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The US Food Safety Modernization Act: Implications in Transnational Governance of Food Safety, Food System Sustainability, and the Tension with Free Trade*

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I.- Introduction and background

We are all European. We are all Asian. We are all American.
Our food systems are global. What we choose to eat in America affects the rest of the world. What Europe and Asia choose to eat affects America.
We could lament the ills of globalizing our food supply, but like Pandora's box, global trade has been opened. Closing it now is not a realistic option. Food supply globalization has not been slowed by international food safety scandals, a worldwide economic downturn, or local food movements.[1] Food manufacturers and marketers feel intense pressure to lower costs. This fuels a quest for efficiency, which in turn leads to increased sourcing abroad. The result is a cycle of increasing complexity in the global supply chain.[2] In short, the days of food manufacturers and marketers sourcing all their ingredients and products in their own backyard are over.[3]
The benefits of global trade are well known. They include lower prices and a wider variety of products. However, increased international trade in food also brings increased risk, including food safety dangers and food system fragility.
History demonstrates that an increasing number of links in the supply chain increases the opportunity for adulteration. The ancient Hellenic and Roman expansions are accompanied by records of problems with food adulteration. In ancient Greece, Theophrastus[4] reported the use of food adulterants to earn a higher profit.[5] In ancient Rome, Pliny the Elder[6] provides evidence of widespread fraudulent adulteration, such as bread adulterated with chalk to make it whiter and pepper adulterated with juniper berries,[7] while Galen[8] wrote about the adulteration of spices.
Similarly, colonial expansion in the Americas during the sixteenth and seventeenth centuries coincided with increased demand for trade in agricultural goods from the New World.[9] The demand and value of imported goods rose along with the incentive and

(*) Portions of this paper were first presented as the lectio magistralis, Università Cattolica del Sacro Cuore, Piacenza, Italy, Feb. 20, 2014.
(1) Cary Coglianese, Adam M. Finkel & David Zaring, *Consumer Protection in an Era of Globalization*, in Import Safety 3–21 (Cary Coglianese & Adam M. Finkel eds., 2009).
(2) U.S. Food and Drug Administration, *Pathway To Global Product Safety And Quality* (2011).
(3) James Ricci & Grant Thornton, *Suppliers Must Reposition Value Proposition*, Industry Week (Mar. 19, 2010) ("The days of sourcing everything in your own backyard are over as 82% of respondents to a Grant Thornton survey indicated that some portion of their supply chain is purchased internationally, up from 77% last year.")
http://www.industryweek.com/articles/suppliers_must_reposition_value_proposition_21382.aspx. [ECG: Sub]
(4) Theophrastus lived from about 372 to 287 B.C.E. Theophrastus, *Introduction* to Theophrastus on Stones 3, 3 (Earle R. Caley & John F.C. Richards trans., The Ohio State University Press, 1956).
(5) Theophrastus, *Enquiry Into Plants and Minor Works on Odours and Weather Signs*, (Sir Arthur Hort trans., G.P. Putnam's Sons, 1916).
(6) Pliny the Elder lived from 23 to 79 C.E. Pliny the Elder, Britannica.com, http://www.britannica.com/EBchecked/topic/464822/Pliny-the-Elder (last visited Feb. 17, 2015).
(7) Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 Ann. Rev. Nutrition 1, 2 (1984) (reference Pliny the Elder, *Natural History*).
(8) Galen of Pergamum lived from 129 to 216 C.E. *Galen of Pergamum*, Britannica.com,
http://www.britannica.com/EBchecked/topic/223895/Galen-of-Pergamum (last visited Feb. 17, 2015).
(9) F. Leslie Hart, *A History of the Adulteration of Food before 1906*, 7 Food Drug Cosm. L. J. 5, 11 (1952).

opportunity to adulterate. Correspondingly, adulteration surged.[10] According to one report from around 1880, 41 percent of the samples of ground coffee in New York were adulterated and 71 percent of the samples of olive oil in New York and Massachusetts were diluted with cottonseed oil.[11] Merchants pushed for new food laws because they recognized that adulterated goods hurt marketability for the whole trade.[12]

The first federal food law is thought to be the Tea Adulteration Act enacted in 1883.[13] In 1890 Congress passed an act providing for inspection meat exports.[14] A live cattle inspection law followed in 1891.[15] In 1899 Congress authorized the Secretary of Agriculture to inspect and analyze any imported food, drug, or liquor when there was reason to believe there was a danger.[16]

To deal with the growing complexity of national and international food supply and the subsequent problems, more comprehensive legislative solutions were enacted with the Pure Food and Drug Act in 1906 and the Food, Drug, and Cosmetic Act in 1938. The increasing complexity of our food supply today with its increasing number of global links in the supply chain calls out for a new comprehensive legislative solution.

Nineteenth century regulatory tools no longer suffice for a twenty-first century market. Our food safety and our food systems are unavoidably a transnational concern.

However, as our food is increasingly produced farther away from where it is consumed, it has become increasingly expensive and difficult to oversee food safety. The more obvious problem is quantitative, the problem of scale. However, the qualitative issues that arise are more difficult. The next section summarizes the nature of the quantitative and qualitative challenges in food safety regulation, which leads into discussion why the U.S. food regulatory regime must add new tools and strategies to extend its reach globally.

I.A.- Twenty-first Century Market, Nineteenth Century Regulation

I.A.1. The Problem of Scale

The simplest difficulty in regulating imported food is the problem of scale. The longer the supply chain, the more risk there is of a weak link. In these long supply chains, identifying a weak link also becomes more difficult.[17]

More than $2 trillion of goods are imported into the U.S. every year from more than 825,000 different exporting companies.[18] International food trade has expanded in volume, scope, and character in ways never seen before. Worldwide trade in agriculture was nearly $2 trillion in 2011, and continues to increase.[19] Using the U.S. as an example, food imports come from more than 150 countries and territories and constitute 15 percent of the total U.S. food supply.[20] However, 60 percent of fresh fruits and vegetables and 80 percent of seafood are

(10) *Id.*
(11) *Id.*
(12) Wallace F. Janssen, *America's First Food and Drug Laws*, 30 Food Drug Cosm. L. J. 665–672 (1975).
(13) *Id.*, at 18 and P. B. Hutt & P. B. Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 Food Drug Cosm. L. J. 2, 45 (1984).
(14) P. B. Hutt & P. B. Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 Food Drug Cosm. L. J. 2, 45 (1984).
(15) *Id.*, at 46.
(16) *Id.*
(17) Interagency Working Grp. on Import Safety, Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety (Sept. 10, 2007), available at http://archive.hhs.gov/importsafety/report/report.pdf.
(18) *Id.*
(19) World Trade Org., World Merchandise Trade Commodity Profiles: Trade in Agricultural Products 2 (2012) (noting total global agriculture trade of imports was $1,745,208,000,000 in 2011).
(20) U.S. Gov't Accountability Office, GAO-10-699T, *FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities*, 1 (May 6, 2010) (testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives).

imported.[21] These percentages are also increasing.[22] The problem of scale calls for some increase in domestic resources toward import regulation. However, simply scaling up existing inspection strategies will never provide the desired level of safety.[23] A new approach is needed to because of the qualitative problems.

