

ARTICLE

THE RISKS WE ARE WILLING TO EAT: FOOD IMPORTS AND SAFETY

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How and what we eat determines to a great extent the use we make of the world—and what is to become of it. – Michael Pollan

Recent efforts to regulate the safety of U.S. food imports have not kept up with the complexity of global trade and the risks that accompany globalization. Congress drafted the Food Safety Modernization Act of 2011 (“FSMA”) in response to heightened food safety risks, surging imports, and an outdated food import safety system. While the FSMA provides the Food and Drug Administration (“FDA”) additional authority to regulate food facilities, establish standards for safe produce, recall contaminated foods, and oversee imported foods, vulnerabilities still exist.

This article exposes problems with the old system of food import rules and significant challenges facing the FDA as it implements the new FSMA rules. Using a hypothetical, the author compares food import risks before and after the FSMA rules to determine which vulnerabilities are likely to remain despite the new rules. She concludes that the growing number of trading partners will further complicate supply chains, and rising trade obligations will exert downward pressure on the United States’ heightened standards.

This article discusses the new FSMA rules, identifies specific challenges, and offers tangible solutions to guide final rulemaking. In light of pressure by the World Trade Organization (“WTO”), Regional Trade Agreements (“RTA”), and Mega-regionals, U.S. food safety regulators need to ensure that the higher food safety standard is not compromised. If the FSMA rules are able to withstand global challenges, these rules have the potential to serve as the global standard for food safety.

I. INTRODUCTION

Food is about trust – when consumers buy food, they assume they are eating something that nourishes, not injures. While the U.S. food supply is among the safest around the globe, rising global trade has made the world more vulnerable to outbreaks of disease caused by contaminated food.¹ An

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¹ *World Prone To Food-Borne Disease Outbreaks*, CITY PRESS (Oct. 13, 2011, 7:14 AM), <http://www.citypress.co.za/news/world-prone-to-food-borne-disease-outbreaks-20111013/>, archived at <http://perma.cc/YPW4-444K> (quoting a World Health Organization representative

expanding presence in international trade requires a set of rules that will ensure food safety for future generations.

As consumers, we see the world as a giant supermarket. The volume of food imports in the United States has doubled over the past decade and the import share of overall consumption is rising steadily.² Over fifteen percent of our food supply comes from imports, and this percentage is even larger for specific groups of products. Imports represent nearly twenty percent of the fresh vegetables we eat, fifty percent of the fresh fruits we eat, and over ninety percent of the fish we eat.³ As food travels from local farms to processors to importers and distributors, and so on, the opportunities for contamination increase with every step in the system. Imported food can be risky – riskier than one would imagine.⁴

While most Americans benefit from a year-round supply of fresh, globally-sourced foods, a series of widely-publicized food safety outbreaks highlights the dangers of imported foods. Illnesses have been linked to adulterated imports including fresh produce, peanut products, baby formula, some meat and poultry products,⁵ pet food, cantaloupes, fish, and shrimp.⁶ According to the U.S. Centers for Disease Control and Prevention (“CDC”), the number of outbreaks attributable to imports rose in recent years, and in 2009-2010, nearly half of the outbreaks were associated with foods imported from areas not previously associated with outbreaks.⁷ Understandably, indi-

as saying that the world has become more vulnerable to outbreaks of disease caused by contaminated food because of growing global trade).

² Andy Jerado, *What Share of U.S. Consumed Food Is Imported?*, AMBER WAVES 36–37 (Feb. 2008), <http://ageconsearch.umn.edu/bitstream/124013/1/Datafeature.pdf>, archived at <http://perma.cc/Q27R-JHL2>.

³ See *Proposed Rules to Ensure the Safety of Imported Food*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359450.htm> (last visited Feb. 15, 2014), archived at <http://perma.cc/3N6E-FH8B>; *Outside the U.S.*, NOAA FISHWATCH U.S. SEAFOOD FACTS, http://www.fishwatch.gov/wild_seafood/outside_the_us.htm (last visited Nov. 5, 2014), archived at <http://perma.cc/F9JQ-2SZ6>.

⁴ *CDC research shows outbreaks linked to imported foods increasing*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 14, 2012), available at http://www.cdc.gov/media/releases/2012/p0314_foodborne.html, archived at <http://perma.cc/T4YU-3DDH> (noting that CDC figures “underestimate the true number of outbreaks due to imported foods as the origin of many foods causing outbreaks is either not known or not reported”).

⁵ RENÉE JOHNSON, CONG. RESEARCH SERV., RS22600, *THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 1* (2011).

⁶ Fred Gale & Jean C. Buzby, *Imports From China And Food Safety Issues*, 52 ECON. INFO. BULL. 2 (2009), <http://www.ers.usda.gov/publications/eib-economic-information-bulletin/eib52.aspx>, archived at <http://perma.cc/U5JT-5S92> (noting that in 2007, “[t]he FDA issued import alerts after it detected melamine in wheat gluten and rice protein products and unsafe veterinary drug residues in five types of farm-raised fish and shrimp from China. In 2008, an import alert for milk products was issued in response to concerns about melamine adulteration. Since the 1980s, FDA’s import alerts for Chinese products have also included red melon seeds (illegal dyes), bean curd (insect filth), dried fungus and mushrooms (filth from animals and insects), fresh garlic (mold, decomposition, insect filth/damage), and honey (fluoroquinolone residues)”).

⁷ See *CDC research shows outbreaks linked to imported foods increasing*, *supra* note 4.

vidual consumers may have difficulty comprehending their individual exposure to import-related foodborne illnesses.

The following example illustrates this point. First, imagine that your freezer stocks a package of frozen fruit mix ready to be blended into a smoothie. The frozen package features a pastoral image of a local farm with organic certification and a less-prominent note on the back panel listing the countries of origin for the respective fruits. You consume the fruit and two weeks later you feel sick, rush to the hospital, and discover that you and many others have been infected with *Hepatitis A*, a liver disease spread by contaminated food and water.⁸ The hospital shares the information with public health officials and the CDC, who trace the illness to the frozen mix. Curiously, the strain of *Hepatitis*, commonly found in North Africa, suggests that a fruit ingredient processed in this region and shipped to the United States is the likely culprit.

This example represents a real outbreak in the United States⁹ before the new proposed rules, promulgated by the FDA in response to the FSMA requirements, were drafted. Do the new food safety rules, codified in the Food Safety Modernization Act of 2011,¹⁰ improve upon the previous rules? For example, do they change the outcome in the above hypothetical such that the illnesses could have been prevented?

In this article, I will argue that the new rules reduce risk to food import transactions. The rules expand regulation beyond border examinations, testing of samples, and compliance to include the following: foreign inspection, foreign facility registration, foreign supplier verification,¹¹ a qualified importer program,¹² third-party certification through accreditation by third-party auditors,¹³ import certifications,¹⁴ bilateral agreements and arrangements,¹⁵ and systems recognition or equivalence assessments of foreign food safety systems. Collectively, these tools are the new food import regulatory toolbox providing assurances that food produced overseas has been pro-

⁸ See *Hepatitis A*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://wwwnc.cdc.gov/travel/diseases/hepatitis-a> (last visited Oct. 30, 2014), archived at <http://perma.cc/PG5P-U5E5>.

⁹ This example corresponds to the 2013 outbreak of Hepatitis A, linked to a frozen berry mix called "Townsend Farms Organic Antioxidant Blend." See *This Summer's Parasites and Viruses Continue to Make People Sick*, FOOD SAFETY NEWS (Sept. 5, 2013), <http://www.foodsafetynews.com/2013/09/summer-outbreak-continue-to-make-people-ill>, archived at <http://perma.cc/E5AX-6WLJ>.

¹⁰ FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of 21 U.S.C.) [hereinafter FSMA] (amending the Federal Food, Drug, and Cosmetic Act); see also Susan A. Schneider, *Notes on Food Law: An Overview of the Food Safety Modernization Act*, 2011 ARK. L. NOTES 39, 39-40 (2011) (providing an overview of the legislation).

¹¹ FSMA § 301 (codified at 21 U.S.C. § 384(a) (2012)).

¹² *Id.* § 302 (codified at 21 U.S.C. § 384(b) (2012)).

¹³ *Id.* § 307 (codified at 21 U.S.C. § 384(d) (2012)).

¹⁴ *Id.* § 303 (codified at 21 U.S.C. § 381 (2012)).

¹⁵ *Id.* § 305 (codified at 21 U.S.C. § 381 (2012)).

duced under conditions that meet U.S. standards or comparable levels of public health protection.¹⁶

The new set of rules need to provide food safety for generations to come because the emergence of new antibiotic resistant pathogens, such as *E. coli* and different strains of *Salmonella*, and new foodborne illness risks will continue to put pressure on all national regulatory systems. In the future, the FSMA's overall success in curtailing foodborne illness risks will be challenged by two growing trends: (1) the growing complexity of modern food supply chains, and (2) pressure exerted by international trade obligations – including the WTO General Agreement on Tariffs and Trade 1947 (“GATT”),¹⁷ the Sanitary and Phytosanitary Agreement (“SPS”),¹⁸ Regional Trade Agreements (“RTAs”), and Mega-regionals¹⁹ – to harmonize national regulatory standards in a downward manner. In terms of pressure exerted by these obligations, recent disputes show how difficult it is to enact food safety laws that withstand criticism from trading partners. For instance, although U.S. consumers are pressing for information on traceability and the origin of their food, attempts to implement corresponding rules would become highly controversial, as illustrated by the controversy regarding the current dispute between Canada and the United States over country-of-origin labeling (“COOL”).²⁰ Laws drafted with food safety in mind may also jeopardize future trade agreements. Malaysia and Vietnam, two countries currently negotiating with the United States over a new Trans-Pacific Partnership, recently challenged the U.S. Department of Agriculture’s (“USDA”) catfish inspection program as a trade barrier under the guise of a food safety measure.²¹

¹⁶ FDA Public Hearing on Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries, FOOD AND DRUG ADMIN. (Mar. 30, 2011), <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm254816.htm>, archived at <http://perma.cc/UJU6-38XS>.

¹⁷ General Agreement on Tariffs and Trade, Oct. 30, 1947, 55 U.N.T.S. 194 [hereinafter GATT], available at http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm, archived at <http://perma.cc/7EDZ-YTPK>.

¹⁸ WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, 1867 U.N.T.S. 493 [hereinafter SPS Agreement], available at http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm, archived at <http://perma.cc/6RDP-9JV9>.

¹⁹ Mega-regionals are big-block trade agreements. For a description, see Sally Razeen, *Is bigger better for ASEAN in a mega-regional world?*, EAST ASIA FORUM (Sept. 10, 2014), <http://www.eastasiaforum.org/2014/09/10/is-bigger-better-for-asean-in-a-mega-regional-world/>, archived at <http://perma.cc/BUS4-CRTV>.

²⁰ The final rule to implement Country-of-Origin labeling [hereinafter COOL] took effect on March 16, 2009. Less than one year after the COOL regulations took effect, Canada and Mexico challenged them in the WTO. The United States lost a panel decision, later appealed, lost on the appeal and is waiting to hear if rules the United States drafted to comply with the WTO ruling comply with our WTO obligations. See REMY JURENAS & JOEL L. GREENE, CONG. RESEARCH SERV., 7-5700, COUNTRY-OF-ORIGIN LABELING FOR FOODS AND THE WTO TRADE DISPUTE ON MEAT LABELING (2013).

²¹ Ron Nixon, *U.S. Catfish Program Could Stymie Pacific Trade Pact, 10 Nations Say*, N.Y. TIMES (June 27, 2014), available at <http://www.nytimes.com/2014/06/28/us/catfish-inspection-trans-pacific-partnership.html>, archived at <http://perma.cc/4SRG-MZRG>.

Part I of the article defines the three pressure points that led to the drafting of the FSMA: namely, (1) the prevalence of foodborne illness, (2) a rise in imports, and (3) a constrained import safety system. Part II describes the new FSMA rules in the context of other national rules and global standard-setting. In Part III, the author presents situations in which the FSMA rules may break down. Emerging pathogens and risks will likely increase the number of foodborne illness outbreaks, a growing number of trading partners will further complicate supply chains, and rising trade obligations will exert downward pressure on U.S. heightened standards.²² For those engaged in FSMA rulemaking and implementation processes, the article presents a useful guide for commenting on proposed rules and guidance documents when they are released. Importantly, the author provides solutions and ways in which we can prepare for these new directions.

II. UNSAFE FOOD AND THE HIGH ROAD TO FOOD SAFETY REFORM

Monitoring and enforcing the safety of our food has never been as difficult as it is today. In the United States, imported foods have been linked to an increasing number of foodborne illnesses. Three of the top ten foodborne illness outbreaks of 2013 implicated fresh fruits and vegetables from Mexico and Turkey,²³ leading to the largest number of reported foodborne illnesses in that year. Partly to blame are new pathogens and emerging food risks, a steady rise in food imports, and an outdated food import safety system. Aimed at raising confidence in food safety while reducing duplication, compliance costs, and information asymmetries,²⁴ the FSMA and the relevant import safety rules which are the focus of this paper, represent a direct response to these challenges with the U.S. food supply.

²² See Lydia Zuraw, *Critics Say Food Safety Standards Could Be Threatened by U.S./E.U. Trade Agreement*, FOOD SAFETY NEWS (May 16, 2014), <http://www.foodsafetynews.com/2014/05/food-safety-standards-could-be-threatened-in-u-s-eu-trade-agreement/>, archived at <http://perma.cc/5TVP-VVHY> (noting that food issues in the Transatlantic Trade and Investment Partnership, the “T-TIP”, between the European Union and the United States are extremely contentious because the European Union’s approach to food safety is grounded in the precautionary principle, which is a higher bar than that of the United States); see also Bruce Silverglade, *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?*, CTR. FOR SCI. IN THE PUB. INT. (May 25, 2014), https://www.cspinet.org/reports/codex/dutch_wto.html, archived at <http://perma.cc/UUR8-V7DF> (noting that under the Sanitary and Phytosanitary Agreement, the WTO may force a nation to choose between weakening its health standards or paying an international penalty).

²³ James Andrews, *The Ten Biggest Foodborne Illness Outbreaks of 2013*, FOOD SAFETY NEWS (Dec. 27, 2013), <http://www.foodsafetynews.com/2013/12/the-10-biggest-u-s-outbreaks-of-2013>, archived at <http://perma.cc/SUY9-WJLH>.

²⁴ See generally Alexia Brunet Marks, *Check Please: Using Legal Liability to Inform Food Safety Regulation*, 50 Hous. L. Rev. 723 (2013) (discussing signaling and incentives). For example, when consumers go uncompensated for every foodborne illness outbreak, firms lack the signaling that they need to take necessary food safety precautions. *Id.* at 729. Additionally, when adulterated foods go undetected on the border due to the low rate of border inspections, firms again do not receive the signaling to take food safety precautions. *Id.*

A. Foodborne Illness

The FSMA was drafted with a concern for foodborne illness at the forefront. With American consumers spending over one trillion dollars per year on what they eat, food is justifiably “big business.”²⁵ And yet, one incident of foodborne illness can result in loss of life, revenue, and reputation. The CDC estimates that each year roughly one out of six Americans (or forty-eight million people) fall ill, 128,000 are hospitalized, and 3,000 people die from foodborne diseases.²⁶ Fortunately, “most foodborne illness can be prevented.”²⁷ However, regulators are continually challenged in isolating the sources and types of risky foods.

Pathogens, such as bacteria and viruses, are the primary cause of foodborne illness and are found in all types of foods, although foods of animal origin are more likely to be contaminated.²⁸ Incidents linked to fresh produce are more infrequent and tend to be smaller in scale relative to foodborne illness outbreaks from meats and processed foods, and often are not ultimately traced back to the farm.²⁹ However, fruits and vegetables present risks as well, particularly because many are eaten raw, and harmful pathogens can be acquired at the farm level.³⁰ In fact, by the 1990s, six percent of foodborne illness outbreaks were associated with fresh produce, up from less than one percent in the 1970s.³¹ More recently, deadly outbreaks of foodborne illness were ultimately traced to fresh produce—including *Listeria Monocytogenes*³² on fresh cantaloupe,³³ *E. coli*³⁴ on strawberries³⁵ and spin-

²⁵ See CDC *Foodborne Illness Trends in 2012*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 18, 2013), <http://www.cdc.gov/features/dsfoodnet2012/>, archived at <http://perma.cc/U72F-VN45>.

