



# The Federal Food Safety Modernization Act: Impacts in Import and Small-Scale Production Sectors

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**The Federal Food Safety Modernization Act:  
Impacts in Import and Small-Scale Production Sectors\***

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\* Submitted in satisfaction of the 2011 Food and Drug Law course requirement.

**Abstract.** This paper examines the recently enacted Food Safety Modernization Act and its effects on small-scale farmers/processors and food importers. Part I examines the exceptional treatment given to small-scale producers and farmers. Part II discusses the heightened regulation of imported foods. Part III demonstrates that the decision to heighten import regulation while providing exemptions for small-scale producers was not predicated on a scientific risk analysis, and argues that this regulatory scheme leaves significant gaps in the food safety system.

## **Introduction**

The regulation of the food supply is one of the most important responsibilities of the federal government.<sup>1</sup> Federal oversight involves fifteen agencies that administer over thirty laws relating to food safety.<sup>2</sup> The Food and Drug Administration (“FDA”) is the oldest comprehensive consumer protection agency in this country, and it has jurisdiction over approximately eighty percent of the nation’s food supply.<sup>3</sup> The FDA derives much of its authority from the Food Drug and Cosmetics Act (“FD&C Act”), which has been amended more than a hundred times since its enactment in 1938.<sup>4</sup>

Recently, a series of high-profile-food-safety incidents put the lives of Americans at risk and brought into question the efficacy of the federal oversight of the nation’s food supply.<sup>5</sup> The most notable outbreaks included the *salmonella* contaminated peanut products in 2008-2009, the melamine contaminated animal food and dairy products in 2007-2008, and the *e. coli* outbreak from spinach in 2006.<sup>6</sup> These incidents exposed significant gaps in the regulation of the food supply that needed to be addressed.

With the recent outbreaks fresh in the public’s mind, the President, Congress, and the FDA all began looking for ways to shift to a more preventive approach to food safety that would better equip the government to identify and avoid such incidents. On March 14, 2009, President Barack Obama announced a Food Safety Working Group to determine “how we can upgrade our

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<sup>1</sup> See President Barack Obama, Weekly Address: President Barack Obama Announces Key FDA Appointments and Tougher Food Safety Measures (Mar. 14, 2009), *available at* [http://www.whitehouse.gov/the\\_press\\_office/Weekly-Address-President-Barack-Obama-Announces-Key-FDA-Appointments-and-Tougher-F/](http://www.whitehouse.gov/the_press_office/Weekly-Address-President-Barack-Obama-Announces-Key-FDA-Appointments-and-Tougher-F/).

<sup>2</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-449T, FEDERAL OVERSIGHT OF FOOD SAFETY: HIGH-RISK DESIGNATION CAN BRING NEEDED ATTENTION TO FRAGMENTED SYSTEM (Feb. 8, 2007), *available at* <http://www.gao.gov/new.items/d07449t.pdf>.

<sup>3</sup> FDA, *History* (July 29, 2010), <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

<sup>4</sup> PETER HUTT, ET AL., FOOD AND DRUG LAW, CASES AND MATERIALS 14 (3d Ed. 2007).

<sup>5</sup> SARAH A. LISTER & JEFFREY S. BECKER, CONG. RESEARCH SERV., R40916, FOOD SAFETY: FOODBORNE ILLNESS AND SELECTED RECALLS OF FDA-REGULATED FOODS (Apr. 15, 2010).

<sup>6</sup> *Id.* at 11-23.

food safety laws for the 21st century.”<sup>7</sup> The 111th Congress announced nearly a dozen food safety bills during its 2009 to 2010 term, among them was the Food Safety Modernization Act (“FSMA” or “the Act”), which aimed to expand FDA authority under the FD&C Act, with an eye towards prevention.<sup>8</sup>

The FSMA garnered support from federal agencies and industry. In Congressional hearings, the Commissioner of the FDA supported the bill’s new focus on prevention, stating “[t]he legislation would indeed transform FDA’s approach to food safety from a system that far too often responds to outbreaks rather than prevents them.”<sup>9</sup> Recognizing the need for changes in federal oversight to ensure consumer confidence, members of industry worked closely in the drafting of the FSMA and voiced their concerns about food safety in congressional hearings.<sup>10</sup>

On December 21, 2010, the House of Representatives passed the Senate version of the FSMA,<sup>11</sup> and on January 4, 2011, the President signed the bill into law.<sup>12</sup> The FSMA amends important provisions of the FD&C Act with the goal of enhancing federal regulation of the food industry, both domestically and abroad.<sup>13</sup> The legislation focuses primarily on enhancing FDA authority and ensuring the safety of the foods that the FDA regulates.<sup>14</sup> The Act “is the largest expansion of FDA’s food safety authorities since the 1930s.”<sup>15</sup>

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<sup>7</sup> President Barack Obama, Weekly Address, *supra* note 1.

<sup>8</sup> RENEE JOHNSON, CONG. RESEARCH SERV., R40443, THE FDA FOOD SAFETY MODERNIZATION ACT (P.L. 111-353), (Feb. 18, 2011).

<sup>9</sup> *Keeping America’s Families Safe: Reforming the Food Safety System*, Before the S. Comm. on Health, Education, Labor and Pensions, 111th Cong., (October 22, 2009) (statement of FDA Commissioner Margaret Hamburg).

<sup>10</sup> *Id.* (statement of Thomas Stenzel, President and CEO, United Fresh Produce Association).

<sup>11</sup> House Vote No. 661, H.R. 2751, (Dec. 21, 2010).

<sup>12</sup> FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) [hereinafter FSMA].

<sup>13</sup> *Id.*

<sup>14</sup> The Act does not directly affect the oversight of most meat and poultry by the U.S. Department of Agriculture. *See id.*

<sup>15</sup> RENEE JOHNSON, CONG. RESEARCH SERV., R41629, FOOD SAFETY ISSUES FOR THE 112TH CONGRESS (Feb. 10, 2011).

The FDA has identified five key elements to the new law.<sup>16</sup> First, the law mandates the establishment of *preventive controls* to ensure the safety of the food supply.<sup>17</sup> Second, the law seeks to enhance both the quantity and effectiveness of FDA *inspections* in order to ensure industry *compliance*.<sup>18</sup> Third, the law focuses on the safety of *imported foods*, by requiring that importers verify that their suppliers use proper preventive techniques.<sup>19</sup> Fourth, the law enhances the FDA's ability to *respond* by giving the agency mandatory recall authority.<sup>20</sup> Fifth, the FSMA enhances *partnerships* among local, state, and federal agencies that work to ensure food safety.<sup>21</sup>

Title I of the Act authorizes the inspection of records related to food, requires agencies to set new standards for produce safety, and, most notably, requires each owner, operator, or agent in charge of a food facility to adopt hazard analysis and risk-based preventive controls (“HARPC”)<sup>22</sup> to prevent food contamination and document the procedures in a written “food plan.”<sup>23</sup> Title II gives the FDA mandatory recall authority and provides for rule-making in other areas to improve food safety by identifying high-risk facilities, establishing a program for food testing, coordinating laboratory networks to respond to foodborne illnesses, enhancing foodborne illness surveillance systems, specifying decontamination and disposal standards and plans, and enhancing the training of state and local food safety officials.<sup>24</sup> Title III aims to ensure the safety of imported foods, by requiring most importers to verify that their foreign suppliers have

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<sup>16</sup> FDA, *Questions and Answers on the Food Safety Modernization Act* (Apr. 20, 2011), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm238506.htm>.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> The HARPC requirements are similar to the preexisting Hazard Analysis and Critical Control Point (“HACCP”) requirements, which apply to canned foods, seafood, and juice.

<sup>23</sup> FSMA, Title I.

<sup>24</sup> *Id.* Title II.

complied with US food safety regulations,<sup>25</sup> providing for a voluntary certification to expedite review and importation for food importers who opt in,<sup>26</sup> and granting the FDA authority to require import certifications of certain foods deemed to be high risk, as well as authority to inspect foreign facilities.<sup>27</sup>

This paper focuses on two important aspects of the broad reform in the FSMA—regulation of small-scale food production and regulation of imported foods—by examining both the reasoning behind the regulations, and the likely impact of the regulations. Part I examines the exceptional treatment given to small-scale producers and farmers. Part II discusses the heightened regulation of imported foods. Part III demonstrates that the decision to heighten import regulation while providing exemptions for small-scale producers and farmers was not predicated on a scientific risk analysis, and argues that this regulatory scheme leaves significant gaps in the food safety system.