I.A.2. The Qualitative Problems

Complex jurisdictional, legal, political, cultural, and practical issues that do not occur with domestic food regulation present qualitative problems in regulating our global food supply.[24] Jurisdictional changes during food production and trade mean differences in the applicable laws. Even if problems are traced back to the overseas source, legal liability may not reach into the foreign country. There can be differences in domestic regulatory priorities. There may also be cultural differences in risk perception.[25] Additionally, documentation kept in another country in another language can present huge logistical difficulties for businesses and regulators. Moreover, such a long and remote supply chain can also leave the absence of a common "social contract" to do right by your neighbors.[26]

In addition, the free market quest for efficiency and cost cutting can fuel a race to the bottom for fewer regulatory controls to minimize compliance costs.[27] That is, businesses can cut costs by operating in nations with lower regulatory burdens. However, this also results in greater risk of pollution, workplace injury, and other harms.[28] Tragically, the cost savings from avoiding domestic food safety regulation can result in foodborne illness being imported back into the country.[29] From any perspective, the race to the bottom in food supply regulation creates a false impression of efficiency and a less sustainable food supply system.

I.A.3. The Need for New Tools and Strategies

These forces cannot be dealt with and the problems cannot be solved using the tools and strategies that were implemented in the Model-T era. When one combines the increased quantitative risk and the added qualitative risks, adulterated food and food safety problems are inevitable. In essence we are faced with millions of people—with varying societal norms and regulatory restraints—who are experimenting with new ways to make money in the competitive food trade.[30] As there are hundreds of thousands of foreign suppliers and nearly two trillion dollars of agricultural trade per year, even a small reduction in deterrence creates potential for serious harm.

In short, our food system has evolved into a more complex, global supply chain with additional regula-

(21) *Id.*
(22) *Id.*
(23) Michael Leavitt, *U.S. Dep't of Health and Human Services, Import Safety: Safety at the Speed of Life* 4 (2008), available at http://archive.hhs.gov/importsafety/importsafety_prolgoue.pdf [hereinafter Speed of life].
(24) Coglianese, Finkel & Zaring, *supra* note 1, at 6.
(25) Ricci & Thornton, *supra* note 3 ("This sourcing approach incorporates other factors into the equation beyond the traditional definition of a total landed cost. In addition to quantifiable costs (component price including labor, overhead as well as international freight, import duties, special packaging, import-export costs, etc.) that companies evaluate when making a product sourcing decision, many companies are also quantifying supply chain risks associated with a particular region and/or country.").
(26) Coglianese, Finkel & Zaring, *supra* note 1, at 5–6.
(27) *See generally*, Thomas O. McGarity, *Bhopal and the Export of Hazardous Technologies*, 20 Tex. Int'l L.J. 333, 333–339 (2015) (discussing environment, labor, and other production-related costs, which includes any cost of regulatory compliance, including food safety regulation).
(28) *Id.*
(29) *Id.* at 334 (that is, avoidance of the cost of safety controls can and does result in unsafe products that may be imported back to the U.S. A similar dilemma with pesticide residues is described as a "circle of poison" when U.S. exported pesticides re-enter the U.S. on imported crops).
(30) Hao Xin & Richard Stone, *Tainted Milk Scandal: Chinese Probe Unmasks High-Tech Adulteration With Melamine*, 322 Science 1310, 1311 (Nov. 2008) ("Li Shaomin, a management professor at Old Dominion University in Norfolk, Virginia, who studies the business environment in China, agrees. 'When millions of people experiment with new ways to make money without moral self-constraint, the chance of new products that can evade existing testing method is pretty high,' he says.")

tory and social considerations and challenges.[31] Yet, our current regulatory systems were essentially put in place to meet international trade conditions that existed at the end of the nineteenth century.[32]

Our traditional controls for ensuring food safety designed substantially for relatively simple food supply chains are ill suited to regulating the current interconnected global web of supply.

A series of large foodborne illness outbreaks in the U.S. focused attention on the weaknesses of the regulatory system. Two of the most prominent examples are, first, melamine contamination of pet food, infant formula, and milk and, second, the Salmonella contamination of peanut products. In 2007, several thousand dogs and cats died from melamine poisoning.

Over 150 brands of food were implicated, and the largest pet food recall in U.S. history followed.[33] Then in 2008, Chinese infant formula and other dairy products were contaminated with melamine.[34] China alone reported 300,000 victims.[35]

The peanut foodborne illness outbreak occurred in 2008 and 2009. Salmonella Typhimurium-contaminated peanuts from the Peanut Corporation of America (PCA) caused nine deaths and the illness of 714 people in 46 U.S. states and Canada.[36] More than 3,900 peanut-containing products produced by more than 200 companies were made with the ingredients from PCA.[37]

The melamine and the PCA cases reveal the degree of interconnectedness of today's food supply.

For instance, PCA only produced 2.5 percent of the peanut paste in the U.S. with $25 million in sales in 2008, but PCA wholesale ingredients were used to produce more than 3,900 products made by other companies.[38]

Consequently the value of recalled product likely exceeded the annual sales of PCA. The total industry losses (including lost sales) are estimated at $1 billion.[39]

Moreover, these cases also demonstrate the interconnectedness of reputation within the food industry. In the aftermath of the foodborne illness outbreak and recall, peanut butter sales plummeted 24 percent for the entire industry. Although Skippy and Peter Pan peanut butter were not part of the foodborne illness outbreak, Skippy peanut butter sales fell 54 percent and Peter Pan sales fell 45 percent for months afterward.[40]

I.B.- The Food Safety Modernization Act

In the face of such scandals, the Congress passed the FDA Food Safety Modernization Act (FSMA), signed into law in 2011.[41] This law may be the most significant addition to U.S. food law in history.

The 1938 Food, Drug, and Cosmetic Act broadly expanded FDA's authority from the 1906 Pure Food

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([31]) John D. Floros et al., *Feeding the World Today and Tomorrow: The Importance of Food Science and Technology*, 9 Comprehensive Reviews in Food Science & Food Safety 572, 573 (2010).