²⁶ See CDC *Estimates of Foodborne Illness in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/foodborneburden/> (last visited Nov. 5, 2014), archived at <http://perma.cc/ZT7-UETC>.

²⁷ *Foodborne Illness: What Consumers Need to Know*, U.S. DEP'T OF AGRIC., FOOD SAFETY AND INSPECTION SERV., http://www.fsis.usda.gov/wps/portal/ffsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/foodborne-illness-what-consumers-need-to-know/ct_index (last visited Nov. 5, 2014), archived at <http://perma.cc/P9E6-UUHW>.

²⁸ Non-biological contaminants are another source of food safety risk. See Andrews, *supra* note 23.

²⁹ See Jason S. Parker et al., *Including Growers in the “Food Safety” Conversation: Enhancing the Design and Implementation of Food Safety Programming Based on Farm and Marketing Needs of Fresh Fruit and Vegetable Producers*, 29 AGRIC. & HUMAN VALUES 303, 304 (2012).

³⁰ See *id.*, at 303; see also RENÉE JOHNSON, CONG. RESEARCH SERV., R41629, FOOD SAFETY ISSUES FOR THE 112TH CONGRESS 2–3 (2011) (describing major U.S. foodborne illness outbreaks since 2007 and the pathogens commonly associated with foodborne illness).

³¹ Diana Stuart, *The Illusion of Control: Industrialized Agriculture, Nature, and Food Safety*, 25 AGRIC. & HUMAN VALUES 177, 178 (2008).

³² See generally *Listeria*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/listeria/> (last visited Jul. 29, 2014), archived at <http://perma.cc/62EX-S5MD>.

³³ *Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/listeria/outbreaks>

ach,³⁶ and *Salmonella*-contaminated peppers.³⁷ Despite the outbreaks and risks related to fresh produce, farmers are not the only ones liable for foodborne illness violations.

Supply chains are becoming more complex, making agricultural producers feel that it is inappropriate to assign responsibility to growers when most outbreaks are connected to processors or handlers.³⁸ Farmers are quick to point out that most food consumed in the United States is grown and processed on such a large scale³⁹ that failing to properly remove contaminants in a single production step can result in contaminated food reaching millions of consumers, given the current system of centralized production and transatlantic shipment.⁴⁰ This problem occurred in 2008 when a deadly *Salmonella* outbreak that sickened thousands was ultimately linked to jalapeno and serrano peppers from a Mexican farm.⁴¹ In that case, the peppers were contaminated by irrigation water and eaten raw after first mistakenly implicating American tomatoes as responsible for the outbreak.⁴²

In a previous article, this author argued that many lawsuits over foodborne illnesses arise from foods consumed in restaurants; as such, increased inspections and controls of restaurants seem warranted.⁴³ Restaurants aside, the author argues that manufacturers, distributors, farmers, importers, and foreign producers are all complicit in foodborne illness incidents.⁴⁴ Previously, the author estimated an empirical model using all of the 320 publicly recorded foodborne illness settlements and verdicts in the United States from 2000 to 2011 to determine factors that influence the plaintiff win rate, resolution time, and plaintiff recovery.⁴⁵ The results suggested that foodborne illness litigation sends a strong signal to firms to increase food safety practices,

/cantaloupes-jensen-farms/index.html (last visited Nov. 5, 2014), archived at <http://perma.cc/CX97-7LD4>.

³⁴ *E. coli*, CTNS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/ecoli/> (last visited July 29, 2014), archived at <http://perma.cc/YK9G-AJPK>.

³⁵ *Lab Tests Confirm Source of E. coli O157 from Deer Droppings in Strawberry Fields in NW Oregon*, OR. HEALTH AUTH. PUB. HEALTH DIV. (Aug. 17, 2011), <http://www.oregon.gov/oha/news/Documents/2011-0817a.pdf>, archived at <http://perma.cc/S8NV-39FS>.

³⁶ Since 1993, there have been over two dozen *E. coli* outbreaks in the United States traced to contaminated leafy green vegetables. See Dennis G. Maki, *Coming to Grips with Foodborne Infection—Peanut Butter, Peppers, and Nationwide Salmonella Outbreaks*, 360 NEW ENG. J. MED. 949 (2009).

³⁷ *Id.* at 949.

³⁸ Parker et al., *supra* note 29, at 316.

³⁹ Maki, *supra* note 36.

⁴⁰ *Id.* at 951.

⁴¹ See *Investigation of Outbreak of Infections Caused by Salmonella Saintpaul*, CTNS. FOR DISEASE CONTROL & PREVENTION (Aug. 28, 2008), <http://www.cdc.gov/salmonella/saintpaul/jalapenol>, archived at <http://perma.cc/DX6G-HLG6>.

⁴² See *CDC Study Vindicates Tomatoes in 2008 Salmonella Saintpaul Outbreak*, UNITED FRESH (Feb. 24, 2011), <http://iuf.unitedfresh.org/newsletters/2011/02/24.php#1>, archived at <http://perma.cc/GXA2-V8HW>.

⁴³ See *supra*, note 24.

⁴⁴ See generally *id.*

⁴⁵ See *id.*

mostly through settlements and not jury verdicts.⁴⁶ The results also highlighted the market failures that exist in food safety—the transaction costs and information costs preventing plaintiffs from suing and recovering fully—presenting valuable information for regulators.

A more detailed analysis of foodborne illness sources can be performed using CDC estimates. Data on confirmed foodborne illness outbreaks and imported food sources between 1991 and 2009 can be found in Table 1 in the Appendix. The list in Table 1 is, however, a fraction of foodborne illness cases as most outbreaks are not confirmed and are not multistate. Nonetheless, according to the Table 1 data, the food categories most often linked to reported outbreaks were seafood, fruits and vegetables, and spices.⁴⁷ Raw foods are a concern because they are combined and processed, and therefore not included in labeling regulations.⁴⁸ For example, raw milk and most vegetables still commonly harbor microorganisms of food-animal origin such as *Campylobacter*,⁴⁹ *Salmonella*, *E. coli*,⁵⁰ and *Listeria*. In addition to the Table 1 data, three of the top ten foodborne illness outbreaks of 2013 implicated fresh fruits and vegetables from Mexico and Turkey.⁵¹ In time, new antibiotic resistant pathogens and new foodborne illness risks will continue to put pressure on all national regulatory systems.

B. Global Food Supply Chains

The FSMA was drafted in response to a rise in demand and consumption of imported food, prompted by a steady and sustained increase in international trade. Between 1950 and 2008, the volume of trade increased twenty-seven times, three times more than the growth in global GDP.⁵² Global trade in goods and services exceeded twenty trillion dollars in 2011, rising from thirty-nine percent of GDP in 1990 to fifty-nine percent of global GDP in 2011.⁵³ In 2012, food exports totaled \$133 billion and imports to-

⁴⁶ See *id.*

⁴⁷ See *infra*, Table 1.

⁴⁸ Food products contained in the COOL include muscle cut and ground meats such as beef, veal, pork, lamb, goat, and chicken; wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng. See Country of Origin Labeling for Fish and Shellfish, 7 C.F.R. § 60 (2009); Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Perishable Agricultural Commodities, Macadamia Nuts, Pecans, Peanuts, and Ginseng, 7 C.F.R. § 65 (2009).

⁴⁹ See generally *Campylobacter*, *General Information*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 3, 2014), <http://www.cdc.gov/nczved/divisions/dfbmd/diseases/campylobacter/>, archived at <http://perma.cc/S5G7-7VQ9>.

⁵⁰ See generally *E. Coli (Escherichia Coli)*, *General Information*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 3, 2012), <http://www.cdc.gov/ecoli/general/index.html>, archived at <http://perma.cc/AFC8-SU6N>.

⁵¹ See Andrews, *supra* note 23.

⁵² BERNARD HOEKMAN, SUPPLY CHAINS, MEGA-REGIONALS AND MULTILATERALISM: A ROAD MAP FOR THE WTO 13 (2014), available at http://www.voxeu.org/sites/default/files/file/WTO_Roadmap.pdf, archived at <http://perma.cc/G9UG-B6FA>.

⁵³ *Id.* at 13.

taled \$110 billion, the surplus due to grain and growing meat exports.⁵⁴ As American consumers seek greater variety, quality, and convenience in the food they consume, grocery stores are showcasing a year-round supply of fresh grapes, kiwis, tomatoes, pears, and spinach, among many other products. At any given meal, food may come from a dozen different countries, regulated by over a dozen different agencies,⁵⁵ with the FDA and the Food Safety and Inspection Service (“FSIS”) of the USDA playing key roles.⁵⁶

The FDA’s goal is to protect public health by assuring that the nation’s food supply is safe and secure.⁵⁷ While regulating all domestic and imported food except meat, poultry, and processed eggs,⁵⁸ the FDA oversees more than 420,000 registered domestic and foreign facilities and conducts food and feed inspections using close to 1,100 full-time staff.⁵⁹ In sum, twenty-five cents of every dollar consumers spend on groceries can be traced to FDA-regulated products.⁶⁰ The United States imports food, and the FDA regulates food, from 150 countries.⁶¹ Within these countries, food processors may be small-to-medium-sized firms, foreign based operations, or large multinational corporations operating transnationally, through ownership of a foreign subsidiary or through subcontracting core functions of the firm.

⁵⁴ Dan Flynn, *Imports and Exports: Americans Shop the World for Food Every Day of the Week*, FOOD SAFETY NEWS (Nov. 4, 2013), <http://www.foodsafetynews.com/2013/11/americans-dining-on-more-imported-food-than-ever/>, archived at <http://perma.cc/63GK-VPNQ>.

⁵⁵ See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-05-549T, STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES 3 (2005). Depending on the particular product, in the United States, over a dozen federal agencies share jurisdiction over food safety, with four playing major regulatory roles: the FDA, which is part of the U.S. Department of Health and Human Services (“HHS”), the Food Safety and Inspection Service (“FSIS”), which is part of the USDA, the Environmental Protection Agency, and the Department of Commerce’s National Marine Fisheries Service. See *id.* at 5.

⁵⁶ Within HHS, the FDA has in its purview all domestic and imported foods marketed in interstate commerce as well as game and exotic meats (e.g., kangaroo, quail, and duck), food additives, animal feed, and veterinary drugs. FDA-regulated meat and poultry products include products that contain less than two percent cooked or three percent raw meat by volume. The FDA allows meat, poultry, or egg products only from an approved source. Jean C. Buzby, Laurian J. Unnevehr, and Donna Roberts, *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports*, 39 ECON. INFO. BULL. 1, 3 (2008), available at <http://www.ers.usda.gov/media/199635/eib39.pdf>, archived at <http://perma.cc/WT4Z-NKHN>; Johnson, *supra* note 5, at 1.

⁵⁷ See *What We Do*, FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/> (last updated Aug. 5, 2014), archived at <http://perma.cc/F9YM-J9V4>.

⁵⁸ See Buzby et al., *supra* note 56, at 3.

⁵⁹ FOOD & DRUG ADMIN., ANNUAL REPORT TO CONGRESS ON FOOD FACILITIES, FOOD IMPORTS, AND FDA FOREIGN OFFICES 2 (2012), available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm>, archived at <http://perma.cc/3BJ4-LBEW>.

⁶⁰ FOOD & DRUG ADMIN., PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY 2 (2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/GlobalProductPathway/UCM262528.pdf>, archived at <http://perma.cc/QE3F-SG2R>.

⁶¹ *Questions and Answers on the Food Modernization Safety Act*, FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm> (last visited Aug. 15, 2014), archived at <http://perma.cc/LC5H-7CLU>.

Import statistics best illustrate these and other notable trends. Table 2 in the Appendix presents the import shares of American food consumption for 2000 to 2009, utilizing the most current data available by the USDA Economic Research Service. Several figures are worth noting. First, according to Table 2, food imports accounted for seventeen percent of all foods consumed in the United States in 2009, up from fourteen percent in 2000.⁶² Next, considering only FDA-regulated foods, eighty-five percent of seafood consumption comes from imports, and ninety-seven percent of tropical products consumption comes from imports.⁶³ Finally, since 2002, horticultural products—fruits, vegetables, nuts, wine, malt beverages, and nursery products, mostly from Mexico and Canada—have accounted for about half of all American agricultural imports.⁶⁴ This data is consistent with other figures showing that the United States imports thirty-eight percent of all fruit and nuts consumed and seventeen percent of vegetables consumed.⁶⁵

The data found in Tables 1 and 2 suggest a link between food trade and foodborne illness. For instance, import shares are higher for some foods that are often linked to microbial foodborne illness. An analysis of 5,000 foodborne illness outbreaks in the United States between 1990 and 2004 demonstrated that the food categories linked to most outbreaks (excluding multi-ingredient foods) were: (1) seafood, (2) fruits, (3) vegetables, (4) poultry, (5) beef, and (6) eggs.⁶⁶ Three out of the top ten foodborne illness outbreaks of 2013 implicated foreign-sourced fresh fruits and vegetables from Mexico and Turkey.⁶⁷ Eighty-four people were injured from a *Salmonella* outbreak traced to imported Mexican cucumbers,⁶⁸ 162 people were injured from a *Hepatitis-A* outbreak traced to pomegranate seeds from Turkey,⁶⁹ and 631 people were injured from an outbreak traced to Mexican lettuce and cilantro used in salads.⁷⁰ Cross-referencing the data on foodborne illness outbreaks

⁶² See *infra* Table 2.

⁶³ FOOD & DRUG ADMIN., GLOBAL ENGAGEMENT 3 (2012), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM298578.pdf>, archived at <http://perma.cc/C6Q2-9L5C>.

⁶⁴ Imports, U.S. DEP'T AGRIC. ECON. RESEARCH SERV. (2012), <http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/imports.aspx>, archived at <http://perma.cc/S7U-D7HA>.

⁶⁵ See *Import Share Consumption, Table 1: Import shares of US Food consumption using the value method*, U.S. DEP'T AGRIC. ECON. RESEARCH SERV. (2012), available at <http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/import-share-of-consumption.aspx#import>, archived at <http://perma.cc/6GD2-CC7A>.

⁶⁶ Buzby et al., *supra* note 56.

⁶⁷ See Andrews, *supra* note 23.

⁶⁸ See *Multistate Outbreak of Salmonella Saintpaul Infections Linked to Imported Cucumbers*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 20, 2013), <http://www.cdc.gov/salmonella/saintpaul-04-13/index.html>, archived at <http://perma.cc/DH86-M9ZU>.

⁶⁹ See *Multistate Outbreak of Hepatitis A Virus Infections Linked to Pomegranate Seeds from Turkey*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 15, 2014), <http://www.cdc.gov/hepatitis/outbreaks/2013/a1b-03-31/index.html>, archived at <http://perma.cc/D4V-DTV2>.

⁷⁰ See *Cyclosporiasis Outbreak Investigations – United States, 2013*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 2, 2013), <http://www.cdc.gov/parasites/cyclosporiasis/outbreaks/investigation-2013.html>, archived at <http://perma.cc/7HFS-9AH7>.

with the data in Table 2, one can see that the foods linked to most outbreaks are also the same foods that have high import shares of consumption. Put simply, the imported foods of which we consume the most are, coincidentally, the ones sickening us.

Another important trend to note is that import sources are widening to include a diverse array of trading partners. The United States imports most of its food from developed and developing countries, with more growth in supply from developing countries. Tables 3 and 4 in the Appendix identify the top twenty-five agricultural import commodities and countries, respectively, using World Bank country classifications. For operational purposes, the World Bank uses gross national income per capita to classify economies⁷¹ and uses these classifications: (1) low income, (2) middle income (divided into lower middle income and upper middle income), and (3) high income.⁷² The first two groups are typically labeled as ‘developing economies’ and the third group, ‘developed economies.’⁷³ Table 4 in the Appendix illustrates that high-income countries have historically supplied most American agricultural imports in the largest agricultural import category of ‘processed high-value products.’⁷⁴ Since 2000, however, the middle-income countries—home to five of the world’s seven billion people and seventy-three percent of the world’s poor⁷⁵—have become increasingly important sources for imports of raw and semi-processed high-value product, two fast-growing agricultural import categories.⁷⁶ As the next section will show, regulators need to broaden risk-based screening efforts to look beyond the country of origin and consider the breadth of the supply chain.

