

# THE U.S. 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 the rest of the world chooses to eat affects us in America.

We could lament the ills of globalizing our food supply, but, like Pandora's Box, global trade has been opened and closing it now is not a realistic option. Food supply globalization has not even been slowed by international food safety scandals, a worldwide economic downturn, or local food movements.<sup>1</sup> Food manufacturers and marketers continue to feel intense pressure to lower costs, fueling a quest for efficiency and leading to increased sourcing abroad. The result is a cycle of increasing complexity in the global supply chain.<sup>2</sup> In short, the days of food manufacturers and marketers sourcing all their ingredients and products from their own backyard are over.<sup>3</sup>

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 were accompanied by records of problems with food adulteration. In Ancient Greece, Theophrastus<sup>4</sup> reported that people used food adulterants to earn higher profits.<sup>5</sup> In Ancient Rome, Pliny the Elder<sup>6</sup> provided evidence of widespread fraudulent adulteration, such as bread adulterated with chalk to make

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. FDA, *PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY* 2 (2011).

3. James Ricci & Grant Thornton, *Suppliers Must Reposition Value Proposition*, *INDUSTRYWEEK* (Mar. 19, 2010), available at [http://www.industryweek.com/articles/suppliers\\_must\\_reposition\\_value\\_proposition\\_21382.aspx](http://www.industryweek.com/articles/suppliers_must_reposition_value_proposition_21382.aspx) (“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.”).

4. Theophrastus lived from about 372 to 287 B.C.E. *THEOPHRASTUS, Introduction*, in *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).

it whiter and pepper adulterated with juniper berries,<sup>7</sup> while Galen<sup>8</sup> 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.<sup>9</sup> The demand and value of imported goods rose along with the incentive and opportunity to adulterate. Correspondingly, adulteration surged.<sup>10</sup> 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.<sup>11</sup> Merchants pushed for new food laws because they recognized that adulterated goods hurt marketability for the whole trade.<sup>12</sup>

In response, Congress passed food related legislation. The first federal food law is thought to be the Tea Adulteration Act enacted in 1883.<sup>13</sup> In 1890 Congress passed an act providing for inspection of meat exports.<sup>14</sup> A live-cattle inspection law followed in 1891.<sup>15</sup> 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.<sup>16</sup> To deal with the growing complexity of the national and international food supply, more comprehensive legislative solutions were enacted with the Pure Food and Drug Act in 1906 and the Food, Drug, and Cosmetic Act in 1938.

Recently, however, it had become apparent that these nineteenth century regulatory tools no longer sufficed for a twenty-first century

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7. Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANN. REV. NUTRITION 1, 2 (1984) (citing PLINY THE ELDER, NATURAL HISTORY 259•63 (H. Rackham ed., 1949)).

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).

10. *Id.*

11. *Id.* at 17, 21.

12. Wallace F. Janssen, *America's First Food and Drug Laws*, 30 FOOD DRUG COSM. L.J. 665, 667 (1975).

13. Hart, *supra* note 12, at 18; Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 45 (1984).

14. Hutt & Hutt, *supra* note 13, at 45–46.

15. *Id.* at 46.

16. *Id.*

market. Our food system has continued to evolve dramatically since these older laws were passed, and globalization in particular has drastically changed the rules of the game. Congress responded by passing the FDA Food Safety Modernization Act (FSMA). This statute, however, will face challenges in application, particularly as it is applied to companies operating in an international market.

#### *A. Twenty-first Century Market, Nineteenth Century Regulation*

Food safety and food system regulation are now, unavoidably, problems of transnational scope and concern. As our food is increasingly produced farther away from where it is consumed, it has become increasingly expensive and difficult to monitor food safety. The obvious problem is quantitative—referred to here as “the problem of scale.” However, difficult qualitative issues also arise. This section undertakes to explicate these quantitative and qualitative challenges to food safety regulation, leading to the conclusion that the U.S. food regulatory regime must adopt new tools and strategies to extend its reach globally.

