits accruing to the offending country.[165] The TPP specifically provided that compensation and suspension of benefits are to be temporary measures, which "shall only be applied until the responding Party has eliminated the non-conformity or the nullification or impairment, or until a mutually satisfactory solution is reached."[166]

The International Programs Director for the Center for Food Safety, Debbie Barker, expressed concern that both provisions might allow countries exporting food to the United States the right to dispute "even laboratory food safety testing and the new food import rules under the Food Safety Modernization Act."[167] Barker's fear was that this dispute mechanism could make it easier for companies to challenge food safety standards than it otherwise would be under prior trade agreements.[168] The Office of the U.S. Trade Representative (the Office) maintained that the dispute mechanism was "a neutral, international arbitration procedure."[169] However, advocacy groups such as the Center for Food Safety asserted that the dispute mechanism was actually "an extrajudicial legal body that allows private corporations to sue national governments over rules that companies believe inhibit their profit-making ability."[170]

For example, advocates such as Barker were concerned that U.S.-owned food and agribusiness companies would be able to challenge "domestic public health laws they do not like through their subsidiaries in TPP countries."[171] Despite this opposition, the Office defended the dispute mechanism, claiming that the TPP had been "carefully crafted both to preserve governments' right to regulate and minimize abuse of the [Dispute Settlement] process."[172] Nevertheless, advocates worried that any U.S. food safety rule (those concerning, for example, pesticide and animal drug use, additives, etc.) could have been challenged as "illegal trade barriers" by other signatories to the Agreement.[173]

Supporters of the TPP generally, and the ISDS mechanism in particular, argued that such mechanisms exist in more than 3,000 trade deals (although not in GATT and its related side agreements) and that the TPP's ISDS mechanism was the clearest and strongest formulation of the mechanism to date.[174] In trying to assuage fears that the ISDS mechanism would somehow be used against the United States and erode domestic food safety laws, TPP proponents pointed to the fact that only 13 cases have been brought against the United States and the United States has prevailed in each one.[175] Moreover, proponents noted that there seemed to be a decreasing trend of filing ISDS cases, as only one had been brought against the United States in the past five years.[176] Thus, it may be that fears of ISDS cases forcing the United States to change or compromise its food safety standards in the event of an eventual conflict under the TPP were somewhat unfounded.

Nevertheless, TPP supporters asserted that, even in the event of a successful ISDS case against the United States, such a scenario did not mean that the United States would have to change the FSMA or any of its food safety laws. Supporters maintained that the ISDS mechanism in the TPP included "new safeguards" that protected Member countries' "right to regulate" in the public interest, especially in the areas of "health, safety, the financial sector, and the environment."[177] TPP advocates also noted that the mere frustration of investor expectations were insufficient to successfully challenge a Member country's public health, safety, or environmental regulation.[178] Moreover, supporters noted that the investors bringing a case against a Member country's government bore the heavy burden of proving all the elements of their claims.[179]

In any event, had the TPP been implemented, the ISDS mechanism would have altered the rules of the game significantly by creating the potential for private companies to oppose health safety measures such as the FSMA's FSVP rule, regardless of whether that potential was realized. If any future deals are contemplated, drafters should consider removing any ISDS mechanism or risk facing strong opposition similar to what was raised against the TPP.

2. SPS Measures

The objective of Chapter 7 of the TPP on SPS measures was to "protect human, animal or plant life or health" in the Parties' territories while promoting trade through a "variety of means to address and seek to resolve sanitary and phytosanitary issues."[180] In addition, Chapter 7 purported to ensure that any SPS measures the parties implement "do not create unjustified obstacles to trade."[181] To this end, the TPP encouraged the parties to develop and

164. *See id.* art. 28.17(4), at 28-14.
165. *See id.* art. 28.20, at 28-16.
166. *Id.* art. 28.20(15), at 28-20. Although the Agreement provides that these measures shall be temporary, a time limit is not placed on the length such measures may remain in place.
167. *Id.*
168. *Id.*
169. *Id.*
170. *Id.*
171. *Id.*
172. *Id.*
173. Press Release, Center for Food Safety, TPP Deal Jeopardizes Food Safety and Public Health (Feb. 3, 2016), http://www.centerforfoodsafety.org/press-releases/4219/tpp-deal-jeopardizes-food-safety-and-public-health#.
174. *See* Office of the U.S. Trade Representative, The Trans-Pacific Partnership: Upgrading & Improving Investor-State Dispute Settlement, *available at* https://ustr.gov/sites/default/files/TPP-Upgrading-and-Improving-Investor-State-Dispute-Settlement-Fact-Sheet.pdf.
175. *See id.*
176. *See id.*
177. *See id.*
178. Peterson Institute, Assessing the TPP, Vol. 1, *supra* note 132, at 110.
179. *Id.*
180. TPP, *supra* note 160, art. 7.2(a).
181. *Id.* art. 7.2(d).