([32]) *E.g.*, Federal Food and Drugs Act of 1906, 21 U.S.C. §§ 1–15 (1934); Federal Meat Inspection Act of 1906, 21 U.S.C. § 601 (2014).

([33]) *Melamine Pet Food Recall – Frequently Asked Questions*, U.S. FDA (Oct. 7, 2009), http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm129932.htm (last visited Jan. 30, 2015).

([34]) *Melamine Contamination In China*, U.S. FDA (Jan. 5, 2009), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm179005.htm

([35]) Tania Branigan, *Chinese figures show fivefold rise in babies sick from contaminated milk*, The Guardian (Dec. 2, 2008, 5:44 AM), http://www.theguardian.com/world/2008/dec/02/china.

([36]) Centers for disease control & prevention, Multistate Outbreak of *Salmonella* Typhimurium Infections Linked to Peanut Butter, 2008–2009 (May 11, 2010), *available at* http://www.cdc.gov/salmonella/typhimurium/update.html (The actual numbers would be higher than the confirmed cases. CDC estimates for every reported case of salmonellosis another 29 cases go unreported.). See Elaine Scallan, *Foodborne Illness Acquired in the United States—Major Pathogens*, 17:1 Emerging Infectious Diseases 11 (Jan. 2011), *available at* http://dx.doi.org/10.3201/eid1701.P11101.

([37]) Kelsey Wittenberger & Erik Dohlman, USDA Econ. Research Serv., *Peanut Outlook: Impacts of the 2008-09 Foodborne Illness Outbreak Linked to Salmonella in Peanuts* 2 (Feb. 2010), *available at* http://www.ers.usda.gov/media/146487/ocs10a01_1_.pdf [hereinafter Peanut Outlook].

([38]) Peanut Outlook, *supra* note 37, at 2.

([39]) *Id.*

([40]) *Id.*

([41]) Pub. Law No. 111–353, 124 Stat. 3885 (2011).

and Drug Act.[42] The 1958 Food Additives Amendment[43] provided more detailed, technical provisions to the law.[44] In comparison, the Food Safety Modernization Act (FSMA) is broad in scope like the 1938 act and also detailed like the 1958 amendments.[45]

FSMA shifts the focus of the U.S. Food and Drug Administration (FDA) from primarily reacting to food safety problems to a more preventative role.[46] FSMA empowers the FDA to order recalls, implement new standards on domestic producers, and place restrictions on importers of food to make sure that imports meet these new standards.[47]

There is now an onus on importers to verify food entering the U.S. from abroad meets U.S. requirements. The next section discusses the key regulatory authorities in the FSMA that apply to imported foods.

II.- Key Regulatory Authorities in the Food Safety Modernization Act that Apply to Imported Foods

II.A.- New Science-Based, Preventive Controls

The FDA Food Safety Modernization Act (FSMA) creates a new paradigm for regulating imported foods. Prevention, not reaction, is the guiding principle. This responsibility for prevention rests primarily on the shoulders of food producers and processors, and applies equally domestically and abroad.[48] The preventive framework is built on a foundation of scientific, risk-based preventive controls.

This section describes the nature of those preventive controls, which consist of new hazard analysis and risk-based preventive controls for food establishments and the new safety standards for fruits and vegetables. Then this section explains how those preventive controls are implemented for imported foods.

II.A.1. Hazard Analysis Risk-Based Preventive Controls

An organizing principle of the new law is prevention with verification. This is based on the understanding that physical inspection and testing of products at the port of entry is inadequate in identifying safety hazards.[49] A scientific approach to identifying, evaluating, and controlling food safety hazards, Hazard Analysis and Critical Control Point (HACCP), was developed in the late 1950s and early 1960s for the National Aeronautics and Space Administration (NASA).[50] The benefits HACCP have been widely

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([42]) The Food, Drug, and Cosmetic Act of 1938 added a requirement for pre-market approval and proof of the safety of drugs; extended government control to cosmetics and therapeutic devices; provided that safe tolerances be set for unavoidable poisonous substances in food; authorized standards of identity, quality, and fill-of-container for foods; authorized factory inspections, and added court injunctions to the previous penalties of seizures and prosecutions.

([43]) Pub. Law No. 85-929, 72 Stat. 1784 (1958).

([44]) The Food Additives Amendment of 1958 requires premarket approval of food additives but additionally specifies detailed science-based requirements that the proponent of a new food additive must provide in a petition to demonstrate a reasonable certainty that no harm, such as the conditions of the proposed use, specimens of its proposed labeling, all relevant data on the physical or other technical effect, the quantity of such additive required to produce such effect, and full reports of investigations made with respect to the safety for use of such additive. FDCA § 409(b)(2); 21 U.S.C. 348(b)(2).

([45]) *See, infra and for more detail, see Neal D. Fortin, The United States FDA Food Safety Modernization Act: The Key New Requirements*, 6:5 Eur. Food & Feed L. Rev. 260, 266 (Oct. 2011).

([46]) Specifically through new preventive control authority to require a written hazard analysis and risk-based preventive control plan for all food establishments unless exempt (FSMA § 103 amended the FDC Act to add a new § 408) and setting new produce safety standard requirement (FSMA § 105 amending FDC Act § 419). *See* section II *infra*.

([47]) FDC Act § 423 (recall); §§ 408 & 409 (risk control plans and produce safety standards); and § 805 (importer verification).

([48]) "Prevention of foodborne illness, not reaction to problems, is now the guiding principle of our food safety law -- with the primary responsibility for prevention resting squarely on the shoulders of food producers and processors." Michael Taylor, *The FDA Food Safety Modernization Act: Putting Ideas into Action*, 2 (Jan. 24, 2011), available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM254885.pdf.

([49]) *See* Speed of Life, *supra* note 23.

([50]) Neal D. Fortin, *The Hang-up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 Food & Drug L.J. 565, 566 (2003).

acknowledged. [51] However, adoption of HACCP into law was slow for many reasons.[52]
At long last FSMA now requires that all FDA-regulated food companies implement hazard analysis and preventive controls unless specifically exempt.[53] All food facilities, including foreign facilities importing food into the US, must implement a written hazard analysis and risk-based preventive control plan, sometimes called a HARPC (pronounced "Harp See") plan.[54] HARPC is essentially an enhanced HACCP system, being broader than HACCP because it requires identification and control of hazards generally, not just at critical control points.[55] In short, FSMA requires the establishment of science-based mitigation strategies to prepare and protect the food supply chain against contamination at vulnerable points.[56]