## **I. Small-Scale and Local Food Production**

In recent years, a significant local and small-scale farming movement has taken hold in the U.S.<sup>28</sup> Popular operations in this sector include direct farm marketing, farmers' markets, and community supported agriculture programs.<sup>29</sup> Direct to consumer sales are a fast growing portion of U.S. agriculture, increasing forty-nine percent from 2002-2007.<sup>30</sup> As of 2009, the number of farmers' markets rose to 5,274, compared to 2,746 in 1998, marking a ninety-two

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<sup>25</sup> *Id.* Title III, sec. 301, § 805.

<sup>26</sup> *Id.* Title III, sec. 302, § 806.

<sup>27</sup> *Id.* Title III, sec. 303, § 801.

<sup>28</sup> STEVE MARTINEZ ET AL., U.S. DEP'T OF AGRIC. ECON. RESEARCH SERV., ERR 97, LOCAL FOOD SYSTEMS: CONCEPTS, IMPACTS, AND ISSUES 5-7 (May 2010), *available at* <http://www.ers.usda.gov/Publications/ERR97/ERR97.pdf> [hereinafter LOCAL FOOD SYSTEMS].

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 5.

percent increase over that time period.<sup>31</sup> As of 2010, there were an estimated 2,500 community supported agriculture programs in the U.S., compared to two in 1986.<sup>32</sup> While the growth of these markets has largely been consumer driven, the U.S. government has also encouraged local food systems through a number of grant programs.<sup>33</sup>

The growth of small-scale processing facilities has not kept pace with the demand of small-scale farming intended for local distribution.<sup>34</sup> This lag has slowed the growth of the local food industry, but there have been efforts to increase small-scale farmers' access to food processing facilities.<sup>35</sup> As the growth in the local-farming movement continues, we are likely to see an increase in the number of small-scale facilities designed to meet the needs of the local distribution farming business. This has been the case in the meat industry, for example, as small-scale, even mobile, meat-processing facilities are on the rise.<sup>36</sup>

During the legislative process, the FSMA faced harsh criticism from those who thought that the bill would stymie the growth of the small and local food production markets.<sup>37</sup> These critics argued that small-scale and local farmers and food processors lack the resources to comply with complex regulations aimed predominantly at large-scale producers with

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<sup>31</sup> *Id.* at 7.

<sup>32</sup> *Id.* at 8.

<sup>33</sup> *Id.*

<sup>34</sup> See, e.g., Vermont Sustainable Jobs Fund, *Farm to Plate Strategic Plan, Food Processing and Manufacturing* (Mar. 14, 2011), available at [http://www.vsjf.org/assets/files/Agriculture/Strat\\_Plan/3.4\\_Food%20Processing.pdf](http://www.vsjf.org/assets/files/Agriculture/Strat_Plan/3.4_Food%20Processing.pdf) (discussing the need to develop Vermont's local food processing infrastructure to meet the demand of local farmers and food producers); Laura Krouse & Teresa Galluzzo, The Iowa Policy Project, *Iowa's Local Food Systems: A Place to Grow* 17 (Feb. 2007), available at <http://www.iowapolicyproject.org/2007docs/070206-LocalFood.pdf> (Conveniently located facilities allowing multiple farmers to meet the minimal processing needs of their buyers would help alleviate [the problem of lack of food processing infrastructure]."; Allison S. Perrett, Appalachian Sustainable Agriculture Project, *The Infrastructure of Food Procurement and Distribution: Implications for Farmers in Western North Carolina* (Apr. 2007), available at <http://www.asapconnections.org/special/research/Reports/Infrastructure%20of%20Distribution%20Final.pdf> ("In re-appropriating the food market from large, distant food businesses, regional processing is a significant consideration.").

<sup>35</sup> *Id.*

<sup>36</sup> Krouse & Galluzzo, *supra* note 34.

<sup>37</sup> See, e.g., Margie MacDonald & Judith McGeary, *S.510 Food Safety Modernization Act: Healthy Local Foods Amendment-Sen. Jon Tester*, [http://smallholdersalliance.com/QA-Tester-Amendment-April-15%20\(2\).pdf](http://smallholdersalliance.com/QA-Tester-Amendment-April-15%20(2).pdf) [hereinafter Tester Amendment Summary].

disproportionate resources.<sup>38</sup> On the other side of the debate, many argued that food-borne pathogens affect small-scale and large-scale farmers and processors alike, and thus legislative loopholes should not sideline safety, even for small-scale operations.<sup>39</sup>

### **A. Legislative History**

Small-scale exceptions were included in the drafting of the FSMA from early on, but as the bill progressed, the interests of small-scale processors and farmers took a more central role, and these groups ultimately secured significant exemptions from the new mandates of the FSMA.<sup>40</sup>

#### **i. Arguments for Small-Scale and Local Exemptions**

Small-scale farmers and producers were opposed to heightened federal regulation of food safety, and they voiced their concerns regarding the new regulations that Congress sought to impose via the FSMA.<sup>41</sup> They based their opposition on a number of arguments, including that state and local governments are better suited to regulate local operations,<sup>42</sup> that small-scale farmers direct relationship with the consumer allows for quality control and consumer reaction,<sup>43</sup> and that empirically, large outbreaks have occurred in national or international food supply chains, thus the costs of adhering to heightened regulations are not cost justified in consideration of the likely public health risks posed by small-scale and local operations.<sup>44</sup>

In light of these types of arguments, members of Congress initially proposed a number of exceptions for small-scale food processors and farmers that did not include an outright

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<sup>38</sup> *Id.*

<sup>39</sup> *See infra* note 52, and accompanying text.

<sup>40</sup> *See* RENEE JOHNSON, CONG. RESEARCH SERV., RL 34612, FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND LEGISLATIVE ACTION 15 (Jan. 18, 2011).

<sup>41</sup> *Id.*

<sup>42</sup> Tester Amendment Summary, *supra* note 37.

<sup>43</sup> *Id.*

<sup>44</sup> RENEE JOHNSON, CONG. RESEARCH SERV., RL 34612, FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND LEGISLATIVE ACTION 17 (Jan. 18, 2011).

exemption from substantive food safety mandates.<sup>45</sup> Some of the more modest recommendations that were adopted in the final bill include exclusions from certain registration and recordkeeping requirements, postponed effective dates for substantive provisions, and the mandatory issuance of compliance guides for small-scale businesses.<sup>46</sup>

## **ii. Introduction of the “Tester Amendment”**

Less than one month before final approval of the bill, Senator Jon Tester proposed an amendment to the Senate version of the FSMA.<sup>47</sup> The Senate Committee on Health Education Labor and Pensions (“HELP Committee”) had already modified the bill in an attempt to address the needs of small scale farmers by adding the requirement that the Department of Health and Human Services (“HHS”) Secretary “provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of raw agricultural commodities, including small business and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities.”<sup>48</sup> Senator Tester, however, found these protections inadequate, and in fact to be contradicted by the substantive requirements that he considered to be quite onerous for small-scale farmers, especially the HARPC requirements for facilities.<sup>49</sup>

In an effort to ensure that the bill would not harm small-scale food producers, Senator Tester introduced an amendment to remove certain small-scale food processors and farmers from federal oversight, leaving them to be regulated by state and local laws.<sup>50</sup> The amendment provided an exemption for certain local farmers from complying with new farming and

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<sup>45</sup> *Id.* at 15.

<sup>46</sup> *Id.* at 15-23.

<sup>47</sup> See 156 CONG. REC. S8219 (Nov. 29, 2010). Amendment language is available at <http://tester.senate.gov/legislation/upload/Tester-Food-Safety-Amendment.pdf>

<sup>48</sup> See, e.g., FSMA, secs. 103, 105.

<sup>49</sup> See Tester Amendment Summary, *supra* note 37.

