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## The Food Safety Modernization Act of 2011: Too Little, Too Broad, Too Bad

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# The Food Safety Modernization Act of 2011:

## Too Little, Too Broad, Too Bad

Nicholas Obolensky\*

### I. INTRODUCTION

The common expression “you are what you eat” is a fitting adage that presents a significant concern when one considers the evolution of food production from family farms to factory farms, and the large agri-businesses that currently supply the majority of American food. Human beings rely on food for sustenance and nutrition, and our health and well-being is dependent on the vitality of the food we consume. Increasing reliance on industrial methods of producing and distributing food threatens our health, nutrition, environment, and culture. Traditionally, local farms produced the food Americans consumed and, for the most part, people ate local, seasonal food. People did not question whether food was “organic” or not because the concept did not exist.<sup>1</sup> All

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1. The word “organic,” referring to an agricultural practice, was first used by Lord Northbourne when he coined the term “organic farming” in his 1940 book *Look to the Land* to contrast organic with chemical farming. John Paull, *The Farm as Organism: The Foundational Idea of Organic Agriculture*, 83 ELEMENTALS: J. BIO-DYNAMICS TAS. 14, 14 (2006), available at <http://orgprints.org/10138>.

food was organic. Over the course of the 20<sup>th</sup> century, as the nation transitioned from the predominately agricultural society of the 19<sup>th</sup> century to an industrial nation with an urbanized population, there was a dramatic shift in the method of food production.<sup>2</sup>

In response to the growing demand of the newly urbanized population, food production shifted away from local production and processing, and toward more industrial processing and national marketing.<sup>3</sup> Food manufacturers met this growing demand by adopting similar techniques to those utilized by the industrial sector.<sup>4</sup> Various technologies and chemicals were developed to sustain this new, streamlined, mega-farm, assembly-line method of food production.<sup>5</sup> The evils inherent in this new food production system first became publicly apparent with respect to the “appalling and grossly unsanitary working conditions in meat packing factories” when Upton Sinclair published his book *The Jungle*.<sup>6</sup> Following this shocking revelation, the legislature responded by enacting the Pure Food and Drug Act (PFDA) and the Meat Inspection Act (MIA) in 1906, thus establishing the initial U.S. food safety statutory framework.<sup>7</sup>

A few decades later, upon recognizing a need to further develop the food safety regulatory framework and provide for direct government oversight, Congress passed the Federal Food, Drug and Cosmetic Act (FD&C) in 1938.<sup>8</sup> The FD&C expanded the Food and Drug Administration’s (FDA) power to regulate food safety by authorizing inspections, adding authority for injunctions, setting tolerance levels for dangerous substances, and requiring labeling standards.<sup>9</sup> Since its inception, the FD&C has

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2. See Chenglin Liu, *The Obstacles of Outsourcing Imported Food Safety to China*, 43 CORNELL INT’L L.J. 249, 253 (2010).

3. Sandra Hoffmann & William Harder, *Food Safety and Risk Governance in Globalized Markets*, 20 HEALTH MATRIX 5, 5 (2010).

4. See Liu, *supra* note 2, at 253.

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.* at 254-55.

9. Shannon G. May, *Importing a Change in Diet: The Proposed Food Safety Law of 2010 and the Possible Impact on Importers and International Trade*, 65 FOOD & DRUG L.J. 1, 4 (2010).

been amended over thirty times, each addition either providing more detailed food production and marketing requirements or granting more authority to federal agencies for implementing safety standards.<sup>10</sup>