II.A.2. Produce Safety Standards

FSMA also directs FDA to work with the U.S. Department of Agriculture (USDA) to create "science-based minimum standards for the safe production and harvesting" of fruits and vegetables for which FDA has determined such standards will minimize the risk of "serious adverse health consequences."[57] FDA's proposed produce rule covers all fruits and vegetables except those rarely consumed raw that are produced for personal consumption or destined for commercial processing, and that will reduce microorganisms of public health concern. The rule must be based on science and risk-analysis and therefore must focus on areas of risk, most notably agricultural water, biological soil amendments, health and hygiene, domesticated and wild animals, and equipment, tools and buildings.[58]

II.B.- Implementing the Regulatory Controls on Imported Foods

The mandatory risk-based preventive controls and produce safety standards provide the preventive framework for the safety of imported and domestic food. To ensure implementation of these preventive standards, FSMA provides a new "regulatory tool kit" for imported foods, consisting of the following elements:

- Foreign supplier verification programs (FSMA sec. 301)
- Voluntary qualified importer program (sec. 302)
- Mandatory certification (sec. 303)
- Enhancements to prior notice (sec. 304)
- Building capacity of foreign governments (sec. 305)
- Improved enforcement authorities (sec. 306)
- Accreditation of third-party auditors (sec. 307)

The scope of this paper does not permit covering all of the above elements and is limited to the most salient points for this discussion, which are definition of an "importer," the foreign supplier verification programs, mandatory certification authority, accreditation of third-party auditors, and increased FDA

([51]) *See*, *e.g.*, Institute of Medicine, National Research Council, National Academy of Science, Ensuring Safe Food: From Production to Consumption 29-30 (1998) ("It is widely accepted by the scientific community that use of HACCP systems in food production, processing, distribution, and preparation is the best known approach to enhancing the safety of foods.")
([52]) Neal D. Fortin, *The Hang-up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 Food & Drug L.J. 565, 571, 590 (2003) (HACCP's benefits are real, but are not recognized in the short-term. The burden of responsibility for producers and processors is immediate and requires them to alter their business practices.)
([53]) The exemptions include juice and seafood whose suppliers are in compliance with the HACCP regulations, food imported for research and evaluation purposes, food imported for personal consumption, alcoholic beverages, food that is transshipped or that is imported for future export and not consumed or distributed in the U.S., and products from facilities subject to FDA's low acid canned food requirements (exempt for microbiological hazards only). Federal Food, Drug, and Cosmetic Act § 418((j)-(k); 21 U.S.C. § 350g(j)–(k) [hereinafter FDC Act].
([54]) *Id.*
([55]) *E.g.*, a HARPC plan also includes protection against intentional contamination, which is not part of HACCP. See FDC Act § 418(b); 21 U.S.C. § 350g(b).
([56]) *See* FDC Act § 418; 21 U.S.C. § 350g.
([57]) FDC Act § 419; 21 U.S.C. § 350h.
([58]) *Id.*

foreign presence.

II.B.1. Definition of an Importer

The definition of an importer is central because it determines responsibility and liability under the law. The importer is a person in the U.S. who has purchased the food being offered for import.[59] If there is no U.S. owner at the time of entry, the importer is the U.S. consignee.[60] If there is no U.S. owner or consignee at the time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee.[61]
The definition targets domestic companies because they have the most incentive to comply and greatest leverage to ensure compliance of those in the supply chain. This approach also leverages those that are most effective within the complex supply chain. Thinking like Archimedes, the levers and fulcrums of the regulatory systems are optimally situated for maximum leverage.

II.B.2. Foreign Supplier Verification Programs

Importers are required to develop, maintain, and follow a foreign supplier verification program for each food product imported unless an exemption applies. The requirements vary based on the type of food product, the category of importer (e.g., very small), the nature of the hazard identified in the food, and who is to control the hazard. Primarily, verification is based on controlling the hazards that are reasonably likely to occur, and verifying that food imported into the U.S. has been produced in a manner that provides the "same level of public health protection" afforded domestic food.[62]
As part of their verification programs, importers must review the compliance status of foods and suppliers, conduct a hazard analysis, verify supplier activities, take corrective actions if necessary, and keep records of the programs.[63] At a minimum, the importer compliance status review must include a check of any FDA warning letters and import alerts.[64]
Importer verification must provide adequate assurance that the hazards identified as reasonably likely to occur are adequately controlled. This may include on-site auditing of foreign suppliers, periodic or lot-by-lot sampling and testing of food, periodic review of foreign supplier food safety records, or other appropriate procedures.[65]
Corrective actions must include at least importer review of complaints received concerning the foods imported, investigation of the cause or causes of adulteration or misbranding as needed, and appropriate corrective actions when necessary, including revision of the verification program.[66] Finally, the importer must keep certain records, including those that document compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and verification plan reassessments.[67]

II.C.- Mandatory Certification Authority

The FDA now has the authority to require certifications to assure particular foods comply with U.S. safety requirements as a condition of entry into the country.[68] The requirement for certification may be shipment specific or by facility.[69] The certification

([59]) FDC Act § 805(a)(2); 21 U.S.C. § 384a(a)(2).
([60]) *Id.*
([61]) *Id.*
([62]) FDC Act §§ 805(a)(1) & (c)(2); 21 U.S.C. §§ 384a(a)(1) & (c)(2) (in particular, subsection (A)(i) refers to the requirements in §§ 350g, 350h).
([63]) *Id.*
([64]) *Id.* (That is, determining compliance would at minimum include verifying there is no FDA record of non-compliance.)
([65]) FDC Act § 805(c)(4); 21 U.S.C. § 384a(c)(4).
([66]) FDC Act § 805(a)(1); 21 U.S.C. § 384a(a)(1) (requiring verification of compliance with FDC Act §§418(e) & (f)) (corrective actions and verification).
([67]) FDC Act § 805(d); 21 U.S.C. § 384a(d).
([68]) FDC Act § 801(q)(1); 21 U.S.C. § 381(q)(1).
([69]) *Id.*

authority is broadly worded but must be science-based and based on known risks, and the measure is intended for high-risk foods.[70] The certifications must be issued by a government representative designated by FDA or by third parties accredited in accordance with provisions in the Food Safety Modernization Act.[71]

II.D.- Accreditation of Third-party Auditors

FSMA directs the FDA to establish a program for the accreditation of third-party auditors for foreign food facilities.[72] FDA can recognize accreditation bodies that in turn accredit third-party auditors to, among other things, conduct food safety audits and issue certifications for foreign facilities and food. Notably, FSMA empowers FDA with the authority to accredit other countries' inspection programs for this purpose.

Voluntary qualified importer program

Certifications issued by accredited third-party auditors may be used to fulfill the requirement for certification as a condition of entry for certain foods that FDA has determined pose a food safety risk.[73] Certifications may also be used in determining whether an importer is eligible to participate in the Voluntary Qualified Importer Program (VQIP), which provides permits for expedited review and entry of food.[74] This is commonly referred to as a "fast track program" or "green-lane."