##### 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.<sup>17</sup>

More than \$2 trillion worth of goods are imported into the United States every year from more than 825,000 different exporting companies.<sup>18</sup> 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.<sup>19</sup> Using the United States as an example, food imports come from more than 150 countries and territories and constitute 15 percent of the total U.S. food supply.<sup>20</sup> Sixty percent of fresh fruits and vegetables

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17. INTERAGENCY WORKING GRP. ON IMPORT SAFETY, PROTECTING AMERICAN CONSUMERS EVERY STEP OF THE WAY: A STRATEGIC FRAMEWORK FOR CONTINUAL IMPROVEMENT IN IMPORT SAFETY 15 (Sept. 10, 2007), *available at* <http://archive.hhs.gov/importssafety/report/report.pdf> [hereinafter IWG, PROTECTING AMERICAS CONSUMERS].

18. *Id.* at 4, 5.

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, FOOD SAFETY: FDA COULD

and 80 percent of seafood are imported.<sup>21</sup> These large percentages continue to increase.<sup>22</sup>

The problem of scale demands an increase in domestic resources allocated to import regulation, but simply scaling up existing inspection strategies will never provide the desired level of safety.<sup>23</sup> More is needed.

## 2. The Qualitative Problems

Although increasing the quantity of inspections will improve our food safety, the qualitative problems in our global food supply chain must also be addressed. 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.<sup>24</sup> Jurisdictional changes during food production and trade create inherent 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.<sup>25</sup> Additionally, documentation kept in another country in another language can present huge logistical difficulties for businesses and regulators. Finally, such a long and remote supply chain disconnects producers from consumers and thereby weakens the “social contract” to do right by one’s neighbors.<sup>26</sup>

In addition to these challenges, the free market’s quest for efficiency and cost-cutting can fuel a race to the bottom by prompting competing countries to minimize regulatory controls as a way to

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STRENGTHEN OVERSIGHT OF IMPORTED FOOD BY IMPROVING ENFORCEMENT AND SEEKING ADDITIONAL AUTHORITIES 1 (May 6, 2010) (providing testimony of Lisa Shames, Director of Natural Resources and Environment before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives).

21. *Id.*

22. *Id.*

23. MICHAEL LEAVITT, IMPORT SAFETY: SAFETY AT THE SPEED OF LIFE 4 (2008), available at [http://archive.hhs.gov/importsafety/importsafety\\_prologue.pdf](http://archive.hhs.gov/importsafety/importsafety_prologue.pdf).

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.

lower compliance costs and attract jobs.<sup>27</sup> This unavoidably results in greater risk of pollution, workplace injury, and other harms, as businesses move to nations with fewer safeguards.<sup>28</sup> Tragically, even while companies move abroad their products are being imported back into the country and may carry the costs of reduced regulation with them.<sup>29</sup> From any perspective, the race to the bottom in food supply regulation creates a false impression of efficiency and leaves us a less sustainable and less safe food supply system overall.

### 3. The Need for New Tools and Strategies

These problems cannot be solved using tools and strategies from the Model-T era. When one combines the increased quantitative risk with the qualitative risks arising from globalization, 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.<sup>30</sup> 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 significant harm.

In short, our food system has evolved into a more complex and globalized supply chain, giving rise to a host of new regulatory challenges and social considerations.<sup>31</sup> Yet our current regulatory system still reflects the international trade conditions that existed at the end of the nineteenth century.<sup>32</sup> Our traditional controls for

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27. See generally Thomas O. McGarity, *Bhopal and the Export of Hazardous Technologies*, 20 TEX. INT'L L.J. 333, 333–39 (1985) (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 (discussing how avoidance of the cost of safety controls can and does result in unsafe products that may be imported back to the United States and how consumers suffer a similar dilemma with pesticide residues, creating a “circle of poison,” when U.S. exported pesticides re-enter the United States on imported crops).

30. Hao Xin & Richard Stone, *Tainted Milk Scandal: Chinese Probe Unmasks High-Tech Adulteration with Melamine*, 322 SCI. 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 methods is pretty high,’ he says.”).

31. John D. Floros et al., *Feeding the World Today and Tomorrow: The Importance of Food Science and Technology*, 9 COMPREHENSIVE REVIEWS IN FOOD SCI. & FOOD SAFETY 1 (2010).

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

ensuring food safety—designed primarily with relatively simple food supply chains in mind—are ill-suited to regulating the current interconnected global web of supply.