<sup>50</sup> 156 CONG. REC. S8069-S8093 (Nov. 18, 2010) (statement of Sen. Tom Harkin); Tester Amendment, *available at* [http://tester.senate.gov/legislation/upload/tester\\_amendment\\_agreement.pdf](http://tester.senate.gov/legislation/upload/tester_amendment_agreement.pdf).

harvesting rules, and an exemption from the HARPC requirements for processors who qualify as “very small” or whose annual operations were under \$500,000 and who sold food within 275 miles of the facility. As expected, many farm groups supported the amendment.<sup>51</sup>

### **iii. Responses to the “Tester Amendment”**

Opponents to the so called “Tester Amendment” argued that it provided a loophole in the federal regulation for small producers, “through arbitrary size and distance threshold-neither of which have any basis in science or risk.”<sup>52</sup> The opponents were not strictly opposed to the consideration of different requirements for small-scale producers, as the original version of the Senate bill allowed, but according to some, the Tester Amendment went one step further by “creat[ing] a loophole for small processing facilities by exempting them from HACCP and traceability requirements for products entering the food supply in ways other than direct sales to consumers...these arbitrarily exempted products would comingle with items that must follow risk-based preventive controls-such as bagged salads. In the case of a foodborne illness outbreak, this exemption will make FDA's job much harder to identify and remove the tainted source from the food chain.”<sup>53</sup> Not all local farmers supported the bill, either. United Fresh Produce Association (UFPA), for example, urged the Senate not to include “exemptions based on the size of the operation, production practices, or geographic location for food being sold in the commercial market.”<sup>54</sup> Consumer groups also voiced concerns about the safety implications of such a loophole.<sup>55</sup>

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<sup>51</sup> See Letter, *Support Fresh, Safe Local Food in the Food Safety Bill* (Nov. 6, 2010), available at [http://tester.senate.gov/Legislation/upload/tester\\_amendment\\_group\\_letter.pdf](http://tester.senate.gov/Legislation/upload/tester_amendment_group_letter.pdf) (letter listing 128 organizations supporting the Tester amendment).

<sup>52</sup> 156 CONG. REC. S8225 (Nov. 29, 2010) (statement of Sen. Saxby Chambliss).

<sup>53</sup> *Id.*

<sup>54</sup> United Fresh Produce Association, *2010 Issues Brief*, [http://www.unitedfresh.org/assets/Issue\\_Brief\\_United\\_Fresh\\_Produce\\_Association\\_2010.pdf](http://www.unitedfresh.org/assets/Issue_Brief_United_Fresh_Produce_Association_2010.pdf).

<sup>55</sup> Consumers Union, *Tester Amendment to S. 510: Unintended Consequences*, <http://www.consumersunion.org/campaigns/notinmyfood/017025indiv.html>.

Despite the opposition, the Senate bill passed with a modified version of the Tester Amendment.<sup>56</sup> Members of the House did not have the opportunity to make changes to the bill before it was signed into law, but they did express their reservations regarding the Tester Amendment. Representative Pitts voiced a common concern, stating “[w]hile we do not want to overly burden small facilities and small farms, we’ve learned in our committee hearings that food-borne pathogens don’t care if you’re a big facility or a small facility, a big farm or a small farm. They affect everyone.”<sup>57</sup> Others noted that the Tester amendment may require the government to “exempt similarly sized companies in developing countries from our standards.”<sup>58</sup>

## **B. Small-Scale and Local Exceptionalism in the FSMA**

The original small-scale limitations in the Senate version of the bill, along with the modified Tester Amendment, made their way into the signed law.<sup>59</sup> The resulting effect of the exemptions for small-scale businesses will not become clear until the bill is implemented by agency rulemaking. The small-scale exceptionalism is readily identifiable, however, by a section-by-section analysis. Most notably, farms with a direct consumer relationship are exempt from the forthcoming produce requirements, and small-scale processing facilities are exempt from the food plan and associated HARPC requirements.<sup>60</sup>

### **i. Registration Requirements**

The Act carves out an important exception in the registration requirements. The FSMA sets new registration requirements, but continues to exempt all “retail food establishments” from registration.<sup>61</sup> The Act clarifies what counts as a “retail food establishment,”<sup>62</sup> by requiring the

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<sup>56</sup> S. Amdt. 4715.

<sup>57</sup> 156 CONG. REC. H8885 (Dec. 21, 2010) (statement of Rep. Joe Pitts).

<sup>58</sup> 156 CONG. REC. H8886 (Dec. 21, 2010) (statement of Rep. Frank Lucas).

<sup>59</sup> See FSMA, secs. 103, 105.

<sup>60</sup> See *id.*

<sup>61</sup> *Id.* sec. 102.

<sup>62</sup> *Id.*

HHS Secretary to amend the definition of a “retail food establishment”<sup>63</sup> to include food sold directly to consumers by a roadside stand or farmers’ market, food sold through a community-supported agriculture program, or any other direct sales platform as determined by the Secretary.<sup>64</sup> The Act requires an increase in inspections of those facilities that are required to register, making the categorization an important identifier to aid in enforcement decisions.<sup>65</sup> Further, only registered facilities are required to comply with the new HARPC food plan requirements, as discussed below.<sup>66</sup>

## **ii. Food Processors: HARPC/Food Plan Requirement**

The FSMA requires that registered facilities enact “hazard analysis and risk-based preventive controls,” and that facilities record these steps in a written food plan.<sup>67</sup> This affirmative requirement is a shift from the FDA’s historical practice of specifying which foods are adulterated or misbranded and reacting to industry failings by policing the market only after a health or safety concern arises.<sup>68</sup> The new prevention-focused requirement seeks to take a more proactive stance in addressing safety concerns by requiring industry to enact controls that identify and prevent hazards before they enter food supply.<sup>69</sup>

Section 103 of the FSMA mandates that owners, operators, or agents in charge of facilities,

evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that

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<sup>63</sup> As defined in 21 C.F.R. § 1.227(b)(11).

<sup>64</sup> FSMA sec. 102(c).

<sup>65</sup> *Id.* sec. 201.

<sup>66</sup> See discussion *infra* Food Processors: HACCP/Food Plan Requirement, at 10.

<sup>67</sup> FSMA sec. 103.

<sup>68</sup> RENEE JOHNSON, CONG. RESEARCH SERV., R40443, THE FDA FOOD SAFETY MODERNIZATION ACT (P.L. 111-353) 11 (Feb. 18, 2011).

<sup>69</sup> *Id.*

such food is not adulterated...or misbranded..., monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.<sup>70</sup>

The Act goes on to specify the types of hazards that should be evaluated,<sup>71</sup> and mandates preventive controls,<sup>72</sup> monitoring,<sup>73</sup> and corrective actions,<sup>74</sup> as well as a two year record keeping requirement.<sup>75</sup> Facilities must prepare a detailed written food safety plan that documents and describes the procedures the facility uses to comply with these new requirements.<sup>76</sup>

The term “facility,” is defined in the FFDCA,<sup>77</sup> and for the purposes of section 103 of the FFSMA, consists of those domestic or foreign entities that are required to register with the FDA.<sup>78</sup> The HARPC food plan is required only of registered facilities, and therefore those entities that are not required to register are also exempt from the requirement to enact the HARPC controls and written food plan.<sup>79</sup> As mentioned previously, this excludes certain direct-consumer sales entities from the HARPC requirements.<sup>80</sup>

In addition to the registration-based exemptions, Section 103 of the Act provides an exemption from the HARPC requirements for certain qualified entities.<sup>81</sup> In order to qualify, the facility must be either a “very small business,” as to be defined in FDA rulemaking, or have an

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<sup>70</sup> FSMA sec. 103, § 418(a).

<sup>71</sup> *Id.* sec. 103, § 418(b).

<sup>72</sup> *Id.* sec. 103, § 418(c).

<sup>73</sup> *Id.* sec. 103, § 418(d).

<sup>74</sup> *Id.* sec. 103, § 418(e).

<sup>75</sup> *Id.* sec. 103, § 418(g).

<sup>76</sup> *Id.* sec. 103, § 418(h).

<sup>77</sup> Food Drug & Cosmetic Act § 415(b), 21 U.S.C. § 350d(b), [hereinafter FD&C Act] (defining a food facility as “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer, or fishing vessels.”).