II.E.- Increased FDA Foreign Presence

In FSMA Congress mandated an increase in the FDA's presence abroad. At the very least, new and expanded FDA offices, in places such as Brussels and Beijing, will serve to increase communication, understanding, and cooperation among nations.[75] On the other hand, Congress also directed the FDA to conduct 600 foreign inspections in 2011 and double the amount every year for five years.[76] FDA would need to increase inspections from 216 in 2010 to 19,200 in 2016.[77] That quantity of foreign inspections is not feasible, and if unaccompanied by the necessary increase in funding, it is impossible.

Transnational regulatory enforcement is more difficult and expensive than domestic enforcement. Language and cultural differences add to concerns for compliance, especially when food safety laws and regulations are arcane or subtle. Government regulators face huge administrative and legal hurdles in holding foreign suppliers accountable for unsafe foods.[78]

From a silver-lining perspective, the impossibility that FDA can carry out this foreign inspection mandate with its own staff creates a strong incentive for the agency to work cooperatively with other nations. FSMA authorizes FDA to enter into reciprocity agreements. Specifically, the FDA could count other nations' audits as "FDA" inspections if they are performed to meet harmonized requirements.[79]

The FDA already has a successful model in the USDA Food Safety Inspection Service (FSIS). As a

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([70]) *See*, FDC Act § 801(q)(2); 21 U.S.C. § 381(q)(2) *and* Interagency Working Grp. on Import Safety, Action Plan for Import Safety: A Roadmap for Continual Improvement (Nov. 2007), *available at* http://archive.hhs.gov/importsafety/report/actionplan.pdf ("While requiring import certifications for all goods is not necessary, in certain circumstances (e.g., high-risk products), this extra step may be warranted. Therefore, the Action Plan recommends mandatory certification for select high-risk products.").

([71]) FDC Act §§ 801(q)(3) & 808; 21 U.S.C. §§ 381(q)(3) & 384a.

([72]) FDC Act § 808(b); 21 U.S.C. § 384a(b).

([73]) *See supra* section II.C.

([74]) FDC Act § 806; 21 U.S.C. § 384b.

([75]) FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 [hereinafter FSMA], § 308 (codified as amended at 21 U.S.C. § 2242) (requiring FDA foreign offices).

([76]) FDC Act § 421(a)(2)(D); 21 U.S.C. § 350j(a)(2)(D).

([77]) FDA conducted 216 foreign food inspections in 2010, the most in the agency's history. Susan Laska, FDA Webinar on Foreign Inspections, May 17, 2011. While the FSMA mandate would nearly triple that amount in the first year to 600 and then increase to 19,200 inspections in five years. FDC Act § 421(a)(2)(D).

([78]) See generally, *Interagency Working Grp. on Import Safety, Action Plan for Import Safety: A Roadmap for Continual Improvement* (Nov. 2007).

([79]) FDA has a long history of counting U.S. state inspections as FDA inspections when conducted to FDA requirements. See, e.g., Office of the Inspector Gen., U.S. Dept. of Health & Human Services, FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability (2000) ("FDA Relies Heavily on State Food Firm Inspections.")

condition for importing meat, poultry, and egg products to the U.S., the FSIS certifies foreign countries that, in turn, certify producers as meeting U.S. requirements for eligibility to export to the US.[80]
Moreover, governments are not alone in facing the challenges of a global food supply system. The food industry also has a need for international food safety management to reduce their risk and maintain consumer confidence. In the 1990s the global food retailers and manufacturers faced audit fatigue as countless in-house standards were developed in isolation with resulting inconsistency.[81] The Global Food Safety Initiative (GFSI) was launched as a non-profit foundation in 2000 by major global retailers, food manufacturers, and food service operators.[82] A major GFSI objective is benchmarking of food safety management systems for equivalence to reduce redundancy and increase efficiency.[83] The difficulties with implementing the FSMA provide FDA an incentive to leverage existing and successful third-party programs, such as the Global Food Safety Initiative (GFSI) benchmarks.
No matter how good the new FSMA authorities are in theory, these new controls will only work if they comply with our World Trade Organization (WTO) free trade agreements. The next section discusses how the FSMA requirements fall under the scope of our WTO agreements.

III.- Consideration of Free Trade Agreements

We can expect our trading partners to scrutinize all the components of the FSMA and its implementing rules that apply to imported food for compliance with our trade agreements. The FDA's expanded statutory authorities over imported foods, the agency's expanded international role, and the accompanying new administrative rules applied to imported foods and the correspondingly applicable to foreign food facilities all raise questions regarding nation's agreements on international free trade.

III.A.- FSMA and the World Trade Organization

The World Trade Organization (WTO) is the institutional foundation of our international trading system. Established on January 1, 1995, as the successor to the General Agreement on Tariffs and Trade (GATT), the WTO agreements provide the legal ground rules for international commerce.[84] Foundational principles from the GATT were incorporated into the WTO. One of those foundational principles is the Principle of Nondiscrimination in Trade.[85] Among members, imported goods must be treated equally with domestic goods.
Those parts of FSMA that apply to imported foods fall under the provisions of international free trade agreements because these new requirements are barriers to the U.S. market. Therefore, depending on how these new authorities are implemented, they could violate WTO agreements. If FSMA places more restrictive requirements on foreign goods than domestic goods, the U.S. could violate its obligations under the WTO.[86] However, additional requi-

([80]) 21 U.S.C. § 620 (requiring USDA certification of meat inspection programs in foreign countries as meeting United States standards as condition of import to the United States).
([81]) The Global Food Safety Initiative GFSI Guidance Document (6th Ed.) 11 (v 6.3) (2013).
([82]) *Id*.
([83]) *Id*.
([84]) GATT 1947 was established on a provisional basis after World War II in the wake of other new multilateral institutions dedicated to international economic cooperation. Despite its provisional nature, the GATT 1947 remained the only multilateral instrument governing international trade from 1948 until the establishment of the WTO in 1995. Annex 1A of the WTO Agreement contains the GATT 1994, which incorporates by reference (and with a few adjustments) the GATT 1947. Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.
([85]) *See* General Agreement on Tariffs and Trade art. I, III, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT] (explaining that a member must not discriminate between "like" products from different trading partners and between its own and like foreign products).
([86]) The WTO agreements covering safety of agricultural products are the GATT, the Agreement on the Application of Sanitary and Phytosanitary Measures, and the Agreement on Technical Barriers to Trade. *See* Gretchen H. Stanton, *Understanding the GATT Agreement on the Application of Sanitary and Phytosanitary Measures*, Food and Agriculture Organization of the United Nations (FAO)

rements on foreign producers for health or safety purposes are permitted if based on sound scientific reasons.[87]