A series of large foodborne illness outbreaks in the United States 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.<sup>33</sup> Then in 2008, Chinese infant formula and other dairy products were contaminated with melamine.<sup>34</sup> China alone reported almost 300,000 victims.<sup>35</sup>

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.<sup>36</sup> More than 3,900 peanut-containing products produced by more than 200 companies were made with contaminated ingredients from PCA.<sup>37</sup>

These cases reveal the degree of interconnectedness of today's food supply. PCA only produced 2.5 percent of the peanut paste in the United States (with \$25 million in sales in 2008), but PCA wholesale ingredients were used to produce more than 3,900 products

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Inspection Act of 1906, 21 U.S.C. § 601 (2012).

33. *Melamine Pet Food Recall – Frequently Asked Questions*, U.S. FDA (Oct. 7, 2009), <http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm129932.htm>.

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. *Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008–2009 (Final Update)*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 11, 2010), <http://www.cdc.gov/salmonella/typhimurium/update.html>. The actual numbers would be higher than the confirmed cases. CDC estimates that for every reported case of salmonellosis another 29 cases go unreported. See Elaine Scallan et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 EMERGING INFECTIOUS DISEASES 7 (2011), available at <http://dx.doi.org/10.3201/eid1701.P11101> (presenting estimates of foodborne illness in the United States).

37. KELSEY WITTENBERGER & ERIK DOHLMAN, USDA ECON. RESEARCH SERV., PEANUT OUTLOOK: IMPACTS OF THE 2008-09 FOODBORNE ILLNESS OUTBREAK LINKED TO *SALMONELLA* IN PEANUTS 13 (Feb. 2010), available at [http://www.ers.usda.gov/media/146487/ocs10a01\\_1\\_.pdf](http://www.ers.usda.gov/media/146487/ocs10a01_1_.pdf).

made by other companies.<sup>38</sup> Consequently the value of recalled product likely exceeded the annual sales of PCA by an extraordinary degree. The total industry losses (including lost sales) from PCA contamination are estimated at \$1 billion.<sup>39</sup>

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.<sup>40</sup>

### *B. The Food Safety Modernization Act*

In the face of such scandals, the Congress passed the FSMA, signed into law in 2011.<sup>41</sup> 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 and Drug Act.<sup>42</sup> The 1958 Food Additives Amendment<sup>43</sup> provided more detailed, technical provisions to the law.<sup>44</sup> In comparison, the FSMA is broad in scope like the 1938 act and also detailed like the 1958 Amendment.<sup>45</sup>

The FSMA shifts the focus of the U.S. Food and Drug

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38. *Id.* at 2.

39. Zach Mallove, *USDA Releases Study on Peanut Industry*, FOOD SAFETY NEWS (Feb. 4, 2010), <http://www.foodsafetynews.com/2010/02/usda-releases-study-on-peanut-industry/#.VRCcTPl4rYg>.

40. *Id.*

41. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).

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. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 (2012).

43. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784.

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 their petition to demonstrate a reasonable certainty of safety. 21 U.S.C. § 348. The requirements include any conditions on 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. 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*, 2011 EUR. FOOD & FEED L. REV. 260, 266 (comparing the FSMA to other food safety laws).



Administration (FDA) from reactive role to a more preventative role in solving food safety problems.<sup>46</sup> The FSMA empowers 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.<sup>47</sup> There is now an onus on importers to verify that 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

The FMSA empowers federal regulators with a variety of tools to address the problem of food adulteration in the international food supply chain. Among these are science-based preventive controls and new techniques for implementing these controls, such as mandatory certification, third party accreditation, and increased authority for FDA to operate beyond U.S. borders.

### A. *New Science-Based, Preventive Controls*

The FSMA creates a new paradigm for regulating imported foods. Prevention, not reaction, is the guiding principle. The responsibility for prevention rests primarily on food producers and processors, and applies equally domestically and abroad.<sup>48</sup> The preventive framework is built on a foundation of scientific controls based upon principles of risk prevention. This section will discuss how these controls work. Additionally, it will discuss the FSMA's specific provisions governing preventive controls in the produce industry.

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46. Specifically, this is done 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 discussion *infra* Part II.