<sup>78</sup> FSMA sec. 103, § 418(o)(2).

<sup>79</sup> *Id.* sec. 103, § 418(o)(2) (“[t]he term ‘facility’ means a domestic facility or a foreign facility that is required to register under section 415”).

<sup>80</sup> *See supra* note 64, and accompanying text.

<sup>81</sup> FSMA sec. 103, § 418 (l).

average annual monetary value of sales under \$500,000, and sell food directly to “qualified end users,” which include consumers, restaurants, and retail food establishments in the same state or within 275 miles.<sup>82</sup> These qualified facilities are exempt from the general requirements of section 103, but “in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility,” the Secretary may withdraw the exemption.<sup>83</sup> In lieu of abiding by the federal HARPC requirements, the entity must demonstrate either that it has identified potential hazards and is implementing and monitoring preventive controls, or that it is “in compliance with State, local, county, or other applicable non-Federal food safety law.”<sup>84</sup>

### **iii. Farms: Produce Safety**

Prior to the enactment of the FSMA, farms that partook only in harvesting, storing or distributing raw agricultural commodities, were generally excluded from complying with current good manufacturing practices.<sup>85</sup> This meant that the farming industry mostly regulated itself. With the outbreak of farm-related food-borne pathogen illnesses, however, this self-regulation came under attack.

The Act mandates agency rulemaking to set standards for the safe production and harvesting of produce—thereby ending the era of self-policing.<sup>86</sup> Facilities that are subject to the produce safety requirements are exempt from the requirement under Section 103 to enact HARPC, which applies only to food processing facilities.<sup>87</sup> Instead, the FDA will determine the proper science-based standards that will apply to affected farms.<sup>88</sup> Specifically, Section 105 of the Act provides for rulemaking “to establish science-based minimum standards for the safe

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<sup>82</sup> *Id.*

<sup>83</sup> *Id.* sec. 103, § 418(1)(3).

<sup>84</sup> *Id.* sec. 103, § 418(1)(2).

<sup>85</sup> *See* 21 C.F.R. § 111; 21 C.F.R. § 110.19(b).

<sup>86</sup> FSMA sec. 105, § 419(a).

<sup>87</sup> *Id.* sec. 103, § 418 (k).

<sup>88</sup> *Id.* sec. 105, § 419(a).

production and harvesting” of fruits and vegetables that present a known safety risk.<sup>89</sup> The Act requires that these rules be flexible enough to apply to small businesses.<sup>90</sup>

The Act provides an important exemption from the forthcoming requirements, however, for those produce suppliers engaged in “direct farm marketing.”<sup>91</sup> Under this provision, a farm is exempt if the majority of the food sold for the previous three year period was sold directly to a consumer, restaurant, or retail food establishment, and the average monetary value of all food sold in that period was less than \$500,000.<sup>92</sup> Farms that qualify for the exemption must label the food with the name and address of the farm, or clearly display the relevant information at the point of purchase if a label is not required.<sup>93</sup> As is the case for exempted small-scale food processors under section 103, in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified farm, the Secretary may withdraw the farm’s exemption under section 105.<sup>94</sup>

### **C. Future Impact of Small-Scale and Local Exceptionalism**

Many of the small-scale exceptions made their way into the FSMA at the last minute, without time for reflection on the potential future impacts of these significant exemptions.<sup>95</sup> Therefore, it is important that consumers and government agencies take time now to reflect on the likely consequences of this exceptionalism. As the FDA engages in rulemaking, it will have discretion to shape the existing loopholes and to tighten them as necessary in order to ensure the safety of all foods—local and imported, small-scale and large-scale.

#### **i. Defining Small and Very Small Businesses**

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<sup>89</sup> *Id.* sec. 105, § 419 (a)(1)(A).

<sup>90</sup> *Id.* sec. 105, § 419 (a)(3).

<sup>91</sup> *Id.* sec. 105, § 419 (f).

<sup>92</sup> *Id.* sec. 105, § 419 (f)(1).

<sup>93</sup> *Id.* sec. 105, § 419(f)(2).

<sup>94</sup> *Id.* sec. 105, § 419(f)(3).

<sup>95</sup> See RENEE JOHNSON, CONG. RESEARCH SERV., RL 34612, FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND LEGISLATIVE ACTION 21 (Jan. 18, 2011).

The future impact on farming and production facilities will depend in part on how the FDA defines small and very small businesses in future agency rulemaking. These rules will affect when certain pieces of the legislation take effect and whether or not a facility qualifies for an exemption.

Currently, agencies differ in how they define a small business.<sup>96</sup> For example, the U.S. Department of Agriculture (“USDA”) often adopts its own standards, but in some cases has adopted the Small Business Administration’s (“SBA”) definition for small businesses, which for most crop and livestock producers includes those who make no more than \$750,000 in sales per year.<sup>97</sup> If the FDA adopts the SBA’s standards for crop and livestock small businesses, almost one-half of commercial crop and livestock producers may be defined as small.<sup>98</sup> In the case of food processors and manufacturers, different standards have applied than for farming. For example, the SBA has used the number of workers as a metric, defining a small businesses in the food processing and manufacturing industry as those with five hundred or fewer employees.<sup>99</sup> Under this definition, ninety-seven percent of all food processors would be considered small.<sup>100</sup>

It is likely that FDA rulemaking will bring about a more industry-specific calculus than that which has been employed by the SBA. It is noteworthy, however, that historically the FDA’s regulations that exempt small processors have in some industries excluded a majority of such producers from existing HACCP requirements.<sup>101</sup> It is also noteworthy that the FDA thresholds for HACCP exemptions are met for “very small businesses” if the entity meets one of

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<sup>96</sup> See RENEE JOHNSON ET. AL., CONG. RESEARCH SERV., R40443, FOOD SAFETY IN THE 111TH CONGRESS: H.R. 2749 AND S.510 19-22 (Dec. 1, 2010).

<sup>97</sup> *Id.*; Small Business Size Regulations, 13 C.F.R. § 121.

<sup>98</sup> RENEE JOHNSON ET. AL., CONG. RESEARCH SERV., R40443, FOOD SAFETY IN THE 111TH CONGRESS: H.R. 2749 AND S.510 19-22 (Dec. 1, 2010).

<sup>99</sup> Small Business Size Regulations, 13 C.F.R. § 121.

<sup>100</sup> RENEE JOHNSON ET. AL., CONG. RESEARCH SERV., R40443, FOOD SAFETY IN THE 111TH CONGRESS: H.R. 2749 AND S.510 19-22 (Dec. 1, 2010).

<sup>101</sup> *Id.*

the following three criteria: “annual sales of less than \$500,000, total annual sales greater than \$500,000 but total food sales less than \$50,000, or operations that employ fewer than an average of 100 full-time equivalent employees and sell fewer than 100,000 units of juice in the United States.”<sup>102</sup>

The FDA should conduct market analyses to set the proper thresholds for exemptions for food processing industries under the “very small business” qualification. The thresholds should be set sufficiently low that it is not economically advantageous to restructure farming and processing operations in a small-scale format in order to avoid mandatory compliance with the food plan or produce requirements by qualifying for a very small business exemption. If this possibility is not accounted for, the regulatory scheme may result in significant market restructuring towards small-scale production, with economic losses from the destruction of economies of scale and reduced effectiveness of the crucial legislative mandates for prevention in the FSMA.

## **ii. Farming Loopholes**

The new produce requirements will change the way that many farms operate, but the requirements will not reach all raw agricultural commodities. First, some fruits and vegetables will categorically fall outside of the new produce safety requirements, and thus the level of appropriate safety will continue to be set by the industry.<sup>103</sup> Second, farms that supply produce subject to the new regulations may seek an exemption by engaging in direct farm marketing, that is, selling to qualified end users and maintaining an annual monetary operation of less than \$500,000.<sup>104</sup>

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<sup>102</sup> Hazard Analysis and Critical Control Point (HACCP Systems), 21 C.F.R. § 120.

<sup>103</sup> See FSMA sec. 105, § 419(a).

<sup>104</sup> See *id.* sec. 105, § 419(f).