Under the Sanitary and Phytosanitary Agreement (SPS), a country that adopts a higher level of sanitary or phytosantitary protection must conduct a risk assessment.[88] In the risk assessment, the country must consider the available scientific evidence and other factors.[89]

Therefore, the validity of many FSMA requirements will hinge on the soundness of the scientific risk assessments considered in writing the rules and implementing the law.[90] The risk assessment must identify the potential adverse effects of a product or practice to be regulated, and if any are identified, the country must evaluate the potential that those adverse effects will occur.[91]

The Agreement on Technical Barriers to Trade (TBT) prohibits imported products being treated less favorably than similar domestic products.[92] Technical regulations cannot be more trade-restrictive than necessary to fulfill a "legitimate objective." Legitimate objectives are defined to include: "national security requirements; the prevention of deceptive practices; [and] protection of human health or safety, animal or plant life or health, or the environment."[93]

III.B.- FSMA Through a WTO Lens

The key areas where the FSMA impacts importers are verification, certification, and audits. The verification program requires that importers verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe and in compliance with U.S. food safety standards.[94] Importers must establish a verification program for each type of food being imported. Therefore, these programs will vary in the details and requirements from supplier to supplier and from country to country. Similarly, the FDA's new authority to require certification as assurance of compliance for high-risk imported foods as a condition of entry into the U.S. by its nature will be applied differently among nations.[95]

III.B.1. Sanitary and Phytosanitary Measures

Document Repository, *available at* http://www.fao.org/docrep/T4660T/-t4660t0h.htm ("All governments accept the fact that some trade restrictions are necessary and appropriate in order to ensure food safety and animal and plant health protection, and this is also reflected in existing GATT rules."); *id.* ("The basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes ...."); *id.* ("The Agreement on Technical Barriers to Trade includes provisions for settling trade disputes arising from the application of food safety measures and other technical restrictions."). Agreement on Technical Barriers to Trade art. 2, 1867 U.N.T.S. 120 [hereinafter TBT]. of the Inspector Gen., U.S. Dept. of Health & Human Services, FDA Oversight of State Food Firm Inspections: A Call for Greater Accountability (2000) ("FDA Relies Heavily on State Food Firm Inspections.")

([87]) GATT article XX(b) provides that member states have the right to restrict trade when "necessary to protect human, animal or plant life or health." GATT art. XX(b). Article 2 of the Sanitary and Phytosanitary Agreement allows member states to restrict trade when necessary to protect "human, animal, or plant life, or health," but qualifies the right by requiring that the measures adopted are "based on scientific principles and [are] not maintained without sufficient scientific evidence."

([88]) *See* Agreement on the Application of Sanitary and Phytosanitary Measures art. 5, Apr. 15, 1994, 1867 U.N.T.S. 493. ("Members shall ensure that their sanitary or phytosanitary measures are based on an assessment[.]").

([89]) *See id*. art. 2 ("Members shall ensure that any sanitary or phytosanitary measure is . . . based on scientific principles and is not maintained without scientific evidence[.]").

([90]) *See* Naomi McNeill, *The Food Safety Modernization Act: A Barrier to Trade? Only if the Science Says So*, 67 Food & Drug L.J. 177, 181 (2012) ("Because of the validity of the scientific justification for a sanitary or phytosanitary measure is the crux of the legal analysis under the WTO system, the scientific basis of a country's risk assessment is crucial.").

([91]) Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, 11, WT/DS26/AB/R (Jan. 16, 1998) ("'Risk', for the purposes of the SPS Agreement, is the 'potential' for the harm or adverse effects arising and, therefore, the mere possibility of risk arising suffices for the purposes of Articles 5.1 and 5.2.") [hereinafter *EC Measures*].

([92]) Agreement on Technical Barriers to Trade, art. 2.1, 1868 U.N.T.S. 120 (in the WTO parlance, imported products cannot be treated less favorably than "like" domestic products).

([93]) *Id.* art. 2.2.

([94]) FDC Act § 805; 21 U.S.C. § 384a (2013).

([95]) FDC Act § 808(c)(2); 21 U.S.C. § 384d(c)(2).

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Unless justified by scientific evidence, applying different rules to foreign imports compared to domestic producers risks an SPS violation determination at the WTO for unfair treatment among trading partners. Additionally, when a safety standard is not based on scientific evidence, it is considered a disguised restriction on trade.[96]

How the FDA will apply the law so as to follow FSMA requirements remains undetermined, but we can analyze the substance of the law. Fundamentally, FSMA holds imported food to the same safety standard as domestically produced food. Therefore, a claim that the overall standard for imported food is unfair based on differing treatment would be difficult to support.

Challenges based on the lack of scientific evidence to support the safety standards would similarly be hard to make on a fundamental level. FSMA requires that importers perform risk-based activities to verify that imported food has been produced in a manner that provides the "same level of public health protection" as that required of domestic food.[97] That is, the importer must verify that the imported food was produced in a manner that complies with the applicable risk-based controls, such as HARPC, HACCP, or the produce safety standards.[98] Essentially, FSMA puts the responsibility for food safety squarely on the shoulders of the importer, paralleling the requirements on the U.S. domestic manufacturer and seller of a food. This requirement for hazard analysis and a risk-based control system is widely accepted as being scientifically sound.[99] Therefore, the requirement is not a disguised restriction on trade or unfair treatment of trading partners that could result in an SPS violation determination.

Moreover, other regulatory regimes have adopted similar preventive food safety requirements. For instance, in the European Union, Regulation (EC) No. 852/2004 establishes a general requirement for systematic, scientific risk-based controls; essentially a HACCP system without requiring specific recordkeeping.[100] In addition, similar to FSMA, the EU General Food Law (Regulation EC/178/2002) places the primary responsibility for ensuring food safety on the food industry, likewise requiring process-based controls, and is aimed at the whole supply chain.[101] The FSMA "same level of public health protection"[102] for imported food can be found conceptually in the European Union principle of equivalence, which is found in art. 11 of Regulation (EC) 178/2002, and is a foundation of the EU import system:

Food and feed imported into the Community for pla-

(96) *See* SPS Agreement art. 5.1 ("[T]he requirement of "sufficient scientific evidence" ... [has] the purpose of ensuring the balance between promotion of international trade and protection of human life and health within the SPS Agreement[.] 'The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures... as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are ... based on scientific principles[.]'" (quoting *EC Measures, supra* note 92, at 176 (internal quotation marks omitted))).

(97) FDC Act § 805(c)(2); 21 U.S.C. § 384a(c)(2).