C. *Beyond Risk-Based Screening*

FSMA was passed in response to rising foodborne illness and a system based on an outdated method of inspecting shipments coming into the United States.⁷⁷ A comparison of other countries’ efforts with regard to inspections provides context for this discussion.

⁷¹ See *Data: Country and Lending Groups*, THE WORLD BANK (2014), <http://data.worldbank.org/about/country-and-lending-groups>, archived at <http://perma.cc/CS5K-B6RK>.

⁷² *Id.*

⁷³ *Id.* (noting that the classification is intended to be used for convenience; classification by income does not necessarily reflect development status or developmental goals).

⁷⁴ See *infra* Table 4.

⁷⁵ See *Middle Income Countries Overview*, THE WORLD BANK, <http://www.worldbank.org/en/country/mic/overview> (last visited Nov. 2, 2014), archived at <http://perma.cc/H7BE-FWZP>.

⁷⁶ See U.S. DEP’T AGRIC. ECON. RESEARCH SERV., *supra* note 65 (noting that high value products are one of three types: raw, semi-processed, and processed); see also *infra* Table 4 (illustrating that high income and upper-middle income countries are the leading suppliers of U.S. agricultural imports).

⁷⁷ See Joan Murphy, *FDA’s Taylor Says Food-Safety Inspections to Change in Post-FSMA*, THE PRODUCE NEWS (Sept. 11, 2014), <http://producenews.com/news-dep-menu/test-featured/13996-fda-s-taylor-says-food-safety-inspections-to-change-in-post-fsma>, archived at <http://perma.cc/534Q-A5AV>; see also Margaret A. Hamburg, *Food Safety Modernization Act: Putting*

Leading up to the FSMA, a survey of nine countries' food import practices revealed that all countries in the sample used risk-assessment to prioritize risk-regulation efforts, and the approaches to ensuring the safety of imported foods varied substantially.⁷⁸ The survey results show that countries trust importers to ensure the safety of imported food, provide guidance to promote good importer practices, and recover some costs from operating their import system.⁷⁹ All countries had export certification programs in place (including exporter registration and/or licensing, and/or certification) that focused on assuring market access for country food exports.⁸⁰ The survey results suggest that while the United States employs risk-assessment, more can be done to monitor export sources.

Before the FSMA, the FDA lacked explicit authority to ensure food safety standards at their source.⁸¹ Instead, the FDA was only authorized to refuse an article of imported food in two circumstances. First, an article of food was refused if it appeared "from the examination of such samples" to be adulterated, misbranded, or in violation of the Federal Food Drug and Cosmetics Act.⁸² Over the years, the FDA has been using compliance data to target inspections on the border, otherwise known as a risk-based screening mechanism, to assess the potential risk of an import prior to entry. For use in these analyses, the FDA generates computerized Import Refusal Reports that record the product, its supplier, country of origin, and the reason that products are refused entry into U.S. commerce.⁸³ Imported food must be free

the Focus on Prevention, FOODSAFETY.GOV, <http://www.foodsafety.gov/news/fsma.html> (last visited Nov. 8, 2014), archived at <http://perma.cc/X3WR-8JR8>.

⁷⁸ See Aylin Sertkaya et al., *Food and Feed Import Practices of Foreign Governments to Improve Food Safety* 10 (Eastern Research Group, Contract No. HHSF2232008100171, Feb. 2013), available at <http://www.fda.gov/downloads/Food/InternationalInteragencyCoordination/UCM344753.pdf>, archived at <http://perma.cc/82P3-DS7M> (surveying food import authorities and private sector involvement in Australia, Canada, Chile, Ireland, Israel, Japan, New Zealand, the Netherlands, and South Africa).

⁷⁹ See *id.* at vii. (Among the countries surveyed, the ones which provide guidance for good importer practices are Canada, New Zealand, Ireland, South Africa, and Australia. The countries which contribute to the cost of operating the import system are New Zealand, Israel, the Netherlands, Ireland, Chile, Canada, and South Africa. The countries which require importers to be registered are Israel, New Zealand, Mexico, and Ireland.)

⁸⁰ *Id.* at viii.

⁸¹ *Hearing to Review Current Issues in Food Safety: Hearing Before the H. Committee on Agriculture*, 111th Cong. 124 (2009) (statement of Michael R. Taylor, J.D., Senior Advisor to the FDA Commissioner), available at <http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg52173/html/CHRG-111hhrg52173.htm>, archived at <http://perma.cc/N4TZ-L9X3>.

⁸² 21 U.S.C. § 381(a); see also *Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded*, FOOD & DRUG ADMIN. (Mar. 20, 2014), available at <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074248.htm>, archived at <http://perma.cc/c64MQ-4WSC>.

⁸³ See *Import Refusal Report for OASIS*, FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/importrefusals/> (last visited Nov. 5, 2014), archived at <http://perma.cc/N68P-CB7G> (showing that FDA assigns violations codes to document the reason for refusal. Multiple violations can be associated with a refusal of a particular entry line); see also *Oasis Refusals by Industry for September 2014*, FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/importrefusals/ir_byProduct.cfm?DYear=2014&DMonth=9 (last visited Nov. 5, 2014), archived at <http://perma.cc/GC7K-SXHC> (showing that refusals include many nonfood

from adulteration, be properly and truthfully labeled in English, and comply with all other American laws and standards.⁸⁴ Shipments are targeted for inspection or other administrative actions to assess existing and emerging problems identified by FDA. For example, products screened prior to entry are given an ‘import alert’ for inspection while some products are intentionally inspected based on the history of that product’s prior entry and the country of origin.⁸⁵ The top six reasons for refusing products are: (1) food adulteration (safety and packaging integrity problems such as leaky containers/swollen cans that may suggest the presence of microbial growth), (2) filth or decomposition, (3) presence of unsafe food additive, (4) prepared or packed in unsanitary condition, (5) leaving valuable materials out (or substituting inferior materials), and (6) misbranding (lack of appropriate labeling such as not declaring food ingredients or major food allergens, and not complying with nutrition information content on label).⁸⁶ Many of these risks are random, some are systemic (faults in a processor’s program and its execution), and yet others simply arise from different countries’ food regulatory systems and standards.

The FDA was also authorized to refuse an article of imported food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“Bioterrorism Act”). Under the Bioterrorism Act, importers are required to provide the FDA with advance notice of any shipment of food imported or offered for import to the United States.⁸⁷ The FDA could refuse or hold food if the food came from an unregistered foreign facility.

While these rules appeared reasonable on paper, in practice the rules epitomized an outdated food import safety system. Even with risk-based screening, the FDA physically inspected only a small proportion of food import shipments. In fiscal year 2011, the FDA physically examined 2.3 percent of the over ten million food import lines under its authority.⁸⁸ Despite risk-based screening, the vast majority of imported food remained uninspected, and could enter the American food supply without scrutiny. Arguably, this inspection system created a perverse economic incentive for foreign food facilities—they could take a gamble in their food safety exports, knowing that the majority of foodstuffs could evade FDA inspectors.

Additionally, many food risks, such as the frozen fruit from the original hypothetical, were not detained because they entered from registered facili-

shipments because the FDA also oversees imports of pharmaceuticals, medical devices, and radiation-emitting equipment).

⁸⁴ See Buzby et al., *supra* note 56.

⁸⁵ See Alli Condra, *FDA Import Alerts: A Primer*, FOOD SAFETY NEWS (Sept. 23, 2011), <http://www.foodsafetynews.com/2011/09/fda-import-alerts/>, archived at <http://perma.cc/G7MK-2JDZ>.

⁸⁶ See Buzby et al., *supra* note 56, at 7-14.

⁸⁷ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C. § 305 (2012).

⁸⁸ FOOD & DRUG ADMIN., 2012 ANNUAL REPORT ON FOOD FACILITIES, FOOD IMPORTS, AND FDA FOREIGN OFFICES (2012).

ties. Of course, if a subsequent screen detected a violation, then the firm would receive an import alert and would be flagged for future screening.

Persistent problems were identified with respect to imported foods. In a study of import refusals from 1998 to 2004, the three food-related industry groups with the most violations were vegetables (twenty percent of total violations), fishery and seafood (twenty percent) and fruits (twelve percent).⁸⁹ Further, violations observed over the entire time period include sanitary issues in seafood and fruit products, unsafe pesticide residues in vegetables, and unregistered processes for canned food products in all three industries.⁹⁰ Fishery and seafood products had the most violations for pathogen adulteration and the vegetables and vegetable products had the most violations for chemical contamination.⁹¹ Using our frozen fruit example, the exporters also had clear track-records of no import refusals or alerts.

Another oft-cited problem is the FDA's inability to inspect foreign operations. The Bioterrorism Act mandated that every domestic and foreign food manufacturing and warehousing facility register with the FDA, whether or not food from the facility entered interstate commerce.⁹² There are currently 449,859 registered food facilities comprised of 278,307 foreign registrations and 171,552 domestic registrations.⁹³ And yet, when the FSMA was signed into law, the FDA was conducting less than 200 foreign food plant inspections per year.⁹⁴ The FSMA requires the FDA to conduct almost 40,000 foreign inspections in the next four years, and at least 19,200 foreign inspections each year after that.⁹⁵ One can only assume that this FSMA requirement was an attempt to narrow the gap between the number of foreign registrations and the number of foreign food plant inspections.

While the rules represent an improvement upon the previous import rules, several trends will continue to challenge the FSMA. Part III describes the new FSMA rules in depth with a parallel discussion of global food safety standard-setting organizations.

III. UNDERSTANDING THE TAXONOMY OF FOOD SAFETY STANDARDS

National governments, international bodies, and private industry all play a role in establishing food safety standards. Developed countries normally set strict food safety standards for their constituencies while developing countries follow minimum standards. If a country is a member of the WTO, other WTO members may challenge strict food safety standards for-

⁸⁹ Buzby et al., *supra* note 56, at iii.

⁹⁰ *Id.* at 11.

⁹¹ *Id.* at 9.

⁹² See 21 U.S.C. § 305 (2012).

⁹³ See Flynn, *supra* note 54.

⁹⁴ See *id.*

⁹⁵ See Maria Utecht, *FDA Recognizes New Zealand Food Safety System As Comparable*, REGISTRAR CORP (Dec. 20, 2012), <http://fda-news.registrarcorp.com/2012/12/fda-recognizes-new-zealand-food-safety-system/>, archived at <http://perma.cc/ZEU8-23BV>.

mally in the WTO as being overly protectionist. If a country is a member of an RTA, regional trade partners may bring claims against RTA members, or may use food safety regulations as bargaining chips in regional trade negotiations. By challenging food safety measures, WTO and RTA members can exert pressure upon other countries to harmonize the rules downward, or to submit to minimal international guidelines.⁹⁶ Conversely, while private industry standards are voluntary, they typically represent a high standard of food safety when adopted.⁹⁷

A. National Food Safety Governance

Across the globe, food safety regulators face a delicate balancing act: to guarantee safe food for their citizens while reducing monitoring and compliance costs. Every country approaches this goal from a different perspective and yet, similarities exist. To oversimplify, developed countries adopt more restrictions on health and safety measures already in place, while developing countries often struggle to meet minimum standards. Ensuring food safety at the national level is costly and a substantial disadvantage for most low-income countries.⁹⁸ Even within these groups of countries, there are differences.

Within the developed world, the new FSMA rules and the European Union General Food Law⁹⁹ contain many similarities including placing primary responsibility of food safety on the food industry, promoting systematic supply-chain oriented food safety regulations and unifying international standards.¹⁰⁰ It is important to note one fundamental difference between food safety regulations in the United States and in Europe. The European Union uses the precautionary principle approach to food safety regulation and to

⁹⁶ See Hilary Bambrick, *Trading in Food Safety? The Impact of Trade Agreements on Quarantine in Australia*, The Australia Institute Discussion Paper No. 73 i, vii (Oct. 2004), available at http://www.tai.org.au/documents/dp_fulltext/DP73.pdf, archived at <http://perma.cc/J6YL-63LJ>.

⁹⁷ See *infra* Section 2.C. As will be discussed later, to participate in some supply chains or sell to certain retailers, private standards are not voluntary.

⁹⁸ Mirriam Jutha, *Why Low Income Countries Should Care about Food Safety*, FOOD SAFETY NEWS (Oct. 11, 2012), <http://www.foodsafetynews.com/2012/10/should-low-income-countries-care-about-food-safety>, archived at <http://perma.cc/9KR8-U4B4>. See also FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS AND THE WORLD HEALTH ORGANIZATION, *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*, FAO FOOD AND NUTRITION PAPER No. 76 (2003), available at <ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf>, archived at <http://perma.cc/3BM4-JPMQ>.

⁹⁹ See European Parliament and Council Regulation 178/2002, Laying Down General Principles and Requirements of Food Law, art. 7(1) 2002 O.J. (L 31) 1 (EC) [hereinafter “European Union General Food Law”], available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>, archived at <http://perma.cc/7KQU-AFAF>.

¹⁰⁰ See Alan Matthews, *Food Safety in the EU-T-TIP Negotiations*, CAP REFORM.EU (June 17, 2014), <http://capreform.eu/food-safety-in-the-us-eu-ttip-negotiations/>, archived at <http://perma.cc/W8QZ-8ALE>.

defining what is “safe.”¹⁰¹ Grounded on potential risk—and not proven risk—this principle encourages taking action in the absence of full, scientific certainty about risk.¹⁰² The U.S. approach on food safety measures, in contrast, is grounded upon risk assessment. They bumped into one another again in the Transatlantic Trade and Investment Partnership (“T-TIP”) negotiations.¹⁰³ This comparison provides valuable context for understanding how the FSMA represents a new U.S. standard for FDA-regulated foods.

Previously under the FDCA, the FDA food safety regulation relied heavily upon efforts to screen imports at the U.S. border. Over time, rising imports, consumer demand for food safety, and costs for inspections all put pressure on the FDA to draft a new set of food safety rules governing imports. The new FSMA rules expand import screening efforts and include more collaboration between public and private entities. Aimed to raise confidence in food safety while reducing duplication, compliance costs, and information asymmetries,¹⁰⁴ the new FSMA rules are stricter than the old rules and encourage regulators to strategically collaborate with foreign state, non-state, and private actors.

As noted earlier, the FSMA adds additional rules that regulate food imports. Familiar tools such as border examinations, testing of samples, and compliance are combined with an array of new tools: foreign inspection, facility registration, foreign supplier verification,¹⁰⁵ a qualified importer program,¹⁰⁶ the required use of accredited laboratories for testing, reliance on the export programs of countries, third party certification through the accreditation of third-party auditors,¹⁰⁷ import certifications,¹⁰⁸ bilateral agreements and arrangements,¹⁰⁹ and systems recognition or equivalence assessments of foreign food safety systems. These options provide layers of assurances and guarantees and can be combined to achieve higher levels of trust for that product.

The author focuses on the following rules which represent innovations that many other countries do not currently have in place: (1) the Foreign Supplier Verification Program (“FSVP”), (2) import certification, (3) in-

¹⁰¹ See e.g., European Union General Food Law, *supra* note 99 (stating “In specified circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment”); Bambrick, *supra* note 96 (describing precautionary principle as used in Australia).

¹⁰² See Bambrick, *supra* note 96.

¹⁰³ European Union General Food Law, *supra* note 99.

¹⁰⁴ Marks, *supra* note 24, at 5.

¹⁰⁵ FSMA § 301 (codified at 21 U.S.C. § 384(a) (2012)).

¹⁰⁶ FSMA § 302 (codified at 21 U.S.C. § 384(b) (2012)).

¹⁰⁷ FSMA § 307 (codified at 21 U.S.C. § 384(d) (2012)).

¹⁰⁸ FSMA § 303 (codified at 21 U.S.C. § 381 (2012)).