Recently, several *Jungle*-like revelations have once again shocked the nation. For example, a 2006 *E. coli* H7 outbreak first recognized by a scientist in Wisconsin and characterized as “one of the largest and deadliest in the country,” caused 3 deaths, 204 illnesses, and 104 hospitalizations in 26 states.<sup>11</sup> A salmonella outbreak in 2008, initially associated with certain types of tomatoes, cost the tomato industry an estimated \$200 million, although jalapeno peppers were later discovered to have been the contaminated source.<sup>12</sup> Shortly after, a much more severe salmonella outbreak, causing 9 deaths and 660 illnesses, was traced back to two processing plants owned by the Peanut Corporation of America (PCA) in Georgia and Texas.<sup>13</sup> The most shocking aspect of the peanut-related salmonella outbreak was not that it cost the industry over one billion dollars, but that the PCA plant in Georgia had been inspected nine times between 2006 and 2008 by state officials under agreement with the FDA, and no action was taken to remedy the abysmal conditions and safety violations they noted.<sup>14</sup> In response to this peanut scandal, as well as growing public concern about imported food safety due to melamine tainted pet foods from China,<sup>15</sup> Congress decided to put food safety at the top of its legislative agenda.<sup>16</sup>

The result, the FDA Food Safety Modernization Act (FSMA), passed by Congress on December 21, 2010, and signed into law by President Obama on January 4, 2011, is the focus of this article.<sup>17</sup>

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10. *Id.*

11. Sara M. Benson, *Guidance for Improving the Federal Response to Foodborne Illness Outbreaks Associated with Fresh Produce*, 65 *FOOD & DRUG L.J.* 503, 508-09 (2010).

12. *Id.* at 510.

13. Rena Steinzor, *High Crimes, Not Misdemeanors: Detering the Production of Unsafe Food*, 20 *HEALTH MATRIX* 175, 176 (2010).

14. *See id.* at 177-78.

15. *See Liu, supra* note 2, at 251.

16. Steinzor, *supra* note 13, at 179.

17. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.). For the purposes of this article and for clarity's sake, all citation and textual references will be made to the sections of the FSMA session laws. This

While there is clearly a societal need for enhanced food safety, the FSMA is an inadequate response because it does too little to minimize safety risks posed by large-scale food production facilities and it does too much by imposing excessive regulatory burdens on small and mid-sized farms and facilities.<sup>18</sup> The comprehensive scheme of the FSMA essentially imposes one-size-fits-all, across-the-board regulations with little regard to the scale of the individual operations, even though “[a]ll of the well-publicized incidents of contamination in recent years . . . occurred in industrialized food supply chains that span national and even international boundaries.”<sup>19</sup> Small and mid-sized farms and food production facilities do not pose the same risks because of the inherent transparency and accountability accompanying a closer proximal relationship to consumers’ food supply.

Conscious of this apparent discrepancy in scale, legislators sought to mitigate potential harms by providing an exemption for small food facilities in the Tester-Hagan Amendment. This highly controversial amendment, ultimately adopted in the final form of the FSMA,<sup>20</sup> does indeed contemplate the discrepancy, but is, unfortunately, too limited in scope, and is undermined by too much agency discretion. The FSMA falls short of achieving its goal for improved food safety because its application to large food production facilities, the primary sources of food-borne illnesses, barely improves the status quo and the requirements imposed on smaller farms and facilities that do not qualify for an exemption under the Tester-Hagan Amendment are a significant impediment

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citation method is used to allow the reader to hone in directly on the FSMA’s language and more efficiently consider this note’s arguments, without needing to differentiate the new FSMA language from the pre-existing FD&C language within the U.S. Code sections.

18. The FSMA is applicable to all food production facilities, farms, and food operations. The main distinctions that will be made in this article are on the basis of scale and not by the type of operation. Where a distinction is necessary, the article will include it, but it is important to note at the outset that, in general, FSMA section 103 relates to facilities and FSMA section 105 relates to farms. *Id.* at §§ 103, 105. The term facility is defined *infra*, note 55.

19. Margie MacDonald & Judith McGeary, *S. 510 Food Safety Modernization Act: Healthy Local Foods Amendment – Sen. Jon Tester*, SMALL HOLDERS ALLIANCE, [http://smallholdersalliance.com/QA-Tester-Amendment-April-15%20\(2\).pdf](http://smallholdersalliance.com/QA-Tester-Amendment-April-15%20(2).pdf) (last visited Oct. 5, 2011).