47. See FDC Act § 423 (recall); *id.* §§ 408–09 (risk control plans and produce safety standards); *id.* § 805 (importer verification).

48. See MICHAEL TAYLOR, THE FDA FOOD SAFETY MODERNIZATION ACT: PUTTING IDEAS INTO ACTION 2 (2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM254885.pdf> (“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.”).

### 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.<sup>49</sup> A scientific approach to identifying, evaluating, and controlling food safety hazards, Hazard Analysis and Critical Control Points (HACCP), was developed in the late 1950s and early 1960s for the National Aeronautics and Space Administration (NASA).<sup>50</sup> The benefits of HACCP have been widely acknowledged,<sup>51</sup> although the adoption of HACCP into law has been slow.<sup>52</sup>

At long last, the FSMA now requires that all FDA-regulated food companies implement hazard analysis and preventive controls unless specifically exempt.<sup>53</sup> All food facilities, including foreign facilities importing food into the United States, must implement a written hazard analysis and risk-based preventive control plan, sometimes called a HARPC (pronounced “Harp See”) plan.<sup>54</sup> 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.<sup>55</sup> In short, the FSMA requires the establishment of science-based mitigation strategies to prepare and protect the food supply chain against contamination at vulnerable points.<sup>56</sup>

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49. *E.g.*, LEAVITT, *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).

51. *See, e.g.*, 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.”).

52. Fortin, *supra* note 50, at 571 (explaining that fear of repercussions from adoption of HACCP took two forms: fear that government regulators would use HACCP against the industry, and fear that HACCP records would be damaging if released during lawsuits).

53. The exemptions include juice and seafood producers 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 United States, and products from facilities subject to FDA's low acid canned food requirements (exempt for microbiological hazards only). FDC Act § 418(j)–(k), 21 U.S.C. § 350g(j)–(k) (2012).

54. *Id.*

55. 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) (2012).

56. FDC Act § 418, 21 U.S.C. § 350g (2012).

## 2. Produce Safety Standards

The 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.”<sup>57</sup> 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 focuses on reducing 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 practices, domesticated and wild animals, equipment, tools, and buildings.<sup>58</sup>

### *B. Implementing the Regulatory Controls on Imported Foods*

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

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

The scope of this paper does not permit covering all of the above elements and is limited to the most salient points, including the definition of “importer,” the foreign supplier verification programs, mandatory certification authority, accreditation of third-party auditors, and increased FDA foreign presence.

### 1. Definition of “Importer”

The definition of an importer is central because it determines responsibility and liability under the law. An importer is a person in

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57. FDC Act § 419, 21 U.S.C. § 350h (2012).

58. *Id.*

the United States who has purchased the food being offered for import.<sup>59</sup> If there is no U.S. owner at the time of entry, the importer is the U.S. consignee.<sup>60</sup> 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.<sup>61</sup>

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. Congress, thinking like a regulatory Archimedes, placed the levers and fulcrums of the regulatory systems for maximum leverage.

## 2. Foreign Supplier Verification Programs

Importers are required to develop, maintain, and follow a foreign supplier verification program for each nonexempt food product imported. 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 United States has been produced in a manner that provides the “same level of public health protection” afforded domestic food.<sup>62</sup>

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.<sup>63</sup> At a minimum, the importer compliance status review must include a check of any FDA warning letters and import alerts.<sup>64</sup>

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

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59. FDC Act § 805(a)(2), 21 U.S.C. § 384a(a)(2) (2012).

60. *Id.*

61. *Id.*

62. FDC Act § 805(a)(1), (c)(2), 21 U.S.C. § 384a(a)(1), (c)(2) (2012). In particular, subsections (a)(1)(A) and (c)(2)(A)(i) refer to the requirements in §§ 350g and 350h.