The FSMA does not change the record keeping requirements for farms, restaurants, and retail establishments, which continue to remain exempt, while the requirements for food processing facilities have become more stringent.<sup>105</sup> This discrepancy is somewhat surprising, as pathogens, which are the leading cause of foodborne illness, are often introduced into the food supply at the farming or harvesting stage and cannot be successfully eliminated through cooking and processing.<sup>106</sup> Given the level of risk associated with farms, enhanced record keeping would help improve traceability, but such a requirement is absent from the Act.

Because most farms continue to be exempt from the registration requirements, and the accompanying new HARPC requirements for facilities, there are incentives for farms with processing operations to discontinue these operations or move them to a separate locale in order to avoid falling under the registration and accompanying record-keeping and HARPC food plan requirements for food processing facilities. The produce safety requirements of FSMA Section 105, and the HARPC requirements of Section 103, are phrased as either/or propositions at an activity-based level—both do not apply to the same *activities* of a facility, although they may apply to the same *facility*.<sup>107</sup>

### **iii. Responding to Outbreaks**

The full impact of the small-scale loopholes will not come to light until there is safety incident arising from foods supplied by a small-scale farmer or producer. When such an incident occurs, there will likely be difficulties with traceability due to a lack of recordkeeping. Even if an investigation into the incident proves that the failure came from a lack of hazard controls and preventive steps, the small-scale nature of the harm may be insufficient to mobilize action to

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<sup>105</sup> *Id.* secs. 101, 204; FD&C Act § 414; 21 C.F.R. § 1.327.

<sup>106</sup> See RENEE JOHNSON, CONG. RESEARCH SERV., RL 34612, FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND LEGISLATIVE ACTION 15 (Jan. 18, 2011).

<sup>107</sup> FSMA, sec. 105, § 419(h) (“This section shall not apply to activities of a facility that are subject to section 418); sec. 103, § 418(k) (“This section shall not apply to activities of a facility that are subject to section 419).

modify the loopholes in the federal regulation. Despite the uncertainty regarding the food-safety outcomes, one thing seems certain—there has been a steady increase in the demand for locally farmed goods.<sup>108</sup> As this phenomenon continues, only time will tell whether federal oversight is necessary, or if safety can be ensured through state and local regulation.

## **II. Importer Regulation**

While the local and small-scale producers and farmers have largely been excluded from heightened regulation and oversight under the FSMA, importers face a regulatory regime that is much stricter than ever before.<sup>109</sup> This heightened regulation is in response to a growing awareness of threats from imported foods that preexisting regulation failed to address.<sup>110</sup>

The U.S. food supply consists of approximately fifteen percent imported foods, with sixty percent of produce and eighty percent of seafood imported from abroad.<sup>111</sup> Prior to the enactment of the FSMA, imported food was regulated only by a small number of FDA inspections.<sup>112</sup> The FDA did not have the authority, like the USDA does, to review or approve the food safety systems of exporting countries.<sup>113</sup> In the past, ensuring the safety of imported foods was largely left up to industry, members of which had an incentive to comply in order to protect their brands, but who possessed limited capabilities to affect foreign food-safety practices.

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<sup>108</sup> See *supra* note 28, and accompanying text.

<sup>109</sup> See FSMA, Title III.

<sup>110</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-699T, FOOD SAFETY: FDA COULD STRENGTHEN OVERSIGHT OF IMPORTED FOOD BY IMPROVING ENFORCEMENT AND SEEKING ADDITIONAL AUTHORITIES 3 (May 6, 2010).

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> See CAROLINE SMITH DEWAAL & DAVID W. PLUNKETT, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, BUILDING A MODERN FOOD SAFETY SYSTEM FOR FDA REGULATED FOODS 8 (2009), available at <http://www.cspinet.org/new/pdf/fswitepaper.pdf>.

A 2010 U.S. GAO Report identified a number of areas in which the safety of the U.S. food supply might be threatened by imports.<sup>114</sup> The study found that gaps in the system allowed for imported foods to evade FDA regulation, in part because of a lack of authority to assess civil penalties on certain violators, the lack of a unique identifier for exporter firms abroad, and the lack of a mandatory recall authority.<sup>115</sup> In drafting the FSMA, members of Congress attempted to address these shortcomings.

#### **A. FSMA Importer Paradigm**

The FDA is a domestic public health protection and promotion agency, but in order to satisfy its domestic mission, it needs to reach abroad—increased reliance on imported foods demands it.<sup>116</sup> The FSMA enhances importer regulation by granting the FDA greater authority, enhancing prohibitions on unsafe foods, and heightening requirements for importers by mandating that their foreign suppliers meet U.S.-equivalent food safety requirements.<sup>117</sup>

##### **i. Increased FDA Presence Abroad**

Title III of the FSMA includes numerous provisions aimed at ensuring the safety of imported food.<sup>118</sup> A number of the provisions indicate a need to have a greater role in food safety of other countries and an enhanced FDA presence abroad.<sup>119</sup> Other provisions focus more directly on ensuring the safety of the food that is imported to the U.S.<sup>120</sup> The FDA plans to rely on extra-agency resources to meet the demands of Title III, for example by establishing a system

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<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-699T, FOOD SAFETY: FDA COULD STRENGTHEN OVERSIGHT OF IMPORTED FOOD BY IMPROVING ENFORCEMENT AND SEEKING ADDITIONAL AUTHORITIES 3 (May 6, 2010).

<sup>117</sup> FSMA, Title III.

<sup>118</sup> See *id.*

<sup>119</sup> See *id.*

<sup>120</sup> See *id.*

to recognize third-party auditors of foreign facilities who will have the authority to certify that foreign suppliers of imported food have met U.S. or equivalent standards for food safety.<sup>121</sup>

The Act grants the FDA the right to inspect in other countries,<sup>122</sup> and requires the FDA to establish additional offices abroad.<sup>123</sup> The goal of these foreign FDA offices is not to regulate foreign markets directly, but rather to ensure the safety of the foods produced in the country that are intended for export to the US.<sup>124</sup> Prior to the enactment of the law, the FDA had 13 foreign posts, which it established primarily in response to the food outbreaks of 2007-2008.<sup>125</sup>

In addition to establishing foreign offices, the Secretary is required to develop a plan “to expand the technical, scientific, and regulatory food safety capacity of foreign governments.”<sup>126</sup> This mandate for capacity building certainly reaches further than prevention focused solely on the safety of imports to the U.S. The FDA plans to rely on “partnerships” with other countries to enhance their regulatory food safety capacity,<sup>127</sup> but it is not clear how the FDA is expected to accomplish this goal, as it does not have resources for international development, nor does it have a significant international team.<sup>128</sup>

## **ii. Preventing Entry of Smuggled and Known Contaminated Food**

The Act contains provisions aimed specifically at protecting U.S. borders from smuggled, adulterated or misbranded food. Section 309 requires the HHS Secretary in coordination with the Secretary of Homeland Security to develop a strategy to prevent the entry of smuggled food,

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<sup>121</sup> FSMA Title III; Michael R. Taylor, Deputy Commissioner for Foods, *The FDA Food Safety Modernization Act: A New Paradigm for Importers*, Speech at Global Food Safety Conference, London, England (Feb. 17, 2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/OfficeofFoods/UCM254881.pdf>.

<sup>122</sup> *Id.* sec. 306, § 807(a).

<sup>123</sup> *Id.* sec. 308.

<sup>124</sup> *Id.*; FDA Public Meeting, *FDA Food Safety Modernization Act: A New Paradigm for Importers*, Transcript at 25 (Mar. 29, 2011) (statement of Murray Lemkin, FDA Deputy Commissioner for International Programs).

<sup>125</sup> FDA, Report to Congress, *Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices* (Apr. 6, 2011), available at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm250569.htm>.

<sup>126</sup> FSMA sec. 305.

<sup>127</sup> Taylor, *supra* note 121.