20. See FDA Food Safety Modernization Act, sec. 103(a), 105(a), §§ 418(l), 419(f).

to the viability of their operations.

In discussing how and why the FSMA misses its target, this article proceeds as follows. Part II will first examine the key provisions of the FD&C that have been amended by the FMSA, and will then focus on the provisions included by the adoption of the Tester-Hagan Amendment. Part III will provide an in depth analysis of (1) the shortcomings of the FSMA with respect to large food production facilities, (2) the disproportionate effect it will have on smaller farms and food production facilities, and (3) the large role agency discretion plays in its implementation and effect on food safety. Part IV will conclude by explaining and suggesting the need for a shift in the role that government plays with respect to food safety, health, and nutrition.

## II. THE FDA FOOD SAFETY MODERNIZATION ACT

Foodborne illness is a significant problem in the United States as demonstrated by the 2011 Center for Disease Control (CDC) findings that estimate “that each year roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.”<sup>21</sup> In an effort to remedy this “largely preventable” public health problem, Congress passed the FSMA to provide the FDA with wider latitude in combating the issue.<sup>22</sup> The major elements of the FSMA can be divided into the following five categories: Preventive Controls, Inspection and Compliance, Imported Food Safety, Response, and Enhanced Partnerships.<sup>23</sup>

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21. *CDC 2011 Estimates: Findings*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (last updated Apr. 19, 2011); see also Steinzor, *supra* note 13, at 178 (noting higher statistics from a 1999 CDC estimate); *Background on the FDA Food Safety Modernization Act (FSMA)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm239907.htm> (last updated Mar. 20, 2011) [hereinafter *Background on the FSMA*]. According to the CDC website, the higher statistics for foodborne diseases shown in the 1999 estimate largely “reflect innovations in data and methodology that have occurred in the past decade.” *Data and Methodological Differences, 2011 and 1999*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/foodborneburden/differences-in-estimates.html> (last updated Apr. 19, 2011).

22. *Background on the FSMA*, *supra* note 21.

23. *Id.*

## A. Key Provisions Established by the FSMA

1. *Preventative Controls*

One of the key elements of the FSMA is the requirement that food production facilities develop preventative controls similar to the Hazard Analysis and Critical Control Point (HACCP)<sup>24</sup> plans already required of seafood producers, juice producers, and the meat and poultry industry. Section 103 of the FSMA, “Hazard Analysis and Risk-Based Preventive Controls” adds a new section 418 to the FD&C, which generally requires facilities to evaluate potential hazards, identify and implement preventative controls to prevent the potential hazards, monitor the performance of the controls, and maintain records of the monitoring.<sup>25</sup> The potential hazards requiring analysis, implementation of controls, and maintenance of records include: biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, unapproved food and color additives, and any naturally occurring or unintentionally introduced hazards.<sup>26</sup>

This new requirement for developing hazard analysis and risk-based control plans (HARCP) basically requires facilities to identify points in their processing system that could become potentially dangerous and then develop controls to prevent that from occurring.<sup>27</sup> It also requires facilities to maintain a written plan and documentation of their HARCP, monitor its effectiveness, take any necessary corrective actions, and verify that the HARCP is adequate to prevent the hazards identified.<sup>28</sup> The plan must be made available to the FDA<sup>29</sup> during inspections

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24. “HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.” *Hazard Analysis & Critical Control Points (HAACP)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/default.htm> (last updated Apr. 27, 2011).

25. FDA Food Safety Modernization Act, sec. 103(a), § 418(a).

26. *Id.* sec. 103(a), § 418(b)(1)(A)-(B).

27. *Id.* sec. 103(a), § 418(a)-(b).

28. *Id.* sec. 103(a), § 418(h)-(i).