63. *Id.*

64. *Id.* That is, determining compliance would at minimum include verifying there is no FDA record of non-compliance.

procedures.<sup>65</sup>

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.<sup>66</sup> 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.<sup>67</sup>

### *C. Mandatory Certification Authority*

FDA may now require certifications to assure particular foods comply with U.S. safety requirements as a condition of entry into the country.<sup>68</sup> The requirement for certification may be shipment-specific or by facility.<sup>69</sup> The certification authority is broadly worded but must be science-based and based on known risks, and the measure is intended for high-risk foods.<sup>70</sup> The certifications must be issued by a government representative designated by FDA or by third parties accredited in accordance with provisions in the FSMA.<sup>71</sup>

### *D. Accreditation of Third-Party Auditors*

The FSMA directs FDA to establish a program for the accreditation of third-party auditors for foreign food facilities.<sup>72</sup> 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, the FSMA empowers FDA with the authority to accredit other countries' inspection programs for this purpose.

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65. FDC Act § 805(c)(4), 21 U.S.C. § 384a(c)(4) (2012).

66. FDC Act § 805(a)(1), 21 U.S.C. § 384a(a)(1) (2012) (requiring verification of compliance with FDC Act § 418(e) and (f)).

67. FDC Act § 805(d), 21 U.S.C. § 384a(d) (2012).

68. FDC Act § 801(q)(1), 21 U.S.C. § 381(q)(1) (2012).

69. *Id.*

70. See FDC Act § 801(q)(2), 21 U.S.C. § 381(q)(2) (2012); INTERAGENCY WORKING GRP. ON IMPORT SAFETY, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT 17 (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 (2012).

72. FDC Act § 808(b), 21 U.S.C. § 384a(b) (2012).

### 1. 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.<sup>73</sup> 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.<sup>74</sup> This is commonly referred to as a “fast track program” or “green-lane.”

#### *E. Increased FDA Foreign Presence*

In the FSMA, Congress mandated an increase in 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.<sup>75</sup> On the other hand, Congress also directed FDA to conduct 600 foreign inspections in 2011 and to double the amount every year for five years.<sup>76</sup> FDA would need to increase inspections from 216 in 2010 to 19,200 in 2016.<sup>77</sup> That quantity of foreign inspections is unrealistic, 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.<sup>78</sup>

There is, however, a silver lining to FDA’s resource constraints in conducting investigations abroad. 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. The FSMA authorizes FDA to enter into reciprocity

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73. See discussion *supra* Part II.C.

74. FDC Act § 806, 21 U.S.C. § 384b (2012).

75. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885, 3966 (2011) (requiring FDA foreign offices).

76. FDC Act § 421(a)(2)(D), 21 U.S.C. § 350j(a)(2)(D) (2012).

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. The FSMA’s mandate would nearly triple that amount in the first year to 600, and then increase to 19,200 inspections in five years. *Id.*

78. See generally IWG, PROTECTING AMERICAN CONSUMERS, *supra* note 17 (discussing challenges government agencies face in implementing food safety regulations).

agreements. Specifically, FDA could count other nations' audits as "FDA" inspections if they are performed to meet harmonized requirements.<sup>79</sup>

FDA already has a successful model for such international cooperation in the USDA Food Safety Inspection Service (FSIS). As a condition for importing meat, poultry, and egg products to the United States, the FSIS certifies foreign countries that, in turn, certify producers as meeting United States requirements for eligibility to export to the United States.<sup>80</sup>

Governments are not alone in facing the challenges of a global food supply system, either. The food industry itself has a need for international food safety management to reduce their risk and maintain consumer confidence. In the 1990s, global food retailers and manufacturers faced audit fatigue as countless, inconsistent, in-house standards were developed in isolation around the globe. 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.<sup>81</sup> A major GFSI objective is benchmarking food safety management systems for equivalence in order to reduce redundancy and to increase efficiency.<sup>82</sup> The impossibility of implementing the FSMA's requirements alone provides FDA with an incentive to leverage existing and successful third-party programs, such as the GFSI benchmarks, to grease the wheels of international cooperation.

No matter how good the FSMA's new controls are in theory, they 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.

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79. FDA has a long history of counting state inspections within the United States as FDA inspections when conducted according 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) (stating that the "FDA Relies Heavily on State Food Firm Inspections").

80. 21 U.S.C. § 620 (2012) (requiring USDA certification of meat inspection programs in foreign countries to meet U.S. standards as a condition of import into the United States).