¹⁰⁹ See FSMA § 305 (codified at 21 U.S.C. § 381 (2012)) (providing for the FDA’s ability to build and leverage the food safety capacity of foreign governments).

spections, and (4) System Recognition. A pre-FSMA survey of nine country import programs and policies showed that the use of third parties to carry out inspection or certification of imported food is limited, that countries do not conduct individual inspections of food manufacturers or shippers in other countries as part of routine surveillance activities, and a lack of mutual recognition agreements between countries for FDA-regulated foods, otherwise known as System Recognition Agreements.¹¹⁰

First, under the FSVP program, within two years importers will be required to perform risk-based foreign supplier verification to ensure that all imported food is as safe as food produced and sold in the United States and is in compliance with the FDA Preventive Control requirements and the FDA Produce Safety Standards.¹¹¹ Importers will need to verify the food safety practices of their supply chain. Without a verification program in place, importers will not be able to bring product into the United States. As the regulation states, “[v]erification activities . . . may 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.”¹¹² The hope is that, by placing pressure and increased accountability on importers, they will in turn insist that foreign facilities use third-party audits to make sure that foreign foods comply with U.S. laws and regulations.¹¹³

Second, the FSMA food import certification conditions build on the Prior Notice requirements for imports included in the Bioterrorism Act of 2002. According to the Prior Notice provision, importers have to notify the FDA when shipping foods destined for the United States, and specify the port of entry the foods will reach.¹¹⁴ The FSMA expands on this notion of traceability and notice by authorizing the Secretary of Health and Human Services to require food imports to be accompanied by a “certification or such other assurances as the Secretary determines appropriate,” ensuring that the food in question complies with some or all requirements of the

¹¹⁰ Specifically, the survey found that the use of third parties to carry out inspection or certification of imported food is limited, that countries do not conduct individual inspections of food manufacturers or shippers in other countries as part of routine surveillance activities, and that there exists a lack of mutual recognition agreements between countries for FDA-regulated foods (otherwise known as System Recognition Agreements). Sertkaya et al., *supra* note 78.

¹¹¹ FSMA § 105 (codified at 21 U.S.C. § 350(h) (2012)).

¹¹² FSMA § 301(a) (codified at 21 U.S.C. § 384(a) (2012)).

¹¹³ See LEAVITT PARTNERS, FOOD SAFETY AND MODERNIZATION ACT: KEY PROVISIONS 10 (2011), available at <http://extension.psu.edu/food/safety/farm/mushrooms/featured-sites/food-safety-modernization-act-key-provisions>, archived at <http://perma.cc/WJ98-EKZR>.

¹¹⁴ See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,975 (Oct. 10, 2003); see also Caroline Dewaal, *FSMA: Import Rules May Foster Global Food Safety*, FOOD SAFETY NEWS (Feb. 14, 2011), available at <http://www.foodsafetynews.com/2011/02/fsma-import-rules-may-foster-global-food-safety/>, archived at <http://perma.cc/6PV6-PN8A>.

FSMA.¹¹⁵ Certification will depend on established safety risks associated with the food or with the country, territory, or region of its origin, or evidence that the foreign governments' programs cannot ensure that the food meets U.S. standards.¹¹⁶ Then, the FSMA provides a range of options for the certifications or assurances.¹¹⁷ The proposed rules state that importers may seek certifications from an FDA-designated agency, a representative of the government of the exporting country, or a person or entity accredited as a "third party auditor."¹¹⁸ If food imports are not certified, they shall be refused admission to the United States.¹¹⁹ Importantly, the Secretary has discretion to refuse any certification or assurance if she determines that such certification or assurance is not valid or reliable.¹²⁰

Third, inspection rules are the foundation of all food safety programs. Before the passage of FSMA, FDA inspection practices were criticized for their emphasis on reacting to unsafe foods at the ports of entry, as opposed to preventing unsafe food from ever making its way to the United States.¹²¹ The new FSMA inspection rules take a more preventative approach to food safety imports. For example, the FSMA grants the FDA inspection authority pre-entry, similar to that of the FSIS of the USDA.¹²² The FSIS inspects and certifies that an exporting country has a food safety inspection program equivalent to that of the United States prior to allowing food imports.¹²³ FSIS is also tasked with determining whether other countries' meat and poultry safeguards are equivalent to those in the United States.¹²⁴ Unless FSIS has determined that the country has a meat or poultry program that provides a level of protection that is at least equivalent to the American system, a foreign plant cannot ship products to the United States. The process involves FSIS officials visiting the exporting country to review its rules and regulations, and to meet with and accompany foreign officials on visits to establishments. After foreign approval is made, FSIS relies on the foreign government to certify eligibility of and to inspect the establishments while it periodically conducts document reviews and annual on-site audits to verify continuing equivalence.¹²⁵

¹¹⁵ FSMA §§ 303(a), 303(b), 303(q) (codified at 21 U.S.C. §§ 381(a), 381(b), 381(q) (2012)).

¹¹⁶ FSMA § 303(q)(2) (codified at 21 U.S.C. § 381 (q)(2) (2012)); *see also* Dewaal, *supra* note 114.

¹¹⁷ FSMA § 307 (codified as amended at 21 U.S.C. § 384(d)).

¹¹⁸ FSMA § 303 (codified as amended at 21 U.S.C. § 381(a)); *see also* LEAVITT PARTNERS, *supra* note 113, at 11.

¹¹⁹ FSMA § 303(a) (codified at 21 U.S.C. § 381(a) (2012)).

¹²⁰ FSMA § 303(b) (codified at 21 U.S.C. § 381(b) (2012)).

¹²¹ *See* Dewaal, *supra* note 114.

¹²² *See id.*

¹²³ 21 U.S.C. §§ 620, 466 (2012) (granting FSIS authority to refuse meat and poultry imports if food safety standards are not equivalent to U.S. food safety standards).

¹²⁴ *See* Federal Meat Inspection Act, 21 U.S.C. § 620 (2012); *see also* Poultry Products Inspection Act, 21 U.S.C. § 466 (2012).

¹²⁵ GEOFFREY S. BECKER, CONG. RESEARCH SERV., RL34198, U.S. FOOD AND AGRICULTURE IMPORTS: SAFEGUARDS AND SELECTED ISSUES 5 (2010).

Under the FSMA, the FDA will implement a similar inspection and certification equivalency mechanism to guarantee that imported foods are safe. The FSMA ensures the FDA's extraterritorial jurisdiction by authorizing the FDA to enter into agreements with foreign governments to facilitate inspections, and to refuse food imports from foreign food facilities that do not permit entry of American inspectors to inspect the food facilities.¹²⁶ To enable facility inspections, FSMA sets up a system whereby third-party auditors are selected based on accreditation guidelines. The auditors are then qualified to conduct food safety inspections and audits of foreign facilities.¹²⁷ Third party certification means that a private certifier will provide assurances that a plant, facility, or a commodity is safe. The third-party auditor may include a foreign government, agency of a foreign government, foreign cooperative, or any other party that the Secretary determines is appropriate.¹²⁸ Thus, FSMA could redistribute FDA's food inspection burden to foreign governments by allowing foreign facility inspection by accredited foreign auditors.

Lastly, as mentioned earlier, System Recognition Agreements have been used by countries to form agreements over certain food imports. System Recognition is a type of mutual recognition, sanctioned as early as 1960 in regulatory circles, that is used as a tool for managing resources to facilitate cooperation with other foreign regulatory bodies concerning inspections, information sharing, inspection results, and regulatory procedures.¹²⁹ These types of agreements were noted again by the FDA in 1974 when the agency encouraged the recognition of "equivalent regulatory control by other nations through bilateral agreements," and in 1995, when the FDA reiterated its "willingness to apply equivalence-based mutual recognition to foreign regulatory systems for food safety."¹³⁰ A System Recognition Agreement requires a U.S. government determination that a foreign country's food safety regulatory system provides a similar set of protections to that of the FDA. As a procedural matter, System Recognition is technically a Memorandum-of-Understanding ("MOU") between two countries. It has been sanctioned by the WTO,¹³¹ which allows countries to enter into preferential

¹²⁶ FSMA § 306 (codified as amended at 21 U.S.C. §§ 384c, 2241 (2012)). Additionally, the biennial registration requirement under FSMA includes the provision that "[t]he registration shall contain an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act." FSMA § 102(a) (codified as amended at 21 U.S.C. § 350d(a)(2) (2012)).

¹²⁷ *Id.* § 307(a)(1) (codified as amended at 21 U.S.C. § 384(d) (2012)).

¹²⁸ *Id.* § 307(a)(3) (codified as amended at 21 U.S.C. § 384(d) (2012)).

¹²⁹ TRANS ATLANTIC CONSUMER DIALOGUE, TACD BRIEFING PAPER ON MUTUAL RECOGNITION AGREEMENTS (MRA's) 8 (March 2001), available at <http://test.tacd.org/wp-content/uploads/2013/09/TACD-TRADE-2001-Briefing-Paper-on-Mutual-Recognition-Agreements.pdf>, archived at <http://perma.cc/PPT6-5FX8>.

¹³⁰ *Id.*

¹³¹ See WORLD TRADE ORGANIZATION, WTO AGREEMENT SERIES: SANITARY AND PHYTOSANITARY MEASURES 3, 30 (2010), available at http://www.wto.org/english/res_e/booksp_e/agrmntseries4_sps_e.pdf, archived at <http://perma.cc/6MYP-AHED>. Article 4 of the

trade agreements. While System Recognition is not part of FSMA, it is referenced throughout the FSVP. With System Recognition, a country's products may gain expedited entry to the United States.

System Recognition Agreements grew out of efforts by the United States agencies—the FDA and USDA (“FSIS”)—to reduce regulatory hurdles between countries by “recognizing” foreign food safety systems as either “equivalent” or “comparable to” those of the United States.¹³² The term “equivalence” allows two different standards to remain intact but treats them as similar because they produce the same or similar results. It differs from “harmonization” which means combining two different standards and procedures into one. Both equivalence and harmonization lead to regulatory convergence and mutual recognition.¹³³

FDA and USDA approaches to mutual recognition both require verification by the importer that suppliers are in compliance with appropriate risk-based preventive controls that provide the same level of public health protection as those required in the United States. The terms “equivalent” and “comparable” are unique to the USDA and FDA, respectively.¹³⁴ The way to recognize a foreign food safety system is to deem it “equivalent.”¹³⁵ FSIS has actually been making “equivalence” findings for decades to implement its import oversight authorities and responsibilities over meat and poultry products.¹³⁶ Under the FSIS program, the exporting country must demonstrate its measures achieve the appropriate level of protection by utilizing different levels of sanitary measures to achieve the same level of food safety.¹³⁷ Lasting from three to four years, an equivalence determination involves the USDA determining that a food safety system is equivalent to, or as good as, the U.S. system, and is required for any USDA-regulated product exported to the United States.¹³⁸ To date, only thirty-three countries exporting meat or poultry have been approved.¹³⁹ Codex provides two guidance documents for equivalence: one provides guidance for entering into bilateral

SPS agreement, for example, states that “[m]embers shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.” *Id.* at 30.

¹³² *Information for Foreign Governments: Frequently Asked Questions on System Recognition*, FOOD & DRUG ADMIN. (Sept. 5, 2013), <http://www.fda.gov/Food/InternationalInteragencyCoordination/ucm367400.htm>, archived at <http://perma.cc/853E-33TM>.

¹³³ TACD, *supra* note 129, at 4-6.

¹³⁴ See FDA Public Hearing, *supra* note 16.

¹³⁵ See *id.*

¹³⁶ See *id.*

¹³⁷ *Id.*

¹³⁸ *Id.* Note that the term “equivalent” here does not mean “equal to.” The U.S. signed the WTO Agreement in 1995 and with it, accepted WTO Article 4 on Equivalence. Article 4.2 talks about how members shall upon request enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of equivalence. In 1995, when the SPS Agreement was developed, the U.S. FSIS standards for eligibility incorporated “equivalent” (instead of their prior “equal to”).

¹³⁹ Julie Schmit, *Four Words Rarely Seen on Unsafe Imported Foods: UNITED STATES REFUSED ENTRY*, USA TODAY, Oct. 10, 2007, at 1B.

and multilateral agreements and the other describes equivalence by sanitary measures applied.¹⁴⁰

For the FDA, the way to “recognize” a foreign food safety system is to pronounce it “comparable” under the System Recognition.¹⁴¹ Comparability is a review of the foreign country’s regulatory systems, statutes, and regulations and implementation procedures to demonstrate that the systems are similar, have similar elements, and provide a similar level of food safety public health protection.¹⁴² To gain recognition, a foreign government must complete a draft International Comparability Assessment Tool (ICAT),¹⁴³ a review of the country’s relevant laws and regulations, inspection programs, response to food-related illness and outbreaks, compliance, and enforcement and laboratory support.¹⁴⁴ When a system is recognized as comparable, it affects the way that the FDA will “make risk-based decisions regarding foreign inspections, admit[] product into the United States and conduct follow-up actions when food safety incidents occur.”¹⁴⁵ Through this initiative, countries with similar food safety systems will not require FSVP importer verification.¹⁴⁶ In this way, the importer now relies on assurances that have been pre-negotiated by governments.

An example will help clarify how all of the rules described above—FSVP, certifications, inspections, and System Recognition—combine to raise the level of food safety. Country X submits a request for System Recognition for a particular product. Normally, the FSMA FSVP rules mandate that importers verify their import sources follow U.S. Preventative Controls for Human Foods,¹⁴⁷ which set standards for water testing and irrigation,

¹⁴⁰ See CODEX ALIMENTARIUS COMM., GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS, CAC/GL 34-1999 (1999); CODEX ALIMENTARIUS COMM., GUIDELINES ON THE JUDGMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS, CAC/GL 53-2003 (2003) (stating an equivalence determination can be sought for a sanitary measure or set of measures relevant to a food product or a group of food product).

¹⁴¹ FDA Public Hearing, *supra* note 16.

¹⁴² *Id.*

¹⁴³ See FOOD & DRUG ADMIN., DRAFT INTERNATIONAL COMPARABILITY ASSESSMENT TOOL, <http://www.fda.gov/downloads/Food/InternationalInteragencyCoordination/UCM331177.pdf> (last visited Jan. 21, 2014), archived at <http://perma.cc/4J7N-CN9Q>.

¹⁴⁴ *FDA Recognizes New Zealand as Having a Comparable Food System*, FOOD & DRUG ADMIN. (Dec. 13, 2012), <http://www.fda.gov/Food/Food/NewsEvents/ConstituentUpdates/ucm331276.htm>, archived at <http://perma.cc/9N56-CEBE>.

¹⁴⁵ *Id.*

¹⁴⁶ See Ted Agres, *Systems Recognition: Designation Will Be Challenging For Most Countries*, FOOD QUALITY & SAFETY (Jan. 2014), http://www.foodquality.com/details/article/5631551/Systems_Recognition_Designation_Will_Be_Challenging_for_Most_Countries.html, archived at <http://perma.cc/EX9J-4LKJ> (noting the streamlined procedures available for those countries that undergo System Recognition).

¹⁴⁷ See *FSMA Proposed Rules for Preventative Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, FOOD & DRUG ADMIN. (Oct. 22, 2014), <http://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>, archived at <http://perma.cc/JPE4-J5KJ>.

including the use of Hazard Analysis Critical Control Points (“HACCP”).¹⁴⁸ After all, if American producers must abide by Prevention Controls, foreign producers exporting food to the United States must do the same. For processors in developed countries who are familiar with and have adopted HACCP or similar practices, this may not be overly burdensome. If the food product is determined to be a “high risk food”¹⁴⁹ for which additional recordkeeping requirements are appropriate and necessary, certification and inspection may be required. If a foreign system has undergone System Recognition, depending on the terms of the comparability review, FSVP verification may not be necessary.

B. Public International Food Safety Governance

At a global level, countries regulate food safety norms and standards by joining food organizations and by signing bilateral and multilateral agreements aimed at harmonizing food safety standards. Among others, the most significant food safety standard setting bodies are the Codex Alimentarius Commission (“Codex”) and the WTO, with RTAs and Mega-regionals becoming increasingly common. As the following section suggests, even when countries are ambitious in setting stringent food safety standards, international trade agreements have the potential to diminish the capacity of countries to employ domestic legislation to protect public health. This section begins with a discussion of Codex, followed by a discussion of the WTO.