29. Throughout this article when the acronym “FDA” is used it is intended as shorthand for “The Commissioner of Food and Drugs,” “The Secretary of Health and Human Services,” as well as for its traditional use as

and must be reevaluated every three years or “whenever a significant change is made in the activities conducted at [the] facility.”<sup>30</sup> Section 418(l) is where the Tester-Hagan Amendment was added to “modif[y] requirements for qualified facilities,” or to exempt certain facilities from the HARCP requirements if they meet certain criteria, which will be discussed more fully below.<sup>31</sup> Within eighteen months of the enactment of the FSMA, the FDA is required to promulgate science-based minimum standards for the section, define the terms “small business” and “very small business,” and “provide sufficient flexibility to be practicable for all sizes and types of facilities.”<sup>32</sup>

Produce safety is addressed in Section 105, which adds section 419 to the FD&C, and requires the Secretary of Health and Human Services to establish “science-based minimum standards” for fruit and vegetables in conjunction with the Secretaries of Agriculture and Homeland Security, and with consideration given to existing standards established under the Organic Foods Production Act of 1990.<sup>33</sup> Special priority is established for raw fruits and vegetables that have known risks.<sup>34</sup> The standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address materials added to the soil (e.g., compost), hygiene, packaging, temperature controls, animals in the growing area, and water.<sup>35</sup>

## 2. *Inspection and Compliance*

To ensure compliance with the preventative control standards established to improve food safety and to enable the FDA to respond effectively to food safety problems that may arise, the FSMA provides for increased mandatory inspection frequency, access to records, and testing by accredited laboratories.<sup>36</sup> Section 201 of the FSMA, adding new section 421 to the FD&C,

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an acronym for the Food and Drug Administration.

30. FDA Food Safety Modernization Act, sec. 103(a), §418(i).

31. *See infra* at Part II.B

32. *Id.* sec. 103(a), § 418(n)(1)-(3).

33. *Id.* sec. 105(a), § 419(a)(1)(A).

34. *Id.* sec. 105(a), § 419(a)(3).

35. *Background on the FSMA, supra* note 21.

36. *Id.*



establishes more frequent mandatory inspections of food facilities based on the Secretary's assessment and classification of the level of risk posed by individual facilities.<sup>37</sup> The risk profile of a facility is determined by the known safety risks of the food produced at the facility, the compliance history of the facility, the facility's hazard analysis and risk-based preventative controls, whether the food produced at the facility meets the criteria for priority under section 801(h)(1), whether the facility has been third-party certified under new sections 801(q) and 806, and in light of any other criteria "deemed necessary and appropriate by the Secretary."<sup>38</sup> Domestic high-risk facilities must be inspected at least once during the first five-year period following the enactment of the FSMA, and again at least once every three years thereafter.<sup>39</sup> Domestic non-high-risk facilities must be inspected at least once during the first seven-year period following the enactment of the FSMA, and then at least once every five years thereafter.<sup>40</sup> Additionally, at least 600 foreign facilities must be inspected within the first year following the enactment of the FSMA and the number of foreign facilities inspected must be doubled every subsequent year for the five years thereafter.<sup>41</sup> To carry out these tasks, as well as other duties required by the FSMA, section 401 authorizes the appropriation of FDA funds for field activities and to increase the number of FDA field staff.<sup>42</sup>

Section 101 of the FSMA amends section 414(a) of the FD&C (21 U.S.C. 350c(a)) by authorizing the Secretary to have access to all records relating to an article of food "the Secretary reasonably believes" will cause "serious adverse health consequences or death to humans or animals," or that might be "likely to be affected in a similar manner."<sup>43</sup>

Section 202 of the FSMA, adding new section 422 to the FD&C, directs the FDA to establish a program for the testing of food by accredited laboratories and establishes a system for laboratory accreditation.<sup>44</sup>

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37. FDA Food Safety Modernization Act, sec. 201(a), § 421(a).

38. *Id.* sec. 201(a), § 421(a)(1)(A)-(F).

39. *Id.* sec. 201(a), § 421(a)(2)(B).

40. *Id.* sec. 201(a), § 421(a)(2)(C).

41. *Id.* sec. 201(a), § 421(a)(2)(D).