81. GLOBAL FOOD SAFETY INITIATIVE FOUNDATION, THE GLOBAL FOOD SAFETY INITIATIVE GFSI GUIDANCE DOCUMENT 11 (6th ed. 2013), *available at* [http://www.mygfsi.com/images/mygfsi/gfsifiles/gfsi\\_guidance/GFSI\\_Guidance\\_Document.pdf](http://www.mygfsi.com/images/mygfsi/gfsifiles/gfsi_guidance/GFSI_Guidance_Document.pdf).

82. *Id.* at 12.

### III. CONSIDERATION OF FREE TRADE AGREEMENTS

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

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.<sup>83</sup> Foundational principles from the GATT were incorporated into the WTO. One of those foundational principles is the Principle of Nondiscrimination in Trade.<sup>84</sup> Among members, imported goods must be treated equally with domestic goods.

Those parts of the 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 the FSMA places more restrictive requirements on foreign goods than domestic goods, the United States could violate its obligations under the WTO.<sup>85</sup> However,

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83. 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.

84. See General Agreement on Tariffs and Trade art. I, III, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 (explaining that a member must not discriminate between "like" products from different trading partners or between its own producers and like foreign products).

85. The WTO agreements covering safety of agricultural products are the GATT, the Agreement on the Application of Sanitary and Phytosanitary Measures, known as the "SPS Agreement," 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) 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 . . . . The basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide



additional requirements on foreign producers for health or safety purposes are permitted if based on sound scientific reasons.<sup>86</sup>

Additionally, under the Sanitary and Phytosanitary Agreement (SPS), a country that adopts a higher level of sanitary or phytosanitary protection must conduct a risk assessment.<sup>87</sup> In the risk assessment, the country must consider the available scientific evidence and other factors.<sup>88</sup> 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.<sup>89</sup> 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 for those adverse effects to occur.<sup>90</sup>

Similarly, the Agreement on Technical Barriers to Trade (TBT) prohibits imported products being treated less favorably than similar domestic products.<sup>91</sup> Technical regulations cannot be more trade-restrictive than necessary to fulfill a “legitimate objective.”

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the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes . . . .”); *see also* Agreement on Technical Barriers to Trade art. 2, 1867 U.N.T.S. 120 (“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.”).

86. 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.” General Agreement on Tariffs and Trade art. XX(b), Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194. 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.” Agreement on the Application of Sanitary and Phytosanitary Measures art. 2, Apr. 15, 1994, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

87. *See* SPS Agreement, *supra* note 86, art. 5 (“Members shall ensure that their sanitary or phytosanitary measures are based on an assessment[.]”).

88. *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 . . . .”).

89. *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.”).

90. Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, ¶ 11, WT/DS26/AB/R (Jan. 16, 1998) [hereinafter *EC Measures*] (“‘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.”).

91. Agreement on Technical Barriers to Trade, *supra*, note 85, art. 2.1 (in the WTO parlance, stating that imported products cannot be treated less favorably than “like” domestic products).

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.”<sup>92</sup>

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.<sup>93</sup> Importers must establish a verification program for each type of food being imported.

The details and specific requirements of these programs can vary from supplier to supplier and from country to country. Similarly, FDA’s new authority to require certification as an assurance of compliance for high-risk imported foods, as a condition of entry into the United States, may be applied differently among nations.<sup>94</sup>

Overall, two principles of international trade law must be considered in the implementation of the FSMA. First, the United States may not impose stricter regulations on the importers of food than it does on its own suppliers. Second, the FSMA must not violate international agreements on technical barriers to trade. In light of these complications, the United States must work cooperatively with other countries to best implement the FSMA.

#### *A. Sanitary and Phytosanitary Measures*

Unless justified by scientific evidence, applying rules to foreign importers that are different than those applied to domestic producers risks an SPS violation 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.<sup>95</sup>

It remains undetermined how FDA will apply the FSMA’s requirements, but the law dictates the general thrust of what to

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92. *Id.* art. 2.2.

93. FDC Act § 805, 21 U.S.C. § 384a (2014).

94. FDC Act § 808(c)(2), 21 U.S.C. § 384d(c)(2) (2014).

95. *See* SPS Agreement, *supra* note 86, 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 90, at 176 (internal quotation marks omitted))).

expect. Fundamentally, the 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 a lack of scientific evidence supporting the safety standards would similarly be hard to make out. The 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 for domestic food.<sup>96</sup> 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.<sup>97</sup> Essentially, the 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.<sup>98</sup> 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.<sup>99</sup> In addition, similar to the FSMA, the E.U. General Food Law (Regulation EC/178/2002) places the primary responsibility for

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96. FDC Act § 805(c)(2), 21 U.S.C. § 384a(c)(2) (2014).