First, “the 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.”¹⁵⁰ If the United States adopts registration and other standards based on Codex recommendations, the adopted standards will be presumed to be consistent with the SPS Agreement and of GATT 1994.¹⁵¹ If a WTO member wishes to apply food safety measures that are stricter than those set by Codex, the member will need to justify the measures with scien-

¹⁴⁸ See generally FOOD & AGRIC. ORG. OF THE UN, FOOD QUALITY AND SAFETY SYSTEMS – A TRAINING MANUAL ON FOOD HYGIENE AND THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM, at § 3 (1998), available at <http://www.fao.org/docrep/w8088e/w8088e05.htm>, archived at <http://perma.cc/5TXZ-7M2P>.

¹⁴⁹ See generally FOOD & DRUG ADMIN., FDA’S DRAFT APPROACH FOR DESIGNATING HIGH-RISK FOODS AS REQUIRED BY SECTION 204 OF FSMA (Feb. 2014), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM380212.pdf>, archived at <http://perma.cc/3U7W-M6SQ>.

¹⁵⁰ Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45730, 45741 (proposed July 29, 2013).

¹⁵¹ Agreement on the Application of Sanitary and Phytosanitary Measures art. 3.2, Apr. 15, 1994, 1867 U.N.T.S. 493, available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf, archived at <http://perma.cc/Y5VQ-83EZ>.

tific evidence.¹⁵² In effect, while Codex recommendations are purely for voluntary application, Codex has a far-reaching impact. The 159 members belonging to Codex cover ninety-nine percent of the world's population.¹⁵³ Moreover, Codex promulgates 336 standards and guidelines, and many of these standards are used to resolve trade disputes and to draft national legislation.¹⁵⁴

Numerous Codex guidelines support the new FSMA import oversight rules. Codex includes rules that describe the general characteristics of food import control systems,¹⁵⁵ language encouraging standards to be based on risk,¹⁵⁶ as well as guidelines that apply to food certification and inspection systems,¹⁵⁷ facility registration,¹⁵⁸ and process safety.¹⁵⁹ One of the most-cited Codex guidelines relates to risk-based preventative controls at the production plant level. The Codex Alimentarius General Principles of Food Hygiene, otherwise known as HACCP principles, address safety-related aspects of product quality to aid in harmonizing food safety standards,¹⁶⁰ and apply to businesses throughout the food chain.¹⁶¹

Next, although primarily a trade-promoting organization, the WTO is an umbrella organization for promoting international standards and policing national food safety rules so that they are not trade-distorting or discriminating in nature. One of the key agreements under the umbrella of the WTO is the SPS Agreement,¹⁶² which includes the 160 member states as signato-

¹⁵² See *The WTO and the FAO/WHO Codex Alimentarius*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/coher_e/wto_codex_e.htm (last visited Nov. 8, 2014), archived at <http://perma.cc/V8SN-N8RS>.

¹⁵³ *Id.*

¹⁵⁴ *Id.* (noting that the standards are used to resolve trade disputes and draft national legislation). See also *About Standards*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/coher_e/wto_codex_e.htm (noting the numbers of standards and guidelines) (last visited November 8, 2014), archived at <http://perma.cc/4R8K-NWVQ>.

¹⁵⁵ See CODEX ALIMENTARIUS COMM'N, GUIDELINES FOR FOOD IMPORT CONTROL SYSTEMS, CAC/GL 47-2003 (2003).

¹⁵⁶ *Id.* As described by the FDA, Codex guidelines even stipulate that “[s]tandards should be based on risk and, as far as possible, applied equally to imported and domestic food (¶¶ 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. ¶ 15).” Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45,730, 45,741 (proposed July 29, 2013).

¹⁵⁷ See CODEX ALIMENTARIUS COMM'N, GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS, CAC/GL/26-1997 (1997).

¹⁵⁸ See *id.*

¹⁵⁹ See CODEX ALIMENTARIUS COMM'N, GENERAL PRINCIPLES OF FOOD HYGIENE, CAC/RCP 1-1969 (1969).

¹⁶⁰ See CODEX ALIMENTARIUS COMM'N, HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION, Annex to CAC/RCP 1-1969, Rev. 3 (1997), available at <http://www.fao.org/docrep/005/y1579e/y1579e03.htm>, archived at <http://perma.cc/W2ZQ-35AK>.

¹⁶¹ *Id.*

¹⁶² See SPS Agreement, *supra* note 18.

ries.¹⁶³ It was negotiated during the Uruguay Round of trade negotiations in 1995, when over one hundred national governments signed the agreement,¹⁶⁴ to prevent WTO countries from enacting food safety measures that act as unfair barriers to trade. Recognizing that WTO member states have the right to enact food safety measures to protect “human, animal or plant life or health,” the SPS Agreement requires that the measures be based on scientific principles and are only applied to the “extent necessary to protect human, animal or plant life or health.”¹⁶⁵ These food safety measures, called “sanitary [human or animal health] and phytosanitary [plant health] measures” (collectively “SPS measures”) under the agreement, must not “arbitrarily or unjustifiably discriminate” against other member countries and must not operate as a “disguised restriction on trade.”¹⁶⁶

There are two categories of food safety measures. The first category includes any measure applied to protect animal or plant life and health from things such as animal diseases or diseases that exist in plants and can be transmitted from one to another. The second category deals with contaminants, toxins, and additives in food products that can cause a problem for humans, if consumed. A requirement to inspect products at the border for certain microbiological contaminants or a maximum established level for pesticide residues are two examples of SPS measures.¹⁶⁷

SPS measures must also consider the technical and economic feasibility of risk mitigation for the importing member as well as alternative or equivalent approaches to limiting risk.¹⁶⁸ Members are required to accept “as equivalent” the SPS measures of other members, “even if these measures differ from their own or from those used by other members trading in the same product, if the exporting member objectively demonstrates to the importing member that its measures achieve the importing member’s appropriate level of sanitary or phytosanitary protection.”¹⁶⁹ A member country must ask itself what is the appropriate level of protection (“ALOP”) that the country in question wants to achieve for its consumers.¹⁷⁰ Once the ALOP has been determined, each measure must follow a set of basic obligations.

¹⁶³ See *Members and Observers*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Nov. 8, 2014), *archived at* <http://perma.cc/P4UH-L3N9> (listing all 160 member states).

¹⁶⁴ Agreement on the Application of Sanitary and Phytosanitary Measures art. 4, Apr. 15, 1994, 1867 U.N.T.S. 493, *available at* http://www.wto.org/english/docs_e/legal_e/15-sps.pdf, *archived at* <http://perma.cc/Y5VQ-83EZ>.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at art. 2.3.

¹⁶⁷ See *Introduction to the SPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s3p1_e.htm (last visited Nov. 8, 2014), *archived at* <http://perma.cc/8S9T-GY69>.

¹⁶⁸ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at arts. 2, 5, 6.

¹⁶⁹ *Id.* at art. 4.1.

¹⁷⁰ CODEX ALIMENTARIUS COMM’N, *supra* note 160.

First, food safety measures must be based on scientific evidence, and have sufficient scientific evidence of some risk to human life and health. Though members are allowed to determine their own ALOP, they are encouraged “to harmonize [SPS] measures on as wide a basis as possible” by utilizing international standards.¹⁷¹ The measures must be based on science, international standards, guides, and recommendations that are put forward by either Codex, the World Organization for Animal Health, the International Plant Protection Convention, or a member’s own risk assessment.¹⁷² An SPS measure that conforms to international standards enjoys a presumption of validity.¹⁷³ If a member adopts an SPS measure that establishes a higher level of protection than the international standard, then the member must demonstrate that the SPS measure is “based on” scientific analysis and evidence and that there is a “rational relationship” between the SPS measures and the risk assessment itself.¹⁷⁴ Recent interpretations of the SPS provisions in the Japan-Apples (2002) and India-Restrictions on Certain Agricultural Products (2012) disputes suggest a continued emphasis on scientific evidence and risk assessment to justify measures.¹⁷⁵

Second, the measure cannot be more trade-restrictive than necessary to achieve the importing country’s ALOP. Finally, the measure cannot discriminate between imported and domestic products or in a manner that discriminates between different foreign suppliers. The risk-assessment process ensures that SPS measures “are not more trade-restrictive than required to achieve their appropriate level of sanitary and phytosanitary protection”¹⁷⁶ and that “control, inspection and approval procedures” do not limit arbitrarily or unjustifiably the importation of food.¹⁷⁷ The risk has to be real, and a country needs to have scientific evidence to support it. To provide an example, an exporting country recognizes that there is risk of an insect infestation in its grape crops and scientific evidence suggests that a producer need only to fumigate to reduce that risk to an acceptable level. If the importing country decides to impose an import ban, this response is far more restrictive than necessary.

¹⁷¹ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at art. 3.

¹⁷² See *Agreement on Sanitary and Phytosanitary Measures*, WORLD TRADE ORG., http://www.wto.org/english/res_e/booksp_e/analytic_index_e/sps_01_e.htm (last visited Nov. 8, 2014), archived at <http://perma.cc/Q3ZN-AMUM>.

¹⁷³ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at arts. 2.4, 3.2.

¹⁷⁴ See *Introduction to the SPS Agreement*, *supra* note 167, at IV(B); see also Appellate Body Report, *EC—Measures Concerning Meat and Meat Products (Hormones)*, ¶ 193 WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC—Hormones*].

¹⁷⁵ OFFICE OF THE U.S. TRADE REP., 2014 REPORT ON SANITARY AND PHYTOSANITARY MEASURES 15–16 (2014), available at http://www.ustr.gov/sites/default/files/FINAL-2014-SPS-Report-Compiled_0.pdf, archived at <http://perma.cc/93CG-JBSB>.

¹⁷⁶ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at art. 5.6.

¹⁷⁷ *Id.* at art. 8, annex C.

As countries develop import safety measures, they need to be consistent with the WTO SPS rules. When the WTO delivers judgments in disputes related to the SPS Agreement, it requires members who violate the Agreement to bring the measure into conformity with WTO rules; in other words, to modify or withdraw their non-compliant sanitary or phytosanitary regulations.¹⁷⁸ While the WTO is unable to force a member government to change its measures, it has the power to authorize those countries adversely affected to retaliate.¹⁷⁹ In such situations, the WTO permits the aggrieved member to impose sanctions by suspending previously granted trade concessions to the violating country.¹⁸⁰

The U.S. government publishes a yearly report of SPS measures facing agricultural producers.¹⁸¹ Over 250 disputes were raised under the WTO's dispute settlement system from April 2002 to 2012, twenty of which centered on violations of the SPS Agreement. In four cases the SPS measures were outside the focus of the dispute. Panels were established in five cases, two focusing on the European Union ban on meat treated with growth-promoting hormones; two concerning Australia's restrictions on imports of fresh, chilled, or frozen salmon; and one addressing Japan's requirement that apples be tested with regard to the efficacy of fumigation treatment.¹⁸² These cases illustrate that SPS measures are actively contested.

Critics rebuke the SPS for not doing enough to promote food safety, claiming that, under the SPS, the "WTO may force a nation to choose between weakening its health standards" or paying a penalty¹⁸³, and "pressure for downward harmonization is built directly into the SPS Agreement, because it is designed to facilitate trade, not to raise health and safety stan-

¹⁷⁸ See *Implementation: Dispute Settlement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c5s1p1_e.htm (last visited November 8, 2014), archived at <http://perma.cc/SK57-4AXG>.

¹⁷⁹ MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 37 (2d ed. 1999).

¹⁸⁰ See *Implementation: Dispute Settlement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c5s1p2_e.htm (last visited November 8, 2014), archived at <http://perma.cc/K29T-BHYE>.

¹⁸¹ See OFFICE OF THE U.S. TRADE REP., *supra* note 175.

¹⁸² See *Implementation: Dispute Settlement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c5s2p1_e.htm (last visited November 8, 2014), archived at <http://perma.cc/VYJ4-KBWA>.

¹⁸³ See Silverglade, *supra* note 22; see also Zuraw, *supra* note 22 (noting that in the Transatlantic Trade and Investment Partnership, the United States and European Union are bargaining for strong positions with respect to agriculture). Specifically, the European Union fears that "[f]its] bans on GE crops, meat from livestock treated with non-therapeutic antibiotics and growth hormones, ractopamine, and chemically washed poultry, plus standards for things such as animal welfare, organic equivalency, chemicals and nanotechnology, would all be in jeopardy under T-TIP." Meanwhile, the United States fears that "standards for feed ingredients that include ruminant materials known to transmit mad cow disease could be relaxed, the zero-tolerance policy for *Listeria* and *E. coli* could be eliminated, GE-labeling initiatives across the United States could be threatened, 'Buy American' policies could be on their way out, and Europe's milk standards could be recognized as equivalent to [those of the U.S]." Zuraw, *supra* note 22.

dards.”¹⁸⁴ Incidentally, most free trade agreements that the United States has signed since 1995 include an SPS chapter.¹⁸⁵

There is also evidence of the United States lowering health and safety standards to accommodate other multilateral trading rules. These cases involve U.S. regulations and the GATT in general, not the SPS specifically, where the United States has had to weaken its domestic regulations after discovering that those rules violated international trade rules.¹⁸⁶ The most current example regards COOL and the WTO Technical Barriers to Trade Agreement (“TBT”). The COOL regulations requires retail food stores “to inform consumers about the country of origin of fresh fruits and vegetables, fish, shellfish, peanuts, pecans, macadamia nuts, ginseng, and ground and muscle cuts of beef, pork, lamb, chicken, and goat.”¹⁸⁷ The rules have been controversial with respect to meat products, leading Canada and Mexico to challenge the rules in the WTO. These countries argued that “COOL has a trade-distorting impact by reducing the value and number of cattle and hogs shipped to the U.S. market, thus violating WTO commitments agreed to by the U.S.”¹⁸⁸ In 2011, a WTO dispute settlement panel found that the rules violated WTO rules.¹⁸⁹ The United States appealed the ruling in 2012.¹⁹⁰ The United States was then asked to amend the rule.¹⁹¹ Now, after doing so, the United States is waiting for a decision from the dispute settlement body compliance panel to determine if the final COOL rule complies with WTO findings.¹⁹²

There is also evidence showing that RTAs place downward pressure on food safety standards. The United States currently has several RTAs in place and two prominent agreements scheduled for the future: the Transatlantic Trade and Investment Partnership (“T-TIP”),¹⁹³ and the Trans-Pacific Partnership (“TIP”).¹⁹⁴ In retrospect, the Australia-US FTA provides an example

¹⁸⁴ See Silverglade, *supra* note 22.

¹⁸⁵ See RENEE JOHNSON, CONG. RESEARCH SERV., 7-5700, SANITARY AND PHYTOSANITARY (SPS) AND RELATED NON-TARIFF BARRIERS TO AGRICULTURAL TRADE 43 (2014) (listing SPS provisions in each agreement in Table 1).

¹⁸⁶ See WORLD TRADE ORGANIZATION PANEL REPORT, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/R (Jan. 29, 1996) (holding that U.S. gasoline cleanliness regulations violated international treaties); see also WORLD TRADE ORGANIZATION PANEL REPORT, *United States – Restrictions on Import of Tuna*, WT/DS21/R (Sept. 3, 1991) (striking down a U.S. ban on any “dolphin-safe tuna” caught with nets that endangered dolphins).

¹⁸⁷ Jurenas, *supra* note 19.

¹⁸⁸ *Id.* at “Summary.”

¹⁸⁹ See *id.*; see also Dan Flynn, *New COOL Rule Might Result in Retaliatory Tariffs*, FOOD SAFETY NEWS (May 24, 2013), <http://www.foodsafetynews.com/2013/05/new-cool-rule-might-result-in-retaliatory-tariffs>, archived at <http://perma.cc/JM3N-CVDD>.

¹⁹⁰ Jurenas, *supra* note 19.

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ The United States is currently engaged in negotiations with the European Union regarding the Transatlantic Trade and Investment Partnership. See Matthews, *supra* note 100.