42. *Id.* sec. 401(a)-(b).

43. *Id.* sec. 101(a), § 414(a).

44. *Id.* sec. 202(a), § 422(a)(1).

Section 402, adding new section 1012 to the FD&C, establishes whistleblower protections for employees of entities involved in the manufacturing, processing, packing, transportation, distribution, reception, holding, or importation of food, who provide information relating to a violation of food safety laws.<sup>45</sup>

### 3. *Imported Food Safety*

A significant portion of the U.S. food supply is imported<sup>46</sup> and in order to ensure that imported foods are safe and meet U.S. safety standards, the FSMA provides the FDA with “unprecedented authority” to regulate imported food, and imposes preventative duties on the industry.<sup>47</sup> Title III of the FSMA includes sections amending the FD&C to improve importer accountability, provide programs for third-party certification, create requirements for certification of high-risk foods, establish voluntary qualified importer programs, and grant authority to deny admission of foreign food products.<sup>48</sup>

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45. *Id.* sec. 402, § 1012(a)(1)-(4).

46. “An estimated 15 percent of the U.S. food supply is imported, including 60 percent of fresh fruits and vegetables and 80 percent of seafood.” *Food Safety Legislation Key Facts*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm237934.htm> (last updated Mar. 20, 2011)

47. *Background on the FSMA*, *supra* note 21.

48. *Id.* Beyond the amendments to the FD&C concerning imported food safety are beyond the scope of this article, a brief summary of their changes will be included here: Section 301 of the FSMA, adding new section 805 to the FD&C, requires importers to “perform risk-based foreign supplier verification activities” to ensure that the food imported has been produced in compliance with HARCP requirements of the FSMA. FDA Food Safety Modernization Act, sec. 301(a), § 805(a)(1). Some of the verification activities that the FDA may require include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, review of the foreign supplier’s HARCP, and periodic testing and sampling of shipments. *Id.* sec. 301(a), § 805(c)(4).

The FDA is permitted to require, under section 303 of the FSMA, that an entity provide certification or assurances that imported food is compliant with FSMA requirements as a condition for admission into the United States. *Id.* sec. 303(b), § 801(q)(1). These assurances or certifications may come from an agency or representative of a foreign country or by persons or entities accredited by the FDA. *Id.* sec. 303(b), § 801(q)(3). In determining whether to require import certification the FDA shall assess such factors as the known risks of the food, the known food safety risks associated with the exporting country, and any finding questioning the food safety programs or standards

#### 4. Response

Another key provision of the FSMA is the improved capacity it provides the FDA for responding to food safety problems. Mandatory recall authority is the most significant and novel authority provided to the FDA by the FSMA but additional authorities granted by the FSMA include: expanded administrative detention, suspension of registration, enhanced product tracing abilities, and additional recordkeeping for high-risk foods.<sup>49</sup> Section 206, adding new section 423 to the FD&C,

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of the exporting country by the FDA that is supported by scientific, risk-based evidence. *Id.* sec. 303(b), § 801(q)(2)(A)-(D).

Section 307 of the FSMA requires the FDA to establish a system for recognizing accreditation bodies that accredit third-party auditors to certify that foreign suppliers are in compliance with the FSMA within two years of its enactment. *Id.* sec. 307, § 808(b)(1)(A)(i). Accreditation bodies are required to ensure that the third-party auditors being accredited agree to submit written and electronic certification that will accompany each food shipment for import into the U.S. coming from a certified facility. *Id.* sec. 307, § 808(c)(2)(A). The FDA is required to develop model standards for third-party auditors and prohibits third-party auditors that have conflicts of interest. *Id.* sec. 307, § 808(b)(2). Audits must be unannounced and auditors are required to immediately notify the FDA upon discovering a condition that could cause or contribute to a serious risk to public health. *Id.* sec. 307, § 808(c)(4)(A). If imported food, certified by an accredited auditor, is linked to an illness outbreak, the FDA must withdraw its accreditation. *Id.* sec. 307, § 808(c)(6)(A)(i).