adopt the implementation of "international standards, guidelines and recommendations" with respect to regulating human, animal, or plant health.[182]

SPS standards refer to health-based restrictions on trade in certain goods and are intended to ensure product and consumer safety and the commensurability of goods across borders (e.g., that there is no demonstrable health risk to consuming chicken from country A relative to chicken from country B)."[183] This chapter of the TPP mandated that countries use science-based risk analyses to evaluate SPS threats; the TPP further required that any science-based risk analyses essentially be harmonized with the procedures employed in the United States, thereby effectively making the U.S. procedures the regulatory standard for the other signatory countries.[184]

To that end, some experts expected the TPP Agreement to "help harmonize food safety standards across member countries."[185] Notably, for the purposes of Chapter 7 (Sanitary and Phytosanitary Measures) and Chapter 8 (Technical Barriers to Trade) of the TPP, the TPP incorporated Article XX, General Exceptions, of GATT 1994.[186] Supporters of the TPP claimed that the SPS provision safeguarded food safety by ensuring that regulations of Member States were developed in a transparent manner, founded on science, and based on risk in the same way that U.S. food safety regulations were developed under the FSMA.[187]

In contrast to SPS provision proponents, critics were concerned by a portion of the SPS measure dubbed the "rapid response mechanism," which provided that border inspections be "limited to what is reasonable and necessary, and is rationally related to the available science."[188] Critics feared that exporting countries seeking to challenge imports denied for findings of nonconformity could create a chilling effect as overtaxed border inspectors would be called upon to justify rejected shipments based on the "reasonable and necessary" grounds or as "rationally related to the available science."[189] TPP naysayers also noted that it remained unclear what constituted "'documented and objective scientific evidence'" or what evidentiary basis would be used to determine food safety.[190] Finally, critics were also wary of a system that could allow industry to set the scientific basis and provide the evidence for certain standards. Food safety advocates warned that although "industry research may form an important pillar of food safety assessment," caution was required against overly relying on potentially unscrupulous industry sources that could "pose a threat to the public interest."[191]

While decreasing time at the border is important, other means may exist to achieve this goal (such as the TFA). If future deals are contemplated, negotiators would be wise to allow for, and even require, the use of independent research in informing food safety assessments, rather than relying solely on industry-funded studies.

IV. Conclusion

> You got to look on the bright side, even if there ain't one.
>
> —*Dashiell Hammett*

As the volume of trade increases and global food supply chains expand around the world, experts have recognized a need to address global food safety issues from a risk-based perspective rooted in prevention, as opposed to a response-driven regulatory regime combating foodborne illness outbreaks after they have already occurred.[192] Preventive controls are crucial, considering that "[a]t any given meal, food may come from a dozen different countries, regulated by over a dozen different agencies, with the FDA and the Food Safety Inspection Service ('FSIS') of the [U.S. Department of Agriculture] playing key roles."[193]

Food is the great equalizer in the world—it is something none of us can do without for long. Food is one of the first sources of comfort when we are young, it is how we begin learning societal norms and rituals as children, and it is an indispensable component of a healthy, happy, productive life throughout adulthood. Food also carries physical, emotional, cultural, and spiritual significance in every society across the globe. Perhaps the potential impacts on food security and food sovereignty partially explain the bitter debate that ensued over trade deals such as the TPP. When people perceive that their food availability, access, safety, and choice are threatened, it is not an exaggeration to say that their very lives become threatened as well.

Ultimately, the bright side in this scenario may be that while the TPP is now a dead letter, it was not even necessary with respect to strengthening global food safety standards after considering the FSMA's operation under GATT. Admittedly, trade experts acknowledge that while GATT has been "regarded as one of the great success stories of the post-WWII era" and "immensely successful" in reducing the number of tariffs that inhibit trade, its success does not render future trade deals such as the TPP unnecessary.[194] Trade analysts note that the WTO is already working quite