¹⁹⁴ The Trans-Pacific Partnership is a “mega-regional” agreement between United States and eleven other countries—Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New

of how trade agreements have the potential to undermine food safety. Before the end of the negotiations, the United States purposefully pressured the Australian government to change several key provisions in Australia's domestic food safety legislation because those provisions were seen as constraining American exports.¹⁹⁵ The United States was particularly aggressive when challenging Australia's use of quarantine to exclude American imports.¹⁹⁶

TABLE 1: SUMMARY OF FOOD SAFETY GOVERNANCE SYSTEMS

| System | Example |
|--|--|
| National Food Safety Governance | Food Safety Modernization Act (FSMA) (Other examples are Canada's Safe Food For Canadian's Act, 2012, The EU General Food Law of 2002) |
| Public International Food Safety Governance | World Trade Organization (WTO); Codex Alimentarius Commission (Codex); Regional Trade Agreements (ex., T-TIP); Mega-Regionals (ex., TPP) |
| Private International Food Safety Governance | Private certification and other supplier management programs, grocery standards, labeling, voluntary codes (ex., ISO, GSFI) |

C. Private International Food Safety Governance

Other standards such as supplier management programs, grocery standards, labeling, and a patchwork of public and private voluntary codes and guidelines influence food trade. In many respects, food trade is now governed by more demanding private standards that importers across the globe must meet, mostly through the use of contracting, regardless of the level of public standards that are agreed upon. Private standards, while not addressed in the WTO provisions, serve the dual functions of "harmoniz[ing] food-safety standards worldwide to reduce audit duplication in the supply chain through benchmarking and equivalency models for food safety."¹⁹⁷

Consumers who are aware of international voluntary codes and quality assurances often pay a premium for them. A consumer may see the certification, "USDA Organic" or "Certified by Quality Assurance International (QAI)"¹⁹⁸—a stamp from a private, third-party verifier of USDA standards

Zealand, Peru, Singapore, and Vietnam. See *Trans Pacific Partnership*, OFFICE OF THE U.S. TRADE REP., <http://www.ustr.gov/tpp> (last visited Nov. 13, 2014), archived at <http://perma.cc/QLP5-9DCE>.

¹⁹⁵ Bambrick, *supra* note 96, at 1.

¹⁹⁶ *Id.*

¹⁹⁷ See Flynn, *supra* note 54.

¹⁹⁸ QAI, a U.S.-based international organic certification company, is "a USDA-accredited certifying agent." See *USDA/National Organic Program*, QUALITY ASSURANCE INTERNATIONAL, http://www.qai-inc.com/about/usda_nop.asp (last visited Nov. 14, 2014), archived at <http://perma.cc/AU4A-VL23>.

which assures consumers that product and process control system risks are being managed according to USDA standards. And yet, international voluntary guidelines and codes may apply even if absent from the package. For example, in 2008, Wal-Mart stores became “the first U.S. grocery chain to adopt internationally recognized Global Food Safety Initiative (“GFSI”) standards for its private label products,” thereby showing adherence to internationally recognized food safety standards.¹⁹⁹

GFSI is not an individual standard, but an organization which approves standards based on a benchmark. Companies choose to benchmark their standards to the GFSI guidance document because it will provide equivalency between existing food safety schemes, while providing individual flexibility in determining standards.²⁰⁰ Each GFSI scheme focuses on preventative controls and food processors must set their own food safety rules that fit their operations.²⁰¹ Companies are free to develop their own schemes and can apply for the scheme to be benchmarked against a GFSI standard.²⁰² Benchmarking begins when GFSI assesses the scheme against the GFSI Guidance Document, a multi-stakeholder document that was drafted with the advice of food safety experts around the world.²⁰³ Certification schemes range from certification of food safety management practices in the whole food chain to certification for parts of the food chain, such as storage and transport. Most companies today accept products that meet international private standards²⁰⁴ and rely on third party certifiers to carry out audits and certify products.²⁰⁵

Certification does not eliminate all risks, however. In July 2014, the Chinese outlets of McDonald’s and KFC stopped using meat from a Shanghai processing company (owned by the Illinois-based OSI Group) accused of

¹⁹⁹ See *Wal-Mart Adopts Global Food Safety Initiative Standards*, AM. NAT’L STANDARDS INST. (Feb. 6, 2008), http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=1731, archived at <http://perma.cc/84LE-3HMF>.

²⁰⁰ See *What is GFSI*, GLOBAL FOOD SAFETY INITIATIVE, <http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html> (last visited Nov. 13, 2014), archived at <http://perma.cc/X5GJ-XZAQ>.

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Benchmarking Overview*, GLOBAL FOOD SAFETY INITIATIVE (GFSI), <http://www.mygfsi.com/gfsi-benchmarking-general.html> (last visited July 29, 2014), archived at <http://perma.cc/XQD7-AW8U>.

²⁰⁴ Examples of benchmarked schemes include the following: PrimusGFS, IFS, Global Aquaculture Alliance Seafood Processing, Global G.A.P., Food Safety System Certification (FSSC) 2200, Global Red Meat Standard (GRMS), Canada GAP, Safe Quality Food (SQF) Code. See *Recognized Schemes*, GLOBAL FOOD SAFETY INITIATIVE, <http://www.mygfsi.com/schemes-certification/recognised-schemes.html> (last visited July 29, 2014), archived at <http://perma.cc/K2E6-AW6C>. For a description of these standards, see Elena Fagotto, *Private Roles in Food Safety Provision: The Law and Economics of Private Food Safety*, 37 EUR. J. L. & ECON. 83 (2014).

²⁰⁵ See Wayne Labs, *The ABCs of GFSI*, FOOD ENGINEERING (June 25, 2014), <http://www.foodengineeringmag.com/articles/print/92466-the-abcs-of-gfsi>, archived at <http://perma.cc/843Q-AR3T>.

using out-of-date meats in their products.²⁰⁶ In this case, a report said that “workers at the meat-processing plant hid [the plant’s] supplies of expired meat while inspectors from McDonald’s carried out an audit, only to resume using them after the inspectors left.”²⁰⁷

IV. LINGERING FOOD SAFETY CHALLENGES AND SOLUTIONS

Under the FSMA, the risky food product hidden in the example above would have been apprehended before entering the United States. This article now examines how the new rules lead to safer outcomes, then employs earlier hypotheticals to illustrate potential challenges facing the FSMA. Namely, the FSMA will be challenged by two lingering concerns: (1) the increasing complexity of modern food supply chains and (2) pressure from international trade rules and standards. This section will later discuss possible WTO SPS claims against FSMA and possible defenses to those claims.²⁰⁸

To start, applying the FSMA rules to the hypothetical proposed earlier in the article, it becomes clear that the frozen fruit mix imported from North Africa and contaminated with *Hepatitis-A*, would have been less likely to enter the United States. With FSMA in place, the food article in question would have required verification and possible certification, by the importer that the article met all applicable U.S. regulations. Before the passage of FSMA, for a country with a clean track record of exporting to the United States (i.e. no prior import refusal record), the fruits would not have been pre-selected for inspection at the border, and would have made their way to the importer’s packaging plant. Consumers therefore had no assurances for the sanitary conditions, nor the employee hygiene rules, operating in the plants where the implicated fruit were stored, packaged and shipped. FSMA, in turn, requires exporters to prove compliance with a set of mandated safety rules, and requires importers to disclose whether another country has refused to accept the same product.²⁰⁹ Under these rules, the North African exporter would be obligated to ensure that its facility followed sanitary practices or had adequate employee-hygiene policies corresponding to U.S. food safety rules. The U.S. importer, in turn, would be obligated to verify that the supplier has met this higher standard. This example highlights how, in theory, the new FSMA rules strive to mitigate more import risks than previously existed.

²⁰⁶ Neil Gough, *Chinese Meat Supplier of McDonald’s and KFC Gets the Ax*, N.Y. TIMES (July 21, 2014), <http://sinosphere.blogs.nytimes.com/2014/07/21/chinese-meat-supplier-of-mcdonalds-and-kfc-gets-the-ax/>, archived at <http://perma.cc/JS4-M5GN>.

²⁰⁷ *Id.*

²⁰⁸ This article focuses on SPS violations as the most significant while pointing out that other WTO violations are possible. In their current proposed form, FSMA rules may provide inappropriate restrictions on international trade, and *de facto* preferential treatment of domestic food supplies.

²⁰⁹ Information Required in Prior Notice of Imported Food, 78 Fed. Reg. 32,359 (May 30, 2013) (to be codified at 21 C.F.R. pt. 1).

A. Tackling Supply Chain Trade and Complex Networks

The rising complexity in supply chains will challenge the FSMA. To illustrate how three specific changes in the supply chain will exert pressure on the FSMA rules, this article re-introduces the hypothetical. First, imagine the following change in the first hypothetical: instead of shipping fruit directly to the United States, the North African seller ships fruit to another and yet another supplier for further processing and shipping. Also imagine that the North African supplier's products had previously been refused entry into the United States due to adulteration, and that the supplier has since changed the company's name. This fact pattern is not unrealistic in a world characterized by increasing global trade and widening of such networks.

World trade now involves global supply chains marked by firms specializing in very specific activities and tasks.²¹⁰ Economic trends such as decreasing information and telecommunications costs have allowed firms to "splinter" or diffuse their production lines, thereby allocating different parts of the production processes to firms in different countries.²¹¹ The end result is that supply chains, or a network of activities involved in moving a product or service from supplier to customer, are unbundled and fragmented in what is called "Supply Chain Trade."²¹² Fueled by foreign direct investment, Supply Chain Trade is transforming food processing as well as manufacturing, textile, apparel, and service industries. Notably, through specialization, this phenomenon creates greater economic access to developing countries. Agribusiness chains became more efficient in the developing world due to the availability and quality of services, such as quality control, logistics, storage facilities, packaging, insurance, and distribution.²¹³

While China appears to be situated at the epicenter of the supply chain explosion, it did not always play a central role. Starting with only four countries in 1985 — Indonesia, Japan, Malaysia and Singapore — by 1995 the list had grown to include South Korea, Chinese Taipei and Thailand, ultimately including the United States in 2000, which along with it, brought in a new supply chain from the Philippines.²¹⁴ By this time, one year prior to China's accession to the WTO, China made its presence known with strong

²¹⁰ Hoekman, *supra* note 52, at 42.

²¹¹ *Id.* at 10.

²¹² Richard Baldwin, *Trade and Industrialization after Globalisation's 2nd Unbundling: How Building and Joining a Supply Chain Are Different and Why it Matters* 2–6 (Nat'l Bureau of Econ. Research, Working Paper No. 17716, 2011) (noting that this "second unbundling" has rapidly progressed in East Asian manufacturing industries); see also Junji Nakagawa, *Global Supply Chains and FTAs in East Asia and the Pacific*, 8 *ASIAN J. WTO & INT'L HEALTH L. & POL'Y* 439, 441 (2013) (noting that there are two globalizations: "the first globalization occurred from the industrial revolution up to the mid-1980s and took the form of geographical decoupling of production and consumption across borders"; "the second globalization began in the mid-1980s, with each segment of production dispersed across borders, according to optimal location theory").

²¹³ Hoekman, *supra* note 52, at 15.

²¹⁴ Nakagawa, *supra* note 212, at 443.

production linkages with South Korea and Chinese Taipei who produced sophisticated intermediary products (parts and components) and exported them to China.²¹⁵ By 2005, China led the market for intermediate products, from which final consumption goods were produced for export, thereby occupying the center of global supply chains.²¹⁶ Hence, the competitiveness of Chinese exports is not only attributable to its inexpensive labor force, but also from the sophisticated intermediate products it receives from East Asian countries. Similar supply chains have been set up between the United States and Mexico, as well as between Germany, Hungary and the Czech Republic, but not to the extent of those in East Asia.²¹⁷

Perhaps the best way to start this discussion is to present two examples. First, take a two-step food import chain: a vertically integrated company which imports from its grower overseas. The example here is a U.S.-based rice company importing from its grower in China. What are the import safety requirements for this product? In short, the U.S. importer would need food safety verification for the Chinese grower and any processing in the United States would be subject to FSMA preventative controls. The standard applied to the overseas producer is the same as the one applied to the domestic producer.

Another example involves a three-step food import chain: a regional supply chain where one country produces a good and it is shipped to a second country for added value, and then shipped to the United States. What would be the outcome in that case? Consider, for instance, that China's accession to the WTO in 2001 lowered Chinese tariffs and encouraged a surge of Chinese food industry investment by both Chinese and multinational companies. There is evidence that low processing costs have contributed to the development of processing factories along the Chinese coast, thereby encouraging some fish, poultry, berries, and other products to be imported to China for further processing and then for re-export.²¹⁸ In this situation, the importer in the United States would seek verification from the Chinese supplier who would presumably need verification from its other suppliers. And yet, the list could go on and on. Chinese outlets of McDonald's and KFC, run by the U.S. firms of OSI Group and Yum Brands, are examples of this phenomenon.²¹⁹

In international business transactions, strategies exist for structuring sales transactions such that the ultimate buyer is unaware of the sub-contract-

²¹⁵ *Id.* at 445.

²¹⁶ *Id.* at 446; see also WTO & INST. DEV. ECON., *An Evolutionary Perspective on Production Networks in the Asia-U.S. Region*, in TRADE PATTERNS AND GLOBAL VALUE CHAINS IN EAST ASIA: FROM TRADE IN GOODS TO TRADE IN TASKS 72, 75 (Hubert Escaith et al. eds., 2011).

²¹⁷ See Fukunari Kimura & Mitsuyo Ando, *Two-Dimensional Fragmentation in East Asia: Conceptual Framework and Empirics*, 14 INT'L. REV. ECON. & FIN. 317, 319-326 (2005).

²¹⁸ Gale and Buzby, *supra* note 6, at 6.

²¹⁹ See Gough, *supra* note 206.

tors hired working to fulfill the original contract, thereby complicating the supply chain. The question becomes at what point in the supply chain do foreign supplier verifications cease to be a regulatory issue? Could supplier management programs and private standards substitute for the verifications or serve as proxies for exemptions?

An import transaction provides another example. A U.S. importer transacts with a foreign exporter who owns multiple companies in a particular country. If the exporter owns multiple companies and one company receives an FDA import refusal report (barring entry for that product and company), then what is to prevent the company from operating under other company names? Another issue is that the FSVP places significant burdens on importers. Since the FSVP requires import verifications from all import sources, then for importers who source from hundreds if not thousands of buyers, the new importer requirements may be overly burdensome. Take for example, the National Association for the Specialty Food Trade, an organization with members many who travel across the globe to find new flavors and products to use as ingredients.²²⁰ Their concern is that they are sourcing from around the world and will face regulation for many, many products when their businesses are making \$200,000 a year to \$2 million.²²¹

Other supply chain issues relate to countries and supply chains that lack sophistication. For coffee growers and roasters in developing countries, the burden is on individual suppliers to pay for inspections.²²² In Ethiopia, there are hundreds of coffee growers with each grower supplying a minimum of one plant's worth of coffee beans. Commercial roasters purchase coffee beans from the growers. In this growing model, the growers are the suppliers, and while they would qualify for a small-scale business exemption from the FSVP rules (the importer would not be required to submit verification from the small sellers), the sellers would still have to register and would face the burden of inspection and possible re-inspection if the seller fails the first inspection.

Since supply chains have become so complex, and since import refusals may not catch an entire value chain, one solution is to place food safety protections in agreements that capture an entire supply chain. Similar to a System Recognition Agreement, but encompassing more than one country, the idea is to draft a product-specific agreement that targets an established supply chain, and not simply the country of origin. The chain would invariably cover developing and developed countries. System Recognition requires a U.S. government determination that a foreign country's food safety regulatory system meets U.S. regulatory requirements.²²³ While the agreement

²²⁰ See FOOD & DRUG ADMIN., *supra* note 143.

²²¹ See *id.*

²²² Interview with Michael Adinew, President, Rift Valley Trading LLC, in L.A., Cal. (October 22, 2014) (discussing the structure of the coffee business in Ethiopia, where each grower contributes the beans from one or two plants for export).

²²³ See FOOD & DRUG ADMIN., *supra* note 143.

would look more like an RTA than a System Recognition Agreement, it would have similar protections to those found within a System Recognition Agreement.

B. *Potential Challenges to the New Food Safety Rules*

The new food safety regime will be challenged on many fronts. This section is divided into two parts—challenges deriving from the System Recognition Agreements and challenges deriving from the FSMA rules themselves. The selection of countries for System Recognition Agreements will be contested by developing countries. For the FSMA rules themselves, possible criticisms range from implementation of the final rules to possible formal challenges by trading partners in the WTO. WTO challenges are likely (see, e.g., the trade dispute with COOL regulations) as is pressure from RTAs (see, e.g., the T-TPP negotiations) and Mega-regionals (see, e.g., the T-TIP). In light of this, the United States can protect its own national interest by ensuring that standards do not become diluted in future trade negotiations. U.S. regulators need to start strategizing for WTO challenges, and continue pressing for higher standards worldwide. Developing countries may be affected by the FSMA rules, but they need not be. There are steps that the United States and developing countries can both take to mollify this concern. These challenges are discussed below in the context of the specific rules.