The FDA is granted the authority to enter into arrangements and agreements with foreign governments to facilitate inspections of foreign facilities, and is required to allocate funds for the inspections of foreign facilities, especially those deemed to present a high risk. *Id.* sec. 306(a), § 807(a). The FDA may also deny admission into the United States of imported foods coming from facilities that refused to allow U.S. inspectors or their accredited proxy to inspect and conduct the necessary audits. *Id.* sec. 306, § 807(b).

Importers and foreign food facilities may request to participate in the voluntary qualified importer program that the FDA is required to establish under section 302. *Id.* sec. 302, § 806(a)(1)(A)-(B). The program essentially expedites the review of imports from participating facilities, allowing for their certification if the facilities meet the eligibility requirements. *Id.* Eligibility is limited to certified facilities and in determining eligibility the FDA is required to consider factors such as the known safety risks of the food imported, the compliance history of the importer and foreign facilities, the regulatory system used by the exporting country, and any other indicia or risk determined appropriate by the FDA. *Id.* sec. 302, § 806(d).

49. *Background on the FSMA*, *supra* note 21. High-risk foods are to be designated by the FDA within one year of the enactment of the FSMA taking into account the known safety risks of a particular food and the likelihood of

authorizes the FDA to issue a cease distribution order to any producer and/or distributor of food that the FDA determines there is a reasonable probability of its adulteration or misbranding (under FD&C sections 402 and 403(w) respectively), which will cause “serious adverse health consequences or death to humans or animals,” after first providing the producer the opportunity to voluntarily cease distribution and recall the food product in question.<sup>50</sup> Civil fines are imposed on any person not complying with a recall order.<sup>51</sup>

Section 207 of the FSMA enhances the FDA’s power to order administrative detentions of food products that may be in violation of food safety requirements.<sup>52</sup> By changing the language of FD&C section 304(h)(1)(A) from “credible evidence or information indicating” to “reason to believe,” this section of the FSMA is essentially lowering the standards for an administrative detention and expanding the circumstances in which a detention may be ordered.<sup>53</sup> Additionally, the standard for which food product is in violation of the food safety requirements is further diminished by changing the language from “presents a threat of serious adverse health consequences or death to humans or animals” to “is adulterated or misbranded.”<sup>54</sup>

Registration of food production facilities with the FDA is required under section 350d(a) of the FD&C,<sup>55</sup> and section 102 of

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microbiological or chemical contamination due to the nature of or processing used for a particular food. FDA Food Safety Modernization Act, sec. 204(d)(2)(A).

50. FDA Food Safety Modernization Act, sec. 206(a), § 423(a).

51. *Id.* sec. 206(c), § 303(f)(2)(A).

52. *See id.* sec. 207(a), § 304(h)(1)(A).

53. *See id.*; *see also E-Alert: Congress Passes the FDA Food Safety Modernization Act*, COVINGTON & BURLING LLP (Dec. 22, 2010), <http://www.cov.com/files/Publication/f673e40b-be7d-4c85-96c5-6334461a2010/Presentation/PublicationAttachment/64d12969-1c13-46a0-ab76-64898d58aec6/Congress%20Passes%20the%20FDA%20Food%20Safety%20Modernization%20Act.pdf>.

54. *See* FDA Food Safety Modernization Act, sec. 207(a)(2), § 304(h)(1)(A).

55. 21 U.S.C. § 350d(a) (Supp. 2011). A facility is: “any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food.” 21 U.S.C. § 350d(c)(1) (Supp. 2011). While farms are not considered facilities, the FDA is required by the FSMA to determine which activities “constitute on-farm packing or holding of food that is not grown, raised, or

the FSMA, amending section 415 of the FD&C, allows the FDA to suspend a facility's registration if it determines that the registrant was responsible for, or knew or should have known that there was a reasonable probability that its food product posed a risk of "causing serious adverse health consequences or death to humans or animals."<sup>56</sup> Section 102 includes the right for a registrant to obtain an informal hearing on an FDA determination to suspend its registration and requires the FDA to vacate the suspension if the FDA determines there are inadequate grounds to continue the suspension.<sup>57</sup> Otherwise, a facility under a suspension order is prohibited from introducing food into interstate or intrastate commerce in the United States.<sup>58</sup> This section also includes a requirement that the FDA promulgate a small entity compliance guide within 180 days of the enactment of the FSMA to assist small entities in complying with registration requirements compelled by section 102, and clarifies the definition of "retail food establishments."<sup>59</sup>