(98) FDC Act § 805(a) & (c)(2); 21 U.S.C. § 384a(a) & (c)(2).

(99) *See, e.g.*, Inst. of Med. & Nat'l Research Council, *Ensuring Safe Food: From Production to Consumption* 29–30 (1998) ("It is widely accepted by the scientific community that use of HACCP systems in food production, processing, distribution, and preparation is the best known approach to enhancing the safety of foods."); Nat'l Research Council, *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients* 329 (1985) ("[G]overnment agencies responsible for control of microbiological hazards in foods should promulgate appropriate regulations that would require industry to utilize the HACCP system in their food protection programs."); Int'l Comm'n on Microbiological Specifications for Food, *Microorganisms in Foods 2* (University of Toronto Press, 2d ed. 1986); Codex Alimentarius Comm'n, *Gen. Principles of Food Hygiene 21* (adopted 1969, last revised 2003) ("The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food.").

(100) *See* Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the Hygiene of Foodstuffs, ("[General implementation of procedures based on the HACCP principles... should reinforce food business operators' responsibility[.] [I]t is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment.").

(101) Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, ("[I]t is necessary to consider all aspects of the food production chain... because each element may have an impact on food safety").

(102) As expressed in the FDA Food Safety Modernization Act and incorporated at FDC Act § 805(c)(2). See *supra* note 63.

cing in the market within the Community, shall comply with the relevant requirements of food law or conditions recognized by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.
While the underlying structure of FSMA does not offend the SPS agreement, the law's implementation could present issues.
For example, FSMA requires that risk-based, scientific data provide the reasons for requiring certifications for importers.[103] This certification is designed to ensure that imported food is "as safe as" domestically produced food.[104] The key will be whether appropriate science and risk-based data are used to require certification and whether a similar standard is applied to domestic producers in like circumstances.[105]
If the law is applied by the FDA as directed by the FSMA, the FDA's regulations and procedures will be science and risk-based, and thus will not violate the SPS.
The nature of the science and risk-based evidence called for by FSMA is well established, specifically the nature of the food, the sanitary and phytosanitary conditions in the area from which it is imported, and so forth.
This evidence is similar to the factors considered by the European Food Safety Authority (EFSA) in performing its risk assessments.[106]

III.B.2. Technical Barriers to Trade

Finally, some provisions of FSMA require conformity with detailed standards and procedures; therefore, the Agreement on Technical Barriers to Trade (TBT) also applies. In particular, TBT article 2.2 requires proportionality; measures may not be more restrictive than necessary to achieve the stated goal.
Record keeping and inspection requirements are all possible sources of a TBT violation. However, U.S. domestic producers must meet similar procedural requirements for record keeping and monitoring. In general, no additional barrier to the U.S. market exists for foreign producers.
Like the public health safety measures, many FSMA technical provisions are not new to the food supply chain.
The European Union, for example, has had a traceability recordkeeping requirement in place since 2002. In the EU, all food businesses must be able to trace their products one step forward and one step back in the supply chain.[107]
The FDA should be able to comply with TBT rules in implementing FSMA because the technical requirements are designed to place the same requirements on foreign as domestic food and have rationales related to scientific, risk-based concerns.[108]
For example, the traceability requirement is important for removing unsafe foods from the marketplace when discovered to reduce the opportunity for

(103) FDC Act § 801(q); 21 U.S.C. § 381(q) ("The Secretary shall base the determination that an article of food is required to have a certification ... on the risk of the food, including ... *known safety risk ... a finding by the Secretary, supported by scientific, risk-based evidence*, that the food safety programs, systems, and standards in the country...are inadequate[.]"(emphasis added)).
(104) FDC Act § 801(q); 21 U.S.C. § 381(q) ("[T]o ensure that the article of food [imported into the United States] is as safe as a similar article of that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act ...").
(105) The EU has had regulations regarding certifications for foreign facilities since 1999 for certain processes. Commission Implementing Decision 2012/277, (updating the list of approved facilities in third countries for the irradiation of food authorized by Directive 1999/2/EC and Commission Decision 2002/840/EC).
(106) *Compare* Regulation 178/2002, of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, art. 22 (listing scientific advice and scientific opinion on human, animal, and plant welfare as factors to be considered), *and* FDC Act § 810(q); 21 U.S.C. § 381(q) (listing scientific, risk-based evidence of food safety to be the basis for certification).
(107) *See* Regulation 178/2002, supra note 102, at art. 18 ("Food and feed business operators shall be able to identify any person from whom they have been supplied with a food[, and] shall have in place systems and procedures to identify the other businesses to which their products have been supplied.").
(108) *See, e.g.*, FDC Act § 801(q), *supra* notes 104 and 105; and FDC Act § 805 requiring persons who import food into the United States to perform risk-based foreign supplier verification that the food is produced in compliance with FDC Act § 418 (concerning hazard analysis and risk-based preventive controls) or § 419 (concerning standards for the safe production and harvesting of fruits and vegetables) and the food is not adulterated under § 402 and not misbranded under § 403(w) (concerning food allergen labeling).

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harm to consumers.[109] The rationale behind most FSMA technical requirements is to move from reaction to prevention of food safety problems, and to do this, FSMA necessarily places the responsibility for food safety squarely on the shoulders of the manufacturer and seller of that food.[110]

III.B.3. Heightened International Cooperation

While the Food Safety Modernization Act imposes significant new responsibilities on importers, its also providing an opportunity for an encouraging international cooperation. The food safety regulatory systems in the U.S. and EU demonstrate that different approaches in regulations and standards can achieve the same goal. Both the EU and the U.S. have high safety standards and well-developed regulatory systems for ensuring safety. Yet because different regulatory approaches are often applied to achieve the same goal, importers have to comply with two separate sets of rules.

Developing the detailed regulations required after passage of FSMA could stimulate a movement toward the pragmatic approach of regulatory regimes working together to achieve the same food safety goals. The Codex Alimentarius Commission (CAC),[111] the World Organisation for Animal Health (OIE),[112] and the International Plant Protection Convention (IPPC)[113] have already laid the groundwork for working together on writing harmonized international standards. The CAC, OIE, and IPPC are recognized as principle references by the World Trade Organization Sanitary and Phytosanitary Agreement and other trade agreements.[114]

We should encourage various national agencies to increase their participation in these international standards-setting organizations.[115] Similarly, we should encourage investment in cooperative ventures between nations, like the International Trade Data System (ITDS), which will enhance information sharing among government agencies and the import community.[116]

Harmonizing the data requirements and electronic data formats for similar customs processes among nations could enhance food safety by providing a platform for customs administrations to share information and providing advance notice of risky shipments.