1. *System Recognition Agreements*

System Recognition is a voluntary program under the FDA.²²⁴ These agreements are not new but they are referenced in the Foreign Supplier Verification Program as a mechanism for importers to gain expedited entry for food products.²²⁵ Policies aimed at promulgating bilateral System Recognition Agreements with numerous trading partners are not unprecedented,²²⁶ even if they are criticized. Since distributing the System Recognition proposed rules, several questions have emerged regarding implementation. First and foremost, System Recognition may not increase food safety standards. “As conceded by U.S. regulators, mutual recognition does not necessarily produce any upward movement in standards or levels of protection. In fact, MRAs can bind together the standards and regulatory procedures of their

²²⁴ See Utecht, *supra* note 95.

²²⁵ See FOOD & DRUG ADMIN., *supra* note 143.

²²⁶ See *Information for Foreign Governments: Frequently Asked Questions on System Recognition Agreements*, FOOD & DRUG ADMIN. (Sept. 5, 2013), <http://www.fda.gov/Food/International/InteragencyCoordination/ucm367400.htm>, archived at <http://perma.cc/7RK7-ST33> (noting previous agreements with New Zealand which led to the signing of the first System Integration Agreement with New Zealand).

parties, thereby stifling innovation and making improvement of regulatory procedures and standards more difficult and less likely.”²²⁷

There are two arguments in favor of curbing U.S. reliance on the use of System Recognition Agreements. First, System Recognition Agreements may have unintended consequences on developing countries as developed countries re-route trade to countries with whom System Recognition Agreements are in place. Given the Agreement with New Zealand²²⁸ and other Agreements with other developed countries in the foreseeable future, there is a potential for these types of agreements to divert trade from the developing world.

Second, since the United States imports from 200 countries and territories and imports products through 300 U.S. ports²²⁹ and since food safety systems vary dramatically (from early stages of development to highly mature food safety systems), how is the United States going to determine future System Recognition Agreement partners? The United States uses the import refusal and foodborne illness data to target countries that export the products of greatest risk to the United States. However, to date, the United States has already signed one System Recognition Agreement with New Zealand (2012),²³⁰ and has additional pilot programs planned with Canada, the European Union and others.²³¹ New Zealand is not the nation’s largest trading partner; it was the 55th largest supplier of goods imports to the United States in 2012.²³² Nor is it one of the countries listed in Table 1 in the Appendix as a country which exports non-compliant food to the United States. And while it appears that Mexico would be a good candidate for a stand-alone agreement, System Recognition Agreements are premised on some conformity between country food safety systems.²³³ Possible candidates for System Recognition Agreements could be countries with which FSIS has equivalency agreements in place, and perhaps FSIS and the FDA can coordinate equivalency efforts.

2. *FSMA Rules*

Despite concerns with the System Recognition approach, the more pressing issue is whether the FSMA rules themselves are consistent with WTO rules. Returning to the frozen fruit hypothetical, if the FSMA rules

²²⁷ Becker, *supra* note 125, at 2.

²²⁸ *U.S.-New Zealand Trade Facts*, OFFICE OF THE U.S. TRADE REP. (May 1, 2014), <http://www.ustr.gov/countries-regions/southeast-asia-pacific/new-zealand>, archived at <http://perma.cc/9C6G-PUF4>.

²²⁹ See FOOD & DRUG ADMIN., *supra* note 143.

²³⁰ See Utecht, *supra* note 95.

²³¹ See FOOD & DRUG ADMIN., *supra* note 143.

²³² *New Zealand*, OFFICE OF THE U.S. TRADE REP., <http://www.ustr.gov/countries-regions/southeast-asia-pacific/new-zealand> (last visited Nov. 13, 2014), archived at <http://perma.cc/7R4D-J56J>.

²³³ See Utecht, *supra* note 95.

result in higher regulatory burdens (inspections, certifications, etc.) for producers and suppliers in North Africa, do heightened standards violate any U.S. international trade obligations? As a preliminary matter, the FSMA rules—and any rules that aim to establish a system of preferences for one country’s goods versus another country’s goods—need to comply with the international rules that govern fair trade, which are the WTO rules. To be consistent with WTO rules, the three key FSMA import programs (importer verification, import certification, and foreign food inspection) need to account for the SPS equivalency requirements and differential treatment recommendations for developing countries. They must also be based on the applicable CODEX guidelines and supported by scientific studies. Each argument will be discussed in turn.

a. Possible WTO Claims Regarding the SPS Agreement

Claims can be raised alleging that the FSMA rules violate the WTO SPS Agreement. The FSMA would almost certainly be considered an SPS measure under the WTO SPS Agreement, and could be analyzed for legality under this Agreement. The SPS Agreement provides that “any measure applied . . . to protect human . . . life or health . . . from risks arising from additives, contaminants, toxins or disease-causing organisms in foods [or] beverages” is an SPS measure.²³⁴ The WTO SPS Committee requests that countries notify other countries of any new changes to SPS measures through the Committee.²³⁵ The United States did precisely this process: after approving FSMA, Congress and the President promptly notified the WTO SPS Committee to allow for comprehensive review of the legislation by U.S. trading partners.²³⁶

There are two possible SPS Agreement challenges rooted in Article 2.2 and Article 5.5. First, Article 2.2 of the SPS Agreement requires that an SPS measure be applied “only to the extent necessary to protect human, animal or plant life or health” and that the SPS measure be based on “scientific principles.”²³⁷ A complaining member may challenge the FSMA under the SPS Agreement’s “extent necessary” limitation, claiming that there are less trade restrictive options available to the United States that would achieve the

²³⁴ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at annex A1.

²³⁵ See *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, WORLD TRADE ORG. (May 1998), http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm, archived at <http://perma.cc/5M9A-L7H7>.

²³⁶ See, e.g., FSMA §§ 101, 102, 104 (codified as amended in scattered sections of 21 U.S.C.); see also Margaret A. Hamburg, Commissioner’s Statement on the Food Safety Modernization Act (Dec. 21, 2010), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm238000.htm>, archived at <http://perma.cc/A46V-85Y4> (stating that the FSMA was designed to help “take the critical steps toward strengthening the food safety system that is vital to the health and security of the American people.”).

²³⁷ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at art. 2.2.

same level of health protection.²³⁸ The complaining member would bear the burden of proof for establishing that less restrictive options are indeed reasonably available to the United States and that these options would realize the end goal of increasing food safety.²³⁹ Next, a complaining member may claim that portions of the FSMA are not based on “scientific principles” and demand evidence of scientific studies that are rationally related to the FSMA provisions in question. The United States would then be required to produce studies demonstrating scientific reasoning bolstering certain FSMA measures.²⁴⁰

Sanitary measures which conform to international standards, guidelines, or recommendations are considered necessary to protect human health. The first concern is for registration standards. If the United States adopts registration standards based on Codex recommendations, the adopted standards will be presumed to be consistent with the SPS Agreement and GATT 1994.²⁴¹ Thus, if the United States is unsuccessful in producing scientific evidence supporting biennial registration requirements, the FSMA should base its food facility registration requirements on the Codex guidelines for guaranteed acceptance (because those are deemed consistent with the SPS).²⁴² At the same time, and perhaps somewhat paradoxically, Codex emphasizes that there is “precedence to the protection of consumers,” meaning that “[i]n the design and operation of food import control systems, prece-

²³⁸ For example, a member might contest the new biennial registration requirements for food facilities, imposed by § 102 of the FSMA. A complaining member could first argue that the two year registration requirement goes further than necessary by placing an undue burden on all importing facilities, while excepting some domestic facilities including retail food establishments, farmers’ markets and farms selling directly to consumers. A complaining member may contend that there are less restrictive registration options reasonably available. This complaint has merit as evidenced by the fact that certain domestic facilities are excluded from biennial registration requirements and the United States has determined that these facilities will still help the United States maintain a safe food supply.

²³⁹ See *EC—Hormones*, *supra* note 174 at ¶ 101.

²⁴⁰ For example, using the biennial registration requirements discussed above in § 102 of the FSMA, a complaining member could demand scientific studies and risk assessments that support the biennial registration requirement for all importing facilities and the exclusion of certain domestic facilities. The scientific evidence must present a “rational relationship” between the FSMA biennial registration provisions and any risk assessment data. If the United States cannot demonstrate rationally related scientific studies supporting biennial registration requirements for all importing food facilities and exceptions for some domestic facilities, the United States may have to amend the biennial registration requirements.

²⁴¹ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at art. 3.2.

²⁴² Codex authorizes food safety legislation to include appropriate provisions for the “registration of establishments” and issuance of penalties in the event of non-compliance. Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems, *supra* note 157, at ¶ 22. Codex does not give more specific guidance on how registration of food facilities should be executed. However, an analogy could be drawn from the Codex guidelines governing *product* registration which provides: “If a product registration system exists or is implemented, a clear rationale for such product registration (e.g. specific and documented food safety concerns) should exist. Such product registrations should treat imported and domestic product in the same or equivalent manner.” Guidelines for Food Import Control Systems, *supra* note 155, at ¶ 38.

dence should be given to protecting the health of consumers and ensuring fair practices in food trade over economic or other trade considerations.”²⁴³ Ultimately, if the FSMA biennial food facility registration requirements exceed the Codex guidelines, and if there are no scientific data reasonably supporting the registration provisions and exemptions, FSMA’s food facility registration requirements may need to be amended so that foreign and domestic food facilities are treated in the same manner to comply with the SPS Agreement and Codex guidelines.

Second, Article 5.5 requires consistency in the application of the SPS measure across comparable situations to achieve the appropriate level of protection with respect to risks to human life or health.²⁴⁴ A member will be in violation of Article 5.5 of the SPS Agreement, if three things occur: (1) if the defendant government provides different levels of health protection in “comparable” situations, (2) if differences in the government’s intended level of protection are “arbitrary or unjustifiable,” and (3) if the health measure embodying these differences results in discrimination or a disguised restriction on international trade.²⁴⁵

By creating numerous exceptions from its food safety requirements for certain facilities, the FSMA may run into an Article 5.5 challenge. In practice, however, these exceptions result in inconsistent application of FSMA safety standards. It could be argued that the exceptions represent unjustifiable or arbitrary discrimination against foreign food importers and that they are as broad as to undermine the goal of the FSMA food safety prevention mandate.

The fact that certain facilities are exempt from safety standards under FSMA § 105 may violate the SPS Agreement, Article 5.5. First, the FSMA § 105 mandates that the Secretary of HHS and the Secretary of Agriculture promulgate new safety standards for farms and food processors. The new safety standards require safe production, harvesting, handling, and packing of fruits and vegetables (raw agricultural commodities) to minimize the risk of serious adverse health consequences and death.²⁴⁶ In particular, FSMA § 105 demands HACCP or equivalent safety standards from foreign food facilities, mandating that “processes and procedures, including reasonably appropriate risk-based preventive controls” must provide the “same level of public health protection” as U.S. standards to ensure that “food imported

²⁴³ Guidelines for Food Import Control Systems, *supra* note 155, at ¶ 12.

²⁴⁴ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at art. 5.5 (“With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.”).

²⁴⁵ See generally *EC—Hormones*, *supra* note 174; see also WTO COMMITTEE ON SANITARY AND PHYTOSANITARY MEASURES, *Guidelines to Further the Practical Implementation of Article 5.5, G/SPS/15* (July 18, 2000).

²⁴⁶ FSMA § 105 (codified as amended at 21 U.S.C. § 350h (2012)).

into the United States is as safe as food produced and sold within the United States.”²⁴⁷ Compliance with the new safety standards will require substantial time and monetary investments for many facilities. Additionally, the safety standards place a heavy burden of compliance on farm functions including: “growing, harvesting, sorting, packing, and storage operations, science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water.”²⁴⁸

Similar to the example illustrated above regarding domestic facility exemptions for biennial registration, the FSMA also exempts certain domestic entities from § 105 safety standards. This time, there is a “direct farm marketing” exemption for certain domestic farm facilities.²⁴⁹ The exemption applies to facilities with limited income, which is triggered “if during the previous 3-year period, the average annual monetary value of the food sold by such farm directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such farm to all other buyers during such period” and “the average annual monetary value of all food sold during such period was less than \$500,000, adjusted for inflation.”²⁵⁰ For facilities meeting the direct farm marketing exemption requirements, the § 105 “standards for produce safety” are eliminated.

The fact that certain facilities are exempt from hazard analysis and preventative controls under FSMA § 103 may also violate the SPS Agreement Article 5.5. The FSMA § 103 offers additional safety exemptions for “qualified facilities” from hazard analysis, risk-based preventative controls, and monitoring requirements.²⁵¹ Under FSMA § 103, qualified facilities include “very small businesses” (a term not yet defined), and any “direct farm marketing” facilities with limited income that were exempted from FSMA § 105, as discussed above.²⁵² A food facility that is not exempted must perform a rigorous hazard analysis, which includes assurances that an evaluation of the hazards that could affect food manufactured and processed by the facility has been done. Further, the facility must implement and monitor preventative controls to significantly minimize the occurrence of such hazards.²⁵³ However, an exempted facility is only required to provide documentation that demonstrates that the person in charge of the food facility “has identified potential hazards associated with the food being produced, is implementing preventative controls to address the hazards, and is monitoring the preventative controls to ensure that such controls are effective.” This documentation may include “licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a state depart-

²⁴⁷ *Id.* at § 301(a) (codified as amended at 21 U.S.C. § 384a(c)(2) (2012)).

²⁴⁸ *Id.* at § 105(a) (codified as amended at 21 U.S.C. § 350h(a)(3)(B) (2012)).

²⁴⁹ *Id.* at § 105(a) (codified as amended at 21 U.S.C. § 350h(f) (2012)).

²⁵⁰ *Id.* at § 105(a) (codified as amended at 21 U.S.C. § 350h(f)(1) (2012)).

²⁵¹ *Id.* at § 103(a) (codified as amended at 21 U.S.C. § 350g(l) (2012)).

²⁵² *Id.*

²⁵³ *Id.* at § 103(a) (codified as amended at 21 U.S.C. § 350g (2012)).

ment of agriculture).”²⁵⁴ An exempted facility will have much more flexibility in meeting the safety requirements of FSMA § 103. Moreover, it is likely that the safety regulations promulgated for exempted facilities will have a lower bar for meeting safety standards through licensing and inspection reports.

Thus, by failing to take the preventative measures required of all other producers, the exempted facilities may undermine FSMA’s goal of preventing foodborne illness. To be sure, the law authorizes that exemptions granted by FSMA §§ 103 and 105 may be withdrawn “in the event of an active investigation of a foodborne illness outbreak that is directly linked to a farm subject to an exemption.”²⁵⁵ However, even with the exemption withdrawal provision, there is an argument that these exemptions undermine the preventative approach to food safety found in the FSMA.

Without a scientific basis, the exemption of certain facilities from FSMA safety standards results in different levels of health protection in comparable situations, a violation of Article 5.5. A member could claim that FSMA §§ 103 and 105 violate Article 5.5 because they offer different levels of health protection in “comparable” situations, resulting in arbitrary or unjustifiable discrimination and disguised restriction on international trade. A complaining member may point to Article 5.5, arguing that the safety standards outlined in FSMA §§ 103 and 105 must be applied in a consistent manner and cannot be applied in an arbitrary or unjustifiable case-by-case basis. It is likely that a foreign food facility would not be able to qualify for “very small business” or “direct farm marketing” status, and it is probable that only domestic facilities will enjoy exemption from FSMA §§ 105 and 103 safety rules.

The complaining member would need to demonstrate that the FSMA provides different levels of health protection in “comparable” situations—or where “similar conditions prevail.”²⁵⁶ Thus, the complaining member has the burden to prove that the exempted facilities are indeed “comparable” to non-exempt facilities because exempted facilities have the same potential to introduce similar safety hazards into the food system. Under this logic, a complaining member would argue that the FSMA is exempting “comparable” facilities from safety standards resulting in an arbitrary restriction of trade. Unless the United States is able to provide some scientific justification behind the FSMA exemptions, the variations in safety standards under §§ 103 and 105 may indeed be found to be discriminatory and a disguised restriction on trade by the WTO’s Dispute Settlement Body (“DSB”).