97. FDC Act § 805(a), (c)(2), 21 U.S.C. § 384a(a), (c)(2) (2014).

98. *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.”); CODEX COMM. ON FOOD HYGIENE, CAC/RCP 1-1969, GEN. PRINCIPLES OF FOOD HYGIENE 21 (2003) (“The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food.”).

99. *See* Regulation 852/2004 of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs, 2004 O.J. (L 139) 3, 5 (“[G]eneral implementation of procedures based on the HACCP principles . . . should reinforce food business operators’ responsibility . . . [and] it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment.”).

ensuring food safety on the food industry, likewise requiring process-based controls, and is aimed at the whole supply chain.<sup>100</sup> The FSMA requirement of “same level of public health protection”<sup>101</sup> for imported food can be found conceptually in the European Union principle of equivalence, which is found in Article 11 of Regulation (EC) 178/2002, and is a foundation of the E.U. import system:

Food and feed imported into the Community for placing on 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 the FSMA does not offend the SPS agreement, the law’s implementation could present issues. For example, the FSMA requires that risk-based, scientific data provide the reasons for requiring certifications for importers.<sup>102</sup> This certification is designed to ensure that imported food is “as safe as” domestically produced food.<sup>103</sup> The keys 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.<sup>104</sup>

If the law is applied by FDA, as directed by the FSMA, FDA’s regulations and procedures will be based on scientific risk assessments, and thus will not violate the SPS. The nature of the

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100. Regulation 178/2002, of the European Parliament and of the Council of 28 January 2002, lays down the general principles and requirements of food law, establishes the European Food Safety Authority, and dictates procedures in matters of food safety. *See* 2002 O.J. (L 31) (“[I]t is necessary to consider all aspects of the food production chain . . . because each element may have an impact on food safety.”).

101. As expressed in the FDA Food Safety Modernization Act and incorporated at FDC Act § 805(c)(2).

102. 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).

103. *See id.* (“[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 . . .”).

104. The European Union has had regulations regarding certifications for foreign facilities since 1999 for certain processes. Commission Implementing Decision of 21 May 2012 amending Decision 2002/840/EC adopting the list of approved facilities in third countries for the irradiation of foods, 2012 O.J. (L 134) 29, 29–30.

scientific and risk-based evidence called for by the 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.<sup>105</sup>

### *B. Technical Barriers to Trade*

Some provisions of the FSMA require conformity with detailed standards and procedures and so the Agreement on Technical Barriers to Trade (TBT) applies, too. 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 recordkeeping 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 European Union, all food businesses must be able to trace their products one step forward and one step back in the supply chain.<sup>106</sup>

FDA should be able to comply with TBT rules in implementing the FSMA because the technical requirements are designed to place the same requirements on foreign food products as on domestic food and have rationales related to scientific, risk-based concerns.<sup>107</sup> For example, the traceability requirement is important for removing

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105. Compare Regulation 178/2002, *supra* note 100, art. 22 (listing scientific advice and scientific opinion on human, animal, and plant welfare as factors to be considered), with FDC Act § 810(q), 21 U.S.C. § 381(q) (2014) (listing scientific, risk-based evidence of food safety to be the basis for certification).

106. See Regulation 178/2002, *supra* note 100, 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.”).

107. See, e.g., FDC Act § 801(q), FDC Act § 384(a) (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 that the food is not adulterated under § 402 and not misbranded under § 403(w) (concerning food allergen labeling)).

unsafe foods from the marketplace whenever they are discovered.<sup>108</sup> The rationale behind most FSMA technical requirements is to move from reaction to prevention of food safety problems, and to do this, the FSMA necessarily places the responsibility for food safety squarely on the shoulders of the manufacturer and seller of that food.<sup>109</sup>