<sup>128</sup> FDA Public Meeting, *FDA Food Safety Modernization Act: A New Paradigm for Importers*, Transcript at 29-30 (Mar. 29, 2011) (statement of Murray Lemkin, FDA Deputy Commissioner for International Programs).

and grants the Secretary authority to give public notification of smuggled food if he “reasonably believes exposure to the food would cause serious adverse health consequences....[and] that the food has entered domestic commerce and is likely to be consumed.”<sup>129</sup> Section 115 grants the FDA authority to require notification of a previous refusal of admittance of food into the U.S., in an attempt to combat port shopping.<sup>130</sup>

### **iii. Foreign Supplier Verification**

One of the most significant grants of authority in the FSMA comes from section 301, which requires importers to verify that their foreign suppliers have complied with the safety precautions equivalent to the requirements of U.S. food safety laws.<sup>131</sup> Within one year of the enactment of the FSMA, the Secretary will issue regulations for the content of these required “foreign supplier verification programs” (“FSVP”).<sup>132</sup> The regulations will require suppliers to use “reasonably appropriate risk-based preventive controls,” based on a written food plan.<sup>133</sup> The risk-based preventive controls for importers are aimed at achieving “the same level of public health protection” as the requirements for domestic facilities.<sup>134</sup> The Act provides that the foreign supplier verification program “may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.”<sup>135</sup>

Importers may agree to participate in a program to expedite the entry of imports by complying with higher safety standards under a “voluntary qualified importer program”

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<sup>129</sup> FSMA sec. 308.

<sup>130</sup> *Id.* sec. 115; *see infra* note 166, and accompanying text.

<sup>131</sup> FSMA sec. 301, § 805.

<sup>132</sup> *Id.* sec. 301, § 805(c).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* sec. 301, § 805(c)(4).

(“VQIP”).<sup>136</sup> The program will operate by granting a certificate that will accompany the food that is imported into the U.S. by qualified importers.<sup>137</sup> Importer eligibility will be based on a review of the applicants in consideration of a number of factors, including “the known safety risks of the food to be imported,” “the compliance history of foreign suppliers used by the importer,” and “the capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food.”<sup>138</sup>

#### **iv. Certification Requirements**

The FSMA grants authority to the HHS Secretary to require certain foods to be certified as in compliance with applicable requirements of the FD&C Act.<sup>139</sup> The factors that the certification requirement must be based on include, “known safety risks associated with the food” and “the country, territory, or region of origin of the food,” as well as scientific, risk-based evidence that the standards of the foreign country are inadequate to meet U.S. standards, and that certification would assist decisions on whether or not to deny the food entry.<sup>140</sup> The foreign governments themselves, or another accredited entity, will provide the certifications.<sup>141</sup> Section 307 of the Act provides the extensive standards for third party auditors to certify that foods to be imported meet U.S. requirements.<sup>142</sup> Third party auditors are intended to be used in conjunction with both the mandatory certification and the voluntary qualified importer sections of the FSMA.<sup>143</sup> Foods that require certification but fail to obtain it “shall be refused admission.”<sup>144</sup>

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<sup>136</sup> *Id.* sec. 302, § 806.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* sec. 303(a).

<sup>140</sup> *Id.* sec. 303, § 801(q)(2).

<sup>141</sup> *Id.* sec. 303, § 801(q)(3).

<sup>142</sup> *Id.* sec. 307, § 808.

<sup>143</sup> See FDA Public Hearing, *Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries*, Transcript (Mar. 30, 2011) (statement of Caroline Smith DeWaal).

## **B. FDA Comment and Rulemaking**

Following the enactment of the FSMA, the FDA began developing and implementing rules for the enforcement of Title III of the Act. The rulemaking process indicates that while there are a number of significant concerns about the effectiveness of the new importer paradigm, there is no doubt that it is a substantial change in the state of regulation. The congressional mandates will have far-reaching impacts for the imported food industry, and in turn, the safety of that portion of the food supply.

### **i. A New Paradigm for Importers**

On March 29th, 2011 the FDA held a public meeting “to discuss implementation of the import safety provisions” of the FSMA.<sup>145</sup> The FDA invited stakeholders to address issues of importer verification, VQIP, import certifications, and third-party accreditation.<sup>146</sup> In attendance were members of the Washington diplomatic corps, federal and state agencies tasked with regulating the food supply, members of industry, and consumer groups.<sup>147</sup>

During the meeting, the FDA described the FSVP requirement as Congress’s effort to place more emphasis on prevention, and to put the onus on industry—including importers and foreign suppliers—to take charge of prevention.<sup>148</sup> The FDA identified its role as laying out the standards for effective prevention, and ensuring a high level of compliance with those standards.<sup>149</sup> Members of industry reminded the FDA that while FSVP may be new to the agency, members of industry have been relying on forms of supply chain compliance assurance

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<sup>144</sup> *Id.* sec. 303, § 801(a).

<sup>145</sup> 76 Fed. Reg. Vol. 49, 13643 (March 14, 2011).

<sup>146</sup> *Id.*

<sup>147</sup> See FDA Public Meeting, *FDA Food Safety Modernization Act: A New Paradigm for Importers*, Transcript (Mar. 29, 2011).

<sup>148</sup> *Id.* at 13 (statement of David Elder, Chair of FDA Import Implementation Team).

<sup>149</sup> *Id.*

for years.<sup>150</sup> Many discussed the option of using benchmark systems similar to those already existing in industry, including those implemented by the Global Food Safety Initiative and the International Food Standards. Others suggested that the program should mirror FDA’s existing HACCP model used for juice and seafood.<sup>151</sup>

On the issue of accredited third party certification, a stakeholder panel voiced their thoughts. The consumer community raised concerns that a shift to third-party accredited certification would detract from the trustworthiness of having an FDA inspection or audit process to ensure compliance.<sup>152</sup> On the other hand, industry stakeholders identified the success of existing benchmarks that are currently being used in the marketplace to provide certification outside of the scope of government mandates or oversight.<sup>153</sup> These industry representatives brought light to the fact that there is already third-party accreditation occurring, and they looked at ways that these systems could be used to meet the FDA mandates for accreditation.<sup>154</sup> Similarly, the USDA discussed the standards that it applies for auditors, which include demonstrated knowledge and an ongoing evaluation process.<sup>155</sup>

In discussing the VQIP, trade groups focused on the importance of providing “tangible commercial benefits such as predictable and expedited import clearance,” as an incentive to enhance industry compliance and participation in the program.<sup>156</sup> Others noted that the program

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<sup>150</sup> *Id.* at 149 (statement of Kathy Means, Produce Marketing Association).

<sup>151</sup> *Id.* at 156-57 (statement of Bob Bauer, Association of Food Industries).

<sup>152</sup> *Id.* at 39 (statement of Caroline Smith DeWaal, Director of Food Safety at the Center for Science in the Public Interest), at 145 (statement of Christopher Waldrop, Consumer Federation of America).

<sup>153</sup> *Id.* at 52-56 (statement of Kristian Moeller, Globalgap); (statement of Mike Robach, Cargill and Global Food Safety Initiative).

<sup>154</sup> *Id.*

<sup>155</sup> *Id.* at 64 (statement of Ken Peterson, USDA Agricultural Marketing Service).

<sup>156</sup> *Id.* at 123 (statement of Marianne Rowden, American Association of Exporters and Importers).

was likely to be popular among produce importers, given the short life span of the product and the need to decrease border wait times.<sup>157</sup>

Many of the comments from agencies and industry focused on how to harmonize pre-existing international standards for food safety and accreditation to achieve the goals of the legislation with efficiency and lack of redundancy.<sup>158</sup> Such international standards include the World Health Organization's CODEX Alimentarius for food safety standards, and the International Organization for Standardization in regards to systems, management, and accreditation.<sup>159</sup>

## **ii. Comparability of Food Safety Systems and Import Practices of Foreign Countries**

On March 30th 2011, the FDA held a public meeting “to discuss FDA’s use of the international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed,” and to identify “lessons learned through equivalence determinations.”<sup>160</sup> The meeting brought together stakeholders from consumer groups, members of industry, and representatives from major U.S. trading partners.<sup>161</sup>

The FDA has stated that implementing the FSMA will require the agency to evaluate foreign food safety systems in order to determine whether they are “comparable” to the U.S. system.<sup>162</sup> At the meeting, FDA unveiled a tool it designed in order to assess foreign food systems, and the agency discussed how the comparability assessment worked in a pilot done in

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<sup>157</sup> *Id.* at 149 (statement of Kathy Means, Produce Marketing Association).