American regulators need to be aware that these challenges are not indefensible. At first glance, the exemption provided by the FSMA §§ 103 and

²⁵⁴ *Id.* at § 103(a) (codified as amended at 21 U.S.C. § 350g(l)(2)(B) (2012)).

²⁵⁵ *Id.* at §§ 103(a), 105(a) (codified as amended at 21 U.S.C. §§ 350g(l)(3)(A), 350h(f)(3)(A) (2012)).

²⁵⁶ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at Art. 5.5.

105 may indeed seem *de facto* discriminatory, as it is almost impossible for foreign farms to enjoy the same exemptions as domestic farms. However, the United States could defend the exemptions and the FSMA provisions so long as they are based on scientific analysis and evidence with a rational relationship between the SPS measures and the risk assessment itself. For example, if there is a risk-assessment showing that the exempted food facilities have not been linked to foodborne illness and therefore do not need to have as stringent safety standards as the types of facilities covered by the FSMA §§ 103 and 105, then the United States will not be in violation of Article 5.5.

Further, the United States could point out that under FSMA § 105 foreign countries are offered the opportunity to request variances from the § 105 safety standards so long as the foreign country can show that its safety standard will protect public health at the same level required by the FSMA.²⁵⁷ However, this defense may not be sustained, particularly given that the variances are not automatically applied—direct farm markets do not need to apply for an exemption, nor do they need to prove any equivalency safety standards under § 105. In addition, the Secretary has full discretion to deny the variance upon determining that the safety standard of the foreign country is not equivalent to the standard promulgated by the FSMA.²⁵⁸ In contrast, the Secretary can only withdraw § 105 exempted status if there is a foodborne illness outbreak.²⁵⁹ Although the United States has relatively strong defenses to the SPS Agreement Article 5.5 violation claims, it is hard to predict what the DSB would rule on this issue—ultimately, it depends on the type of scientific risk assessments that the United States provides to back up the FSMA safety measures.

In the future, the FDA will likely be required to provide scientifically-based risk assessments in order to uphold the FSMA exemptions from safety standards. The risk assessments must provide evidence that justifies the exemption of certain limited-income food facilities and small or direct-market farms from the rigorous safety standards and registration requirements of the FSMA. The risk assessment must: (1) identify the problem/disease to be prevented; (2) evaluate the probability (not just possibility) of entry of such problems/diseases; and (3) evaluate the likelihood of entry according to the SPS measure that might be applied.²⁶⁰ If the United States fails to take into account any of these three risk-assessment elements in promulgating FSMA regulations, then the regulations will likely be null and void, and a member will have a strong case against the United States for violating its obligations under the SPS Agreement.

²⁵⁷ FSMA § 105(a) (codified as amended at 21 U.S.C. § 350h(c)(2) (2012)).

²⁵⁸ *Id.* at § 105(a) (codified as amended at 21 U.S.C. § 350h(c)(2)(C) (2012)).

²⁵⁹ *Id.* at § 105(a) (codified as amended at 21 U.S.C. § 350h(f)(3)(A) (2012)).

²⁶⁰ See WORLD TRADE ORGANIZATION APPELLATE BODY REPORT, *Japan – Measures Affecting Agricultural Products*, ¶¶ 112–114 WT/DS76/AB/R (Feb. 22, 1999).

A loftier question, and one outside the scope of this article, is whether the SPS rules, drafted in 1995, are adequate to meet today's food safety challenges. There are some food safety disputes which the WTO has taken longer than usual to resolve, such as the ongoing SPS dispute concerning the European Union and Agricultural Biotechnology,²⁶¹ which reveal deficiencies in the system. It has been ten years and counting since the United States challenged the European Union's *de facto* moratorium on approvals of American genetically modified corn and soybean products.²⁶² The WTO SPS rules were drafted in 1995 to provide flexibility in the way governments establish protective measures so that the measures are not trade-distorting. Yet, perhaps WTO norms are not adequate enough to meet new challenges that the FDA faces. The counterargument is that WTO norms are adequate to meet new challenges, and that there is sufficient "play" in the rules to enable governments to innovate and protect themselves using measures.

C. Support from the Codex Alimentarius Commission

While WTO members could challenge the FSMA biennial registration requirements and the FSMA exemptions under the WTO SPS Agreement, one likely counterargument would be that the FSMA inspection and certification rules conform to Codex guidelines.

The principles outlined in the Codex guidelines require that the U.S. certification program not be overly burdensome, and that the United States accept "alternative arrangements that provide equivalent assurances with respect to food safety."²⁶³ Finally, the Codex certification guidelines mandate that countries using certificates take responsibility to assure that certificates are valid.²⁶⁴

In addition to these principles governing certification, Codex also outlines certain inspection requirements. First, Codex allows for extraterritorial jurisdiction in its assertion that "inspection of food may occur at any stage in the production and distribution process."²⁶⁵ Codex maintains that any food import control legislation should provide an importing country with the authority and ability to "inspect, including the authority to enter premises within the importing country, physically examine the food and its packaging; collect samples and initiate analytical testing; inspection of documentation provided by an exporting country authority, exporter or importer; and verifi-

²⁶¹ OFFICE OF THE U.S. TRADE REP., *supra* note 175.

²⁶² *Id.*

²⁶³ See CODEX ALIMENTARIUS COMM'N, GUIDELINES FOR DESIGN, PRODUCTION, ISSUANCE AND USE OF GENERIC OFFICIAL CERTIFICATES, CAC/GL 38-2001, at ¶ 11 (2001).

²⁶⁴ CODEX ALIMENTARIUS COMM'N, PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION, CAC/GL 20-1995, at ¶ 19 (1995). ("Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification.")

²⁶⁵ *Id.* at ¶ 2.

cation of product identity against documentary attestations.”²⁶⁶ Under this provision, there should be no question as to the legitimacy of FSMA’s authority to enter into foreign food facilities to perform appropriate inspections.

Moreover, Codex requires that food safety inspection systems be based on objective risk assessment, appropriate to the circumstances and based on scientific evidence.²⁶⁷ To avoid discrimination or a disguised restriction on trade, risk assessments should avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate.²⁶⁸

For both certifications and inspections, Codex requires that countries should recognize that different inspection and certification systems may be capable of meeting the same objective and are therefore equivalent—in which case, the exporting country has the obligation of demonstrating equivalence.²⁶⁹ Finally, Codex recommends that the capabilities of developing countries should be taken into account in the design and application of food inspection and certification systems, and special and differential treatment should be provided to these countries if necessary.²⁷⁰

So long as the FSMA Import Certification and Foreign Food Facility regulations are based on the Codex Guidelines, they will be deemed “necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this SPS Agreement.”²⁷¹ If the FSMA certification or inspection systems are found to exceed Codex requirements, there must be a scientific rationale behind the “measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations.”²⁷²

V. CONCLUSION

Improving food safety and expanding international trade need not be incompatible goals. While the FSMA is a national effort toward food safety, and the WTO is an international effort toward food safety, both have common ground. The FSMA increases the FDA’s ability to monitor the U.S. food supply by increasing the FDA’s inspection authority and requiring that all imported foods that come from foreign food facilities meet requisite safety standards and are able to provide certification of said standards to U.S. food

²⁶⁶ Guidelines for Food Import Control Systems, *supra* note 155, at ¶ 10.

²⁶⁷ Principles for Food Import and Export Inspection and Certification, *supra* note 264, at ¶ 7.

²⁶⁸ *Id.* at ¶ 9.

²⁶⁹ *Id.* at ¶ 3.

²⁷⁰ *Id.* at ¶ 17.

²⁷¹ Agreement on the Application of Sanitary and Phytosanitary Measures, *supra* note 164, at art. 3.2

²⁷² *Id.* at art. 3.3.

importers.²⁷³ Overall, the FSMA is a reasonable and practical food safety measure to protect public health and achieve a safer food supply. And yet, the FSMA will be challenged by expanding supply chains, receive WTO challenges, and face downward pressure from regional trading partners. To overcome WTO challenges mentioned herein, scientific studies can be drafted to support FSMA rules. Ideally, if the United States can further support the reasoning behind its rules and resist pressure from WTO and RTA members to dilute the new rules, the high standards established by the FSMA will set the new global floor for food safety.

System Integration Agreements are not part of the new FSMA rules but are linked to FSMA rules through the Foreign Supplier Verification Program. When such an agreement is in place, importers are eligible for expedited entry. Unlike some of the FSMA rules, these agreements are not at risk of WTO or RTA challenge. As such, these agreements can be drafted to target specific country and commodity food safety risks. The United States can use risk-based methodologies and enhanced intelligence of food safety risks on a country-by-country, commodity-by-commodity basis to determine the best candidates for future agreements. In this area, future research can examine whether it is feasible for the target of an agreement to focus on a supply chain, rather than to focus on one country at a time. Together, FSMA and System Integration Agreements have great potential to reduce compliance costs, increase harmonization of food safety rules and increase the overall safety of our food import system. If the FSMA rules are able to withstand challenges by the international trade community, these rules have the potential to be the new global standard for food safety.

²⁷³ FSMA §§ 105, 303 (codified as amended at 21 U.S.C. §§ 350h, 381 (2012)).

APPENDIX

TABLE 1: **FOODBORNE ILLNESS OUTBREAKS FROM IMPORTED FOOD, 1991-2009.**

| Illness | Food | Country | Calendar Year |
|-------------|-----------------|-------------|---------------|
| Cyclospora | Snow peas | Guatemala | 2004 |
| | Raspberries | Guatemala | 1996 & 1997 |
| Hepatitis A | Green onions | Mexico | 2003 |
| | Strawberries | Mexico | 1997 |
| | Cheese | Mexico | 1996 |
| Salmonella | Alfalfa Sprouts | Netherlands | 1995 |
| | Snack Food | Israel | 1994 |
| | Mangoes | Brazil | 2000 |
| | Pepper Corns | Vietnam | 2009 |
| | Cantaloupe | Honduras | 2008 |
| Shigella | Green Unions | Mexico | 1994 |
| | Parsley | Mexico | 1998 |
| Vibrio | Coconut Milk | Thailand | 1991 |
| | Crab Meat | Ecuador | 1991 |

Note: Author's data.²⁷⁴

²⁷⁴ Source data is on file with the author.

TABLE 2: IMPORT SHARES OF U.S. FOOD CONSUMPTION
USING THE VOLUME METHOD.

| Food Groups | 2000 | 2002 | 2004 | 2006 | 2008 | 2009 |
|--------------------|------|------|------|------|------|------|
| Total agriculture | 13.5 | 14.3 | 15.2 | 17 | 17.5 | 16.8 |
| Animal products | 5.7 | 6.4 | 6.6 | 6.4 | 5.7 | 5.5 |
| Red meat | 8.9 | 9.4 | 10.4 | 9 | 7.6 | 7.7 |
| Poultry and eggs | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.3 |
| Dairy products | 2.7 | 3 | 3 | 2.7 | 2 | 2.2 |
| Fish and shellfish | 68.3 | 77.5 | 84.3 | 86 | 85 | 85.2 |
| Plant products | 19.1 | 20.1 | 21.5 | 25.1 | 26.6 | 25.6 |
| Grains | 14.2 | 14.2 | 12.6 | 14.8 | 15.6 | 13.4 |
| Fruits and nuts | 28.9 | 29.7 | 32.3 | 36.9 | 40.5 | 38.5 |
| Vegetables | 10.8 | 13.8 | 14.8 | 16.4 | 17.6 | 17.5 |
| Sweeteners | 15.3 | 15 | 17 | 25 | 23.1 | 22.4 |
| Tropical products | 99.2 | 93.9 | 98 | 97.1 | 95.8 | 97.2 |
| Wine and beer | 15.1 | 16.5 | 19.2 | 19.6 | 23.5 | 23 |

Note: Data from the USDA's Economic Research Service.²⁷⁵

²⁷⁵ *Import shares of U.S. food consumption using the volume method*, U.S. DEP'T AGRIC. ECON. RESEARCH SERV., http://www.ers.usda.gov/media/563776/import_1.xls (last visited Nov. 30, 2014) (last visited Nov. 30, 2014), archived at <http://perma.cc/M602-UYK9>.

TABLE 3: TOP 25 AGRICULTURAL IMPORT COMMODITIES OF CALENDAR YEAR 2012, WITH LEVEL OF PROCESSING, MEASURED BY CURRENT DOLLARS FROM CALENDAR YEAR 2012

| | Commodity Group | Level of Processing | Billion\$ |
|----|-------------------------------------|---------------------|-----------|
| 1 | Coffee and Coffee Products | Processed | 7.0 |
| 2 | Miscellaneous Horticulture Products | Processed | 5.7 |
| 3 | Wine | Processed | 5.1 |
| 4 | Cocoa and Cocoa Products | Processed | 4.1 |
| 5 | Malt Beverages | Processed | 3.7 |
| 6 | Rubber/allied Gums Crude | Raw | 3.4 |
| 7 | Beef and Veal | Processed | 3.4 |
| 8 | Biscuits and Wafers | Processed | 2.9 |
| 9 | Other Grains | Processed | 2.5 |
| 10 | Other Beverages | Processed | 2.5 |
| 11 | Sugar Cane and Beet | Semi-processed | 2.3 |
| 12 | Essential Oils | Processed | 2.2 |
| 13 | Bananas/Plantains | Raw | 2.1 |
| 14 | Other Fruits | Processed | 1.9 |
| 15 | Tomatoes Fresh | Raw | 1.9 |
| 16 | Rapeseed Oil | Semi-processed | 1.8 |
| 17 | Cattle and Calves | Raw | 1.8 |
| 18 | Feeds/Fodders | Semi-processed | 1.6 |
| 19 | Drugs Crude Natural | Processed | 1.5 |
| 20 | Confectionery Products | Processed | 1.5 |
| 21 | Seeds Field and Garden | Raw | 1.4 |
| 22 | Other Dairy Products | Processed | 1.2 |
| 23 | Berries | Raw | 1.2 |
| 24 | Oilcake and Meal | Semi-processed | 1.1 |
| 25 | Cheese | Processed | 1.1 |

Note: Data from the USDA's Economic Research Service.²⁷⁶

²⁷⁶ *Top 25 agricultural import commodities, with level of processing, current dollars by calendar year*, U.S. DEP'T OF AGRIC. ECON. RESEARCH SERV., http://www.ers.usda.gov/data/files/Foreign_Agricultural_Trade-of_the_United_States_FATUS/Calendar_Year/By_Year/cy_top25shupimp.xls (last visited Nov. 30, 2014), archived at <http://perma.cc/39ZM-ESSH>.

TABLE 4: TOP 15 U.S. AGRICULTURAL IMPORT SOURCES, IN CALENDAR YEAR 2011, \$U.S. VALUE

| | Country | World Bank Category | Calendar Year 2011 |
|----|-------------------|---------------------|--------------------|
| 1 | World Total | High Income | 98,945,879,784 |
| 2 | Canada | High Income | 18,918,408,937 |
| 3 | European Union-27 | High Income | 16,069,440,642 |
| 4 | Mexico | Upper Middle Income | 15,835,003,265 |
| 5 | China | Upper Middle Income | 3,992,009,133 |
| 6 | Brazil | Upper Middle Income | 4,055,747,749 |
| 7 | Australia | High Income | 2,362,180,452 |
| 8 | Chile | High Income | 2,369,848,355 |
| 9 | Indonesia | Lower Middle Income | 4,287,596,850 |
| 10 | Colombia | Upper Middle Income | 2,462,331,237 |
| 11 | New Zealand | High Income | 1,967,626,649 |
| 12 | Thailand | Upper Middle Income | 2,630,353,252 |
| 13 | Guatemala | Lower Middle Income | 1,888,301,976 |
| 14 | Malaysia | Upper Middle Income | 2,423,980,421 |
| 15 | India | Lower Middle Income | 2,675,828,323 |
| 16 | Costa Rica | Upper Middle Income | 1,448,844,990 |

Note: Data from USDA's Economic Research Service and the World Bank.²⁷⁷

²⁷⁷ See *id.*, *supra* note 71.