Perhaps most important, mutual recognition of equivalent systems can create more effective coopera-

(109) *See* Codex Alimentarius Commission, *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System* (CAC/GL 60-2006) (5th ed. 2006) (noting that traceability can improve effectiveness of the food safety and prevention of food fraud).

(110) *E.g*, FDC Act § 805 (requiring importer verification of compliance with food safety requirements of the U.S.) and FDC Act § 418 (requiring hazard analysis and risk-based preventive controls).

(111) The Codex Alimentarius Commission (CAC) was established during 1961 and 1962 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The CAC has two primary objectives: protecting the health of consumers and ensuring fair practices in food trade. The CAC accomplishes these objectives through the development and publication of international food standards and guidelines. These published standards are referred to collectively as Codex Alimentarius, or simply Codex. "Codex Alimentarius" is Latin for the "Food Book" or "Food Code." *See, generally*, www.codexalimentarius.org.

(112) The Office International des Epizooties (OIE) was established by international agreement signed on January 25th 1924. In 2003 the name was changed to the World Organisation for Animal Health, but it kept its historical acronym, "OIE". The OIE is the intergovernmental organization responsible for setting worldwide standards related to animal health and zoonoses. The OIE publishes two codes (Terrestrial and Aquatic) and two manuals (Terrestrial and Aquatic). *See, generally,* www.oie.org.

(113) The International Plant Protection Convention (IPPC) is an international plant health agreement, established in 1952 with the goal of protecting cultivated and wild plants from the introduction and spread of pests. IPPC is the international standard setting organization for plant health. *See, generally*, www.ippc.int.

(114) *See, e.g.*, SPS Agreement art. 3.2 ("Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.")

(115) *See* Interagency Working Grp. on Import Safety, *supra* note 17 (encouraging U.S. departments and agencies to increase their participation in international standards-setting organizations).

(116) *Id.*, at 16–18 ("When fully implemented, ITDS will facilitate the processing of legitimate import transactions, improve how imported products are identified and classified, strengthen entry screening capabilities, and help to target inspection resources to areas of greatest risk.").

tion and the leveraging of mutual resources.[117] For example, the FDA has recognized the food safety regulatory system of the New Zealand Ministry for Primary Industries (MPI) as providing comparable level of food safety as the FDA's regulatory system; and conversely New Zealand recognized the FDA system as comparable to MPI.[118] This recognition and harmonization lessens the regulatory burden for both countries by removing unnecessary duplication of regulatory oversight for foods traded between the countries.

Moreover, because the regulatory systems achieve comparable food safety levels, FDA should be able to coordinate so the MPI food inspections of New Zealand exporters (which export to the U.S.) as counting towards the total number of FDA foreign inspections. Ultimately, future coordination could allow application of MPI food inspections of other nations' food exporters to the count of total foreign inspections. For example, a New Zealand regulatory food inspection of a South African food export company could be coordinated to count as an FDA inspection. Similarly, the New Zealand MPI could coordinate counting an FDA inspection of a Chinese food exporter towards the New Zealand foreign inspection goals.

Further coordination of inspection results through harmonized electronic data formats could allow faster response to food safety problems. For instance, if a New Zealand MPI inspection revealed a potential problem with a food exporter, the inspection results could be electronically transmitted and available as quickly to the U.S. FDA as the New Zealand MPI. This data coordination would allow the FDA to issue a timely import alert for suspect foods from that exporter or to apply other appropriate heightened scrutiny, such as targeted product sampling and testing.

We humans all share the same food safety vulnerabilities; therefore, the food safety policies of many nations share similar goals. In addition, many nations share our goal of a high level of public health protection in the food supply. This creates the opportunity to leverage our resources in assuring the safety of global food sources.

IV.- Conclusion

While global supply chains have made purely domestic regulation less effective, great potential exists for gaining efficiencies and effectiveness in both regulation and in trade through mutual recognition and cooperation among national regulatory systems. The FSMA provides, for the first time, a framework in which the FDA can weave a transnational regulatory system through mutual recognition and cooperation. Such an interconnected international system would magnify the benefits of each nation's vigilance.

For industry, this new cooperation will mean more uniform and consistent inspections, especially for companies with facilities in multiple jurisdictions. For consumers, it will mean more effective and coordinated government response to problems. For government agencies, it will mean more respect for each other, the ability to operate more effectively and strategically, and greater confidence by the public in government.

The circumstances are ripe for a new age of global governance of food safety. Tragic foodborne illness outbreaks provide stark illustration of the risks that exist in regulating a complex twenty-first century, global food supply system with nineteenth century tools.

The additional verification and certification measures in FSMA make it harder for foreign food suppliers to access the U.S. market. However, in essence the FSMA insists that imported food meet the same standards as domestically produced food. While raising potential WTO concerns, the overarching principle of the new FSMA standards is appli-

(117) *See, e.g.*, Food Safety Systems Recognition Arrangement between the Ministry for Primary Industries of New Zealand and the Food and Drug Administration of the United States, U.S.-N.Z., Dec. 10, 2012, *available at* http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/-ucm331907.htm (last visited Feb. 14, 2015) (memorializing an agreement between the nations that describes the areas of cooperation that they intend to relate to the safety of foods traded between them).

(118) *Id*.

cation of science-based, preventive controls applied uniformly to foreign and domestic food. Thus, if FDA implements the law as mandated, FSMA will not offend the WTO SPS or TBT agreements.

Ironically, FSMA measures for increasing the safety of the U.S. food supply by extending the FDA's regulatory reach to imported food will also improve the safety of the entire global food system. Enforcing U.S. food safety standards on imported foods eliminates the incentive to export externalities. In turn this can reduce the number of weak links in the global food supply chain and improve food safety worldwide.

This paper began with reference to Pandora's box. The opening of Pandora's box was at the end of a chain of events that began with bringing fire to mankind. Opening the box unleashed many ills, but fire brought blessings that balanced the ills. Similarly, the problems of a globalized food supply are accompanied by the blessings of global trade that most would agree outweigh the associated ills. Moreover, the spirit of hope was also in Pandora's box. Our world of globalization brings hope. It is up to us to turn that hope into something great. Now is the time to knock down barriers to transnational cooperation on food safety.

ABSTRACT

Our national food systems are global and interconnected. This has made domestic regulation less effective. Mutual recognition and cooperation among national regulatory systems is necessary to increase both efficiency and effectiveness. The US Food Safety Modernization Act (FSMA) provides the US Food and Drug Administration (FDA), for the first time, a legal framework in which the agency could weave itself into a transnational regulatory system through mutual recognition and cooperation. This authority raises potential World Trade Organization concerns, but if properly implemented, such an interconnected international system would magnify the benefits of each nation's vigilance without offending any trade agreements.

□