<sup>158</sup> *See id.*

<sup>159</sup> *See id.*

<sup>160</sup> 76 Fed. Reg. 49, 13638 (March 14, 2011).

<sup>161</sup> FDA Public Hearing, *Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries* (Mar. 30, 2011), Meeting Agenda, available at <http://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM248664.pdf>

<sup>162</sup> *See* FDA Public Hearing, *Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries*, Transcript (Mar. 30, 2011) (statement of Michael Taylor).

New Zealand.<sup>163</sup> Stakeholders responded to the viability of FDA’s proposed comparability model. FDA also sought information on the policies employed by foreign countries to ensure the safety of the food that they import and export.<sup>164</sup> FDA plans to use this information to improve the safety of foods imported into the US.<sup>165</sup>

### **iii. Anti-Port Shopping Rule**

On May 5th 2011, the FDA issued an interim final rule that requires anyone importing food into the United States to inform the FDA if any country has refused entry to the same product, including food for animals.<sup>166</sup> The FDA adopted this rule under the authority granted in section 304 of the FSMA, which amends section 801(m) of the FD&C Act to require that additional information be provided in a prior notice of imported food submitted to the FDA. The “prior notice” is required of all food imported to the U.S., and food imported without prior notice is subject to refusal at the border. The FDA stated that the “new requirement will provide the agency with more information about foods that are being imported, which improves the FDA’s ability to target foods that may pose a significant risk to public health.”<sup>167</sup>

## **III. Small-Scale Exemptions and Heightened Importer Regulation: Risk-Driven Resource Allocation or De Facto Protectionism?**

The FSMA will certainly bring enhanced federal oversight of the nation’s food supply. With the FDA focused on import regulation and capacity building in foreign countries under Title III, however, the legislation leaves small-scale producers, and local farmers to continue to

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<sup>163</sup> *Id.* (statements of Roberta Wagner, Donald Kraemer, and Julie Callahan).

<sup>164</sup> 76 Fed. Reg. 49, 13638 (March 14, 2011).

<sup>165</sup> *Id.*

<sup>166</sup> 76 Federal Register 87, 25542-25545 (May 5, 2011).

<sup>167</sup> FDA, *Letter to Stakeholders* (May 5, 2011), available at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm254310.htm>

self-regulate. The significant loopholes for small-scale food production threaten to put lives at risk. The odd balance, with the heavy hand on the regulation of overseas markets, was the outcome of a lengthy legislative process, but it was not premised on a scientific or risk-based analysis. Instead, it was based largely on last minute exceptions advocated on behalf of small-scale producers.

The contrast between regulation of locavore and small-scale domestic producers and regulation of imported foods should raise eyebrows, both domestically and abroad. Consumers ought to be concerned with the safety of food from small-scale processing facilities and local farms that is excluded from the FSMA's prevention-based mandates. At the same time, those exporters who are being asked to comply with substantive U.S. food safety law should question why this heightened regulation is not being applied to small-scale domestic producers and farmers.

#### **A. Lack of Scientific or Risk-Based Analysis of Local and Small-Scale Food Production**

In adopting the modified Tester Amendment, which created the small-scale loopholes in the FSMA, Congress did not have the luxury of holding hearings and discussing the effects of the amendment at length in Committee. Rather, the amendment was tacked on at the eleventh hour, leaving Congress with a take it or leave it proposition. This process failure indicates that experts in the field have not had the chance to properly evaluate the risks related to small-scale production and local farming.

There are certainly economic arguments to encourage local and small-scale food production. For one, local-production bolsters local economies through import substitution and

localization of processing activities.<sup>168</sup> As a USDA study noted, “[i]f consumers purchase food produced within a local area instead of imports from outside the area, sales are more likely to accrue to people and businesses within the area.”<sup>169</sup> While this sort of economic reasoning seems straightforward and persuasive, it is insufficient to justify a weaker regulation paradigm for small-scale and local producers. The goal is safety of the food supply, not economic viability alone.

Similarly, there have been numerous claims regarding the enhanced nutritional or health benefits of local food. Some assert that local foods provide more nutrients because they are fresher and less processed.<sup>170</sup> Others argue that consumers make healthier diet choices when there are local foods available in their communities.<sup>171</sup> Whether local foods actually increase health or nutrition is, however, largely an unresolved empirical question.<sup>172</sup> Moreover, increased health and nutrition are not the goal of the FSMA, which is directed at securing the safety of the nation’s food supply through prevention.

Although Congress did not study these theories thoroughly before adopting the provisions of the Tester Amendment in the FSMA, many have argued that small-scale and local food production is, in fact, safer.<sup>173</sup> With the publicized outbreaks of food-borne pathogens sourced from industrial farming, the arguments relating to the safety of local and small-scale food have become increasingly more common.<sup>174</sup> Many claim that the increased accountability

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<sup>168</sup> LOCAL FOOD SYSTEMS, *supra* note 28, at 44-45.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 46.

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> See Sustainable Table, *The Issues: Food Safety* (Sept. 2009) available at [http://www.sustainabletable.org/issues/foodsafety/index\\_pf.html](http://www.sustainabletable.org/issues/foodsafety/index_pf.html); Kristin Choo, *Hungry for Change*, A.B.A. J. 56, 61 (Sept. 2009).

<sup>174</sup> See, e.g., Newsweek, *The Tomato Pickle* (June 13, 2008), <http://www.newsweek.com/2008/06/13/the-tomato-pickle.html>.

and traceability of local food lends itself automatically to safer food. Yet, whether this “know your farmer, know your food” mantra is backed by science, is still an unresolved issue.<sup>175</sup>

The literature in support of the Tester Amendment largely relied on anecdotal evidence, for example, stating

All of the well-publicized incidents of contamination in recent years-whether in spinach, peppers, or peanuts-occurred in industrialized food supply chains that span national and even international boundaries. The food safety problems in this system can and should be addressed without harming the local food systems that provide an alternative for consumers.<sup>176</sup>

The lack of scientific evidence regarding the safety of locally sourced food and small-scale operations, and the de minimis debate in Congress on the issue, signify that the exemptions in the FSMA are based on small-farmer politics and the locavore culture of the day, not on explicit science-based risk analysis. This leaves Americans at risk, and with the FDA focused on implementing all of the provisions of the FSMA under tight deadlines, little effort is likely to be devoted to addressing the unanswered questions relating to the safety of local food until there is a significant safety problem brought to the attention of the federal government. Given the nature of local and small-scale operations, however, outbreaks are fewer in number and localized, thus they will be less likely to reach the attention of the federal government.<sup>177</sup> This does not mean, however, that the harm these incidents can cause is insignificant, nor that regulators could not prevent the harm by requiring small-scale farmers and processors to adhere to the HARPC food plan and forthcoming produce standards required of larger operations.

## **B. Trade Obligations and Importer Regulation**

The new import requirements have raised a number of trade-related concerns. As a member of the World Trade Organization (“WTO”), the U.S. has certain obligations to its

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<sup>175</sup> William Marler, Huffington Post, *What is the “Future of Food” Without Food Safety?* (May 9, 2011) [http://www.huffingtonpost.com/william-marler/what-is-the-future-of-foo\\_b\\_859605.html](http://www.huffingtonpost.com/william-marler/what-is-the-future-of-foo_b_859605.html).

<sup>176</sup> Tester Amendment Summary, *supra* note 37.

<sup>177</sup> Marler, *supra* note 175.

trading partners. As these obligations relate to food safety, the most important come from the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (“the SPS Agreement”).<sup>178</sup> The SPS Agreement applies to measures that affect international trade directly or indirectly, adopted by a government to protect human, animal, or plant life or health from certain risks, including disease, contaminants, toxins, and additives.<sup>179</sup> The SPS Agreement recognizes a country’s right to put in place certain protective measures, even if they have a negative impact on imports.<sup>180</sup> The SPS Agreement prohibits, however, such measures that have overly burdensome or unduly restrictive requirements on imports that do not apply equivalently to domestic products.<sup>181</sup>

In enacting the FSMA, Congress worked hard to make the law WTO compliant, even going so far as to include section 404, which states that the provisions of the Act “shall not be construed in a manner inconsistent with the agreement establishing the World Trade Organization....” The FDA is also aware of the trade implications. The agency gave formal notification of the new legislation to the WTO, and it held a special informational session on the law in Geneva. Thus, the government is well aware of the concerns that the FSMA’s heightened importer regulations present.