182. *Id.* art. 7.2(f).
183. Peterson Institute, Assessing the TPP, Vol. 1, *supra* note 132, at 57.
184. *Id.*
185. *Id.* Although genetically modified organisms (GMOs) are beyond the scope of this Article, it is noteworthy that the TPP does not provide for any SPS measures regarding GMOs; rather, GMOs are discussed in Chapter 2 of the TPP in terms of national treatment and market access. *Id.*
186. TPP, *supra* note 160, art. 29.1(1), at 29-1. *See infra* Part II.
187. Office of the U.S. Trade Representative, The Trans-Pacific Partnership: Benefits for U.S. Agriculture, *available at* https://ustr.gov/sites/default/files/TPP-Benefits-for-US-Agriculture-Fact-Sheet.pdf.
188. TPP, *supra* note 160, ch. 7, art. 7.11, para. 5.
189. *See* Food & Water Watch, The TPP Attack on Commonsense Food Safety Standards 2 (2015), *available at* http://www.safsf.org/wp-content/uploads/2016/03/FWW-TPP-food-safety-analysis.pdf.
190. Peterson Institute, Assessing the TPP, Vol. 1, *supra* note 132, at 58.
191. *Id.*
192. *See* Bernard Hoekman, Supply Chains, Mega-Regionals, and Multilateralism: A Road Map for the WTO, European University Institute 9 (CEPR Press 2014), *available at* http://ycsg.yale.edu/sites/default/files/files/WTO_Roadmap.pdf; *see also* Carruth, *supra* note 15, at 70.
193. Marks, *supra* note 37, at 133.
194. Stephen Olson, *The TPP and the Sputtering Global Trade System: Can Agreements Like the Trans-Pacific Partnership Fortify a Troubled International*

well, but the TPP would have reached areas such as environmental and labor protections that the WTO currently fails to address.[195]

However, an analysis of the FSMA, GATT, and the TPP demonstrates that it is far from certain whether adoption of the trade deal would have helped the United States to set rules with respect to food safety beyond what GATT and the FSMA already provide. Given the sheer volume of Chinese food imports and the plethora of contamination concerns, it might be surprising that so few heeded President Obama's admonition to set the rules of the game with the TPP. On the other hand, for those concerned with food safety, reluctance to sign the TPP may be understandable because it seems that not much was to be gained from the trade deal in light of existing food safety protections, but much could be wagered and lost with respect to the TPP's ISDS and rapid response mechanisms.

With the TPP out of the picture and no similar trade deals on the horizon,[196] it is worth asking whether the FSMA and GATT secure food safety, especially as trade increases with countries such as China. Given the long-standing problems in China—including corruption, regulatory loopholes, and rampant environmental pollution that jeopardize the quality of food produced under such conditions—the efficacy of the FSMA rules in maintaining the integrity of the U.S. food supply in the face of increasing Chinese imports remains to be seen.[197] Experts note that, "with so few controls on pollution, much of China's air, water and soil are so contaminated, sourcing any food there is risky business."[198] However, the requirements contained in the FSMA necessitating the development and monitoring of HACCP plans and the submission of verification activities at the border seem to create steps in the right direction so far as food safety is concerned.

In any event, it seems that GATT and the FSMA will have to suffice given that they are all we have. China is already bound by the WTO and must adhere to the FSMA if it hopes to continue exporting billions of dollars of food to U.S. markets. While TPP proponents are likely to lament lost opportunities to set rules regarding environmental and labor protections or to address intellectual property issues, as far as food safety is concerned under GATT and the FSMA, the epic saga of the TPP has largely culminated in much ado about nothing.

Trade System?, Diplomat, Jan. 26, 2016, http://thediplomat.com/2016/01/the-tpp-and-the-sputtering-global-trade-system.

195. Simon Lester, *The WTO vs. the TPP*, Huffington Post, July 2, 2014, http://www.huffingtonpost.com/simon-lester/the-wto-versus-the-tpp_b_5252810.html.

196. Since the November 2016 U.S. election, China has been championing support for the Regional Comprehensive Partnership—a trade deal intended as a counterweight to the TPP. In the weeks following the election, some countries remained reticent, preferring to "wait and see if TPP can somehow regain traction once Trump is in office." Jason Scott & David Roman, *China Set to Push Asia Trade Deal Harder After Trump Win*, Bloomberg, Nov. 15, 2016, https://www.bloomberg.com/news/articles/2016-11-15/trump-trade-snub-set-to-boost-china-s-bid-for-its-own-asia-pact. Unless President Trump acts quickly to begin negotiating a replacement for the TPP, countries may sign on with China to the Regional Comprehensive Partnership deal. However, it seems that any future trade deals with the United States are unlikely. President Trump has committed his administration to establishing a new National Trade Council to assess the country's "manufacturing capabilities and the defense industrial base." *See* Philip Brasher, *Trump Picks China Critic to Head New White House Trade Council*, AgriPulse, Dec. 21, 2016, http://www.agri-pulse.com/Trump-picks-China-critic-to-head-new-trade-council-12212016.asp. President Trump has selected Peter Navarro, a critic of China and U.S. trade policy—including the TPP—to lead the new National Trade Council (*see id.*).

197. *See generally* Czarnezki et al., *supra* note 11.

198. *Where Does Our Food Come From?*, *supra* note 40, quoting Burlington Industries Distinguished Professor in Supply Chain Management at Clemson University and Visiting Faculty Fellow of the Texas A&M University Institute for Advanced Study Aleda Roth.