### *C. Heightened International Cooperation*

While the FSMA imposes significant new responsibilities on importers, it also provides an opportunity to encourage international cooperation. The food safety regulatory systems in the United States and E.U. demonstrate that different approaches in regulations and standards can achieve the same goal. Both the European Union and the United States 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 the FSMA could stimulate a movement toward the cooperation of various regulatory regimes working together to achieve the same food safety goals. Numerous steps, including the formation of the Codex Alimentarius Commission (CAC),<sup>110</sup> the World Organisation for Animal Health (OIE),<sup>111</sup> and the International Plant Protection

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108. See CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS CAC/GL 60-2006, PRINCIPLES FOR TRACEABILITY/PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM (noting that traceability can improve effectiveness of food safety regulations and can prevent of food fraud).

109. See, e.g., FDC Act § 805 (requiring importer verification of compliance with food safety requirements of the United States); FDC Act § 418 (requiring hazard analysis and risk-based preventive controls).

110. 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.” *About Codex*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/about-codex/en/> (last updated Mar. 3, 2015).

111. The Office International des Epizooties (OIE) was established by international agreement signed on January 25 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). *About Us*, WORLD ORG. FOR ANIMAL HEALTH, <http://www.oie.int/about-us/> (last visited Apr. 2, 2015).

Convention (IPPC)<sup>112</sup> 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.<sup>113</sup>

We should encourage various national agencies to increase their participation in these international standards-setting organizations. 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.<sup>114</sup> 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 by providing advance notice of risky shipments.

Perhaps most importantly, mutual recognition of equivalent systems can foster effective cooperation and encourage agencies to better leverage each others' resources.<sup>115</sup> For example, FDA has recognized that the food safety regulatory system of the New Zealand Ministry for Primary Industries (MPI) provides a level of food safety comparable to FDA's regulatory system. Conversely, New Zealand recognized the FDA system as comparable to MPI's.<sup>116</sup> This recognition and harmonization lessens the regulatory burden for both countries by removing unnecessary duplication of regulatory

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112. 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. INTERNATIONAL PLANT PROTECTION CONVENTION, <http://ipcc.ch/organization/organization.shtml>.

113. See, e.g., SPS Agreement, *supra* note 86, 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.").

114. See INTERAGENCY WORKING GRP. ON IMPORT SAFETY, *supra* note 17, at 17 ("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.").

115. 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 March 26, 2015) (memorializing an agreement between the nations that describes areas of cooperation pertaining to the safety of foods traded between them).

116. *Id.*

oversight for foods traded between the countries.

Moreover, because the regulatory systems achieve comparable food safety levels, FDA should be able to coordinate so that MPI food inspections of New Zealand exporters (which export to the United States) count towards the total number of FDA foreign inspections. Future coordination could allow MPI's inspections of *other* nations' food exporters to count towards FDA's total foreign inspections, too. 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, MPI could coordinate counting an FDA inspection of a Chinese food exporter towards New Zealand's foreign inspection goals.

Further coordination of inspection results through harmonized electronic data formats could allow faster response to food safety problems. For instance, if an MPI inspection revealed a potential problem with a food exporter, the inspection results could be electronically transmitted and available as quickly to FDA as to MPI. This data coordination would allow 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.

The food safety policies of most nations have similar goals: human health and safety. This creates the opportunity to leverage one another's resources in assuring the safety of global food sources.

#### IV. CONCLUSION

While global supply chains have made purely domestic regulation less effective, mutual recognition and cooperation among national regulatory systems would provide opportunities for all countries involved to increase both efficiency and effectiveness in regulation and in trade. The FSMA provides, for the first time, a framework in which 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, and less redundancy, 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 regulation.

The circumstances are ripe for a new age of global governance over food safety. Tragic foodborne illness outbreaks provide stark illustrations 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 the 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 the application of science-based, preventive controls applied uniformly to foreign and domestic food. If FDA implements the law as mandated, the FSMA will not offend the WTO SPS or TBT agreements.

FSMA measures for increasing the safety of the U.S. food supply by extending 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 numerous blessings that most would agree outweigh the associated ills.

The spirit of hope was also in Pandora's Box. Our world of globalization brings hope, too, but it is up to us to turn that hope into a reality. Now is the time to knock down barriers to transnational cooperation on food safety and take proper advantage of globalization's gifts.