Despite these precautions, however, implementation of the bill could raise a number of trade issues if measures act as non-tariff barriers by increasing the transaction costs of importing food to the U.S. and privileging domestic producers.<sup>182</sup> For example, in exercising the authority to require certifications, FDA may violate the WTO agreement if the required certifications are

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<sup>178</sup> Agreement on the Application of Sanitary and Phytosanitary Measures art. 2, (Apr. 15, 1994), 1867 U.N.T.S. 493 art 2 [hereinafter SPS Agreement], *available at* [http://www.wto.org/english/does\\_e/legal\\_e/15-sps.pdf](http://www.wto.org/english/does_e/legal_e/15-sps.pdf).

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> *See* WTO, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures* (May 1998), *available at* [http://www.wto.org/english/tratop\\_e/sps\\_e/spsund\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm).

not properly scientifically based on a known risk, or there is a failure to take into account trade consequences of requiring such a certification that unfairly discriminates against imported products.<sup>183</sup> In addition, FDA must not give preference to any country in regards to certifications that is not justified based on objective evidence, or it may violate the prohibitions on discrimination outlined in the SPS Agreement.<sup>184</sup>

### **C. The Small-Scale Importer Loophole**

When the domestic small-scale and local exemptions are juxtaposed with heightened requirements for importers, the contrast will raise questions abroad. The small-scale domestic loophole may extend to importers as well, however, given the U.S. obligations under the SPS Agreement.

The FSMA provides that the regulations shall require that importers verify that foreign suppliers process foods in a manner “that provides the same level of public health protection as those required under section 418 or 419.”<sup>185</sup> Whether this means that the small-scale exemptions could apply to importers appears to be unresolved, however, as a representative from United Fresh during public comments, asked, “how will FDA define this exemption for the Foreign Supplier Verification and the Voluntary Qualified Importer Programs into their regulatory guidance to industry members?”<sup>186</sup> There was no clear answer from the agency.

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<sup>183</sup> SPS Agreement, *supra* note 178; See also FDA Public Meeting, *FDA Food Safety Modernization Act: A New Paradigm for Importers*, Transcript at 160 (Mar. 29, 2011) (statement of John Bode, Cheese Importers Association of America) (“Excessive use of the authority to require import certificates would not be consistent with U.S. obligations under the WTO SPS agreement, would inhibit free trade in food, and would lead to retaliation against U.S. food exports.”).

<sup>184</sup> SPS Agreement, *supra* note 178; see also FDA Public Hearing, *Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries*, Transcript (Mar. 30, 2011) (statement of Clete Willems) (discussing the potential for claims of discrimination under SPS-Agreement based on implementation of the FSMA).

<sup>185</sup> FSMA sec. 310, § 805(c).

<sup>186</sup> FDA Public Meeting, *FDA Food Safety Modernization Act: A New Paradigm for Importers*, Transcript at 87 (Mar. 29, 2011) (statement of Robert Guenther, United Fresh Produce Association).

The exemption from compliance with the new produce standards of section 105 for direct marketing farms may apply to importers, even if they do not sell directly to consumers in the U.S.<sup>187</sup> For example, under the text of the statute, a foreign farm would qualify for the exemption if it sold just over half of its food directly to consumers or retail food establishments in the country of origin, and then exported the remainder of its product to the U.S., so long as the average annual value of its food production did not exceed \$500,000.<sup>188</sup>

Similarly, food-processing facilities that sell over half of their food to qualified end-users with an average annual value less than \$500,000 qualify for an exemption from the HARPC requirements of Section 103.<sup>189</sup> Small-scale facilities that qualify as very small businesses are eligible for an exemption even if they do not sell the food that they process to a qualified end user.<sup>190</sup> Therefore, foreign facilities that qualify as very small businesses would likely be exempt from the requirements of Section 103 if the same domestic standards apply.<sup>191</sup>

Again, this is a place where implementation could raise free trade concerns. If the loophole does not extend to importers in regulations that the FDA promulgates, this may provide an unfair advantage to domestic producers in violation of U.S. trade agreements. The FDA must take this into consideration when adopting regulations. There will likely be an outcry from consumer groups, however, if the agency proposes regulations that allow exemptions for small-scale foreign suppliers, because of the incidence of more fragmented, non-industrial size operations in these overseas markets. Depending on how the terms “very-small business” and “average monetary value of food” are defined, the number of exporters that could potentially

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<sup>187</sup> See FSMA sec. 105, § 419(f).

<sup>188</sup> See *id.*

<sup>189</sup> See *id.* sec. 103, § 418(l).

<sup>190</sup> See *id.*

<sup>191</sup> See *id.*

qualify for the loophole may be incredibly large.<sup>192</sup> While many firms have vertical supply chains that include processing or farming operations in foreign countries, other firms rely on foreign suppliers for these services.<sup>193</sup> Moreover, if food processors in foreign countries can take advantage of the exemption only if they do not affiliate with larger U.S.-based firms, this may create an incentive to discontinue establishment of such vertical supply chains that have the potential to provide valuable industry oversight.<sup>194</sup> If the exemption applies to imports, foreign farms may qualify for the exemption even if affiliated with a firm whose annual production of food exceeds \$500,000, so long as the farm itself does not.<sup>195</sup>

It is important to note, however, that even without the FSMA mandating HARPC, many foreign food production operations that import to the U.S. have established HARPC-type food plans in order to be competitive in the market.<sup>196</sup> Therefore, whether the existence of a loophole will create a large difference in the safety of these operations will depend on how substantively they differ from the existing industry-based benchmarks.<sup>197</sup>

#### **D. Tough Choices Going Forward**

The foregoing demonstrates that the FDA will be faced with difficult choices in upcoming rulemaking. If the Act is interpreted to apply equivalently to domestic and foreign suppliers, the impact of the new Title III importer paradigm may be greatly reduced, unless the FDA can define the small-scale loopholes incredibly narrowly. On the other hand, if the

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<sup>192</sup> See *id.*

<sup>193</sup> NORA BROOKS ET AL., U.S. DEP'T OF AGRIC. ECON. RESEARCH SERV., FAU 125, U.S. FOOD IMPORT PATTERNS, 1998-2007 (Aug. 2009), available at <http://www.ers.usda.gov/publications/fau/2009/08aug/fau125/fau125.pdf>

<sup>194</sup> FSMA, sec. 103, § 418(l) (standards for qualifying facilities are based on the facility itself, including any subsidiary or affiliate of the facility).

<sup>195</sup> See *id.* sec. 105, § 419(f) (the exemption for direct farm marketing is based on the food produced by the farm alone, without reference to subsidiaries or affiliates).

<sup>196</sup> Oliver Masakure, Spencer Henson and John Cranfield, *Standards and export performance in developing countries: Evidence from Pakistan*, 18 JOURNAL OF INTERNATIONAL TRADE & ECONOMIC DEVELOPMENT 3, 395-419 (September 2009); Deodhar, *Motivation for and Cost of HACCP in Indian Food Processing Industry* Indian Institute of Management (IIMA Ahmadabad: India), Working Paper (May 3, 2003).

<sup>197</sup> See Discussion *supra* regarding the comments from industry during the public meeting regarding the pre-existing standards.

exemptions do not apply to foreign suppliers, the U.S. may run into trade difficulties in requiring foreign supplier verification, and, especially, certification for small-scale foreign entities that would be exempt domestically. Even if the U.S. does not face retaliation through the WTO, it would likely face trade retaliation in the markets, which would affect U.S. exports. Moreover, the U.S. will face greater difficulty in its newly stated aim of capacity building in foreign countries if it is not seen as being a fair player in the international market.

## **Conclusion**

The FSMA brings the hope of a safer U.S. food supply, and this significant piece of legislation will set the stage for federal oversight in the decades to come. It is important in these coming years, however, that consumers, regulators, and members of industry do not lose sight of the importance of ensuring the safety of food produced within U.S. borders. As we focus on harnessing the effects of a globalized food market and ensuring the safety of imported foods, we must also keep an eye on our own back yard.