The FDA is directed by section 204 of the FSMA to establish a system to enhance its ability to track and trace both domestic and imported foods.<sup>60</sup> The FDA must create pilot projects "to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats" of serious harm resulting from adulterated food.<sup>61</sup> Lastly, the FDA is directed to publish a notice of proposed rulemaking establishing recordkeeping requirements for facilities it designates as producing high-risk foods.<sup>62</sup>

### 5. *Enhanced Partnerships*

Throughout the FSMA there are numerous sections that

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consumed on such farm or another farm under the same ownership" and which activities "constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership." FDA Food Safety Modernization Act, sec. 103(c)(1)(A). Essentially, the FDA will ultimately clarify to what degree processing transforms a farm into a facility.

56. FDA Food Safety Modernization Act, sec. 102(b), § 415(b)(1).

57. *Id.* sec. 102(b), § 415(b)(3).

58. *Id.* sec. 102(b), § 415(b)(4).

59. *Id.* sec. 102(b)(2), § 415(b); *id.* sec. 102(c)(1).

60. *Id.* sec. 204; *Background on the FSMA*, *supra* note 21.

61. FDA Food Safety Modernization Act, sec. 204(a)(1).

62. *Id.* sec. 204(d)(1).

require the FDA to consult with other agencies, such as the Department of Health and Human Services and the Department of Homeland Security, as well as foreign government agencies, recognizing the need for interagency cooperation in order to achieve public health goals through an integrated system.<sup>63</sup> For example, it is up to the Secretary of Health and Human Services to issue guidelines with respect to “activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed” on that farm<sup>64</sup> and rule-making for produce standards must be done in coordination with the Secretary of Agriculture, representatives of state departments of agriculture, and the Secretary of Homeland Security.<sup>65</sup> With respect to imported food, the FSMA directs the FDA to “develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. food safety requirements.”<sup>66</sup> The small farm exemption, provided by the Tester-Hagan Amendment (addressed below), includes a reliance on state and local agencies to address the safety measures used by these exempt facilities.<sup>67</sup>

#### B. Tester-Hagan Amendment

As this article focuses on the requirements imposed by the FSMA on small and mid-sized farms and facilities, it is necessary to provide a more in-depth analysis of the provisions and exemptions added by the Tester-Hagan Amendment in sections 103 and 105. Recognizing that all of the well-publicized incidents of contamination in recent years occurred in industrialized food supply chains, Senators Jon Tester and Kay Hagan sponsored this amendment to remove small, local food growers and processors from federal oversight, leaving them to the existing regulatory framework of states and localities.<sup>68</sup> While Part III of this article will discuss the pros and cons of the FSMA generally and will examine them specifically in relation to the Tester-Hagan

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63. *See Background on the FSMA, supra* note 21.

64. FDA Food Safety Modernization Act, sec. 103(c)(1)(A).

65. *Id.* sec. 105(a), § 419(a)(1)(A).

66. *Background on the FSMA, supra* note 21.

67. FDA Food Safety Modernization Act, sec. 103(a), § 418(l)(2).

68. MacDonald & McGeary, *supra* note 19.

Amendment, this section is limited to describing its facial provisions.

It is first important to note that the Tester-Hagan Amendment pertains only to Title I of the FSMA and particularly to the HARCP requirements of the FSMA, and does not extend to other provisions of the FSMA. In section 102 of the FSMA (registration of food facilities), the Tester-Hagan Amendment clarifies the definition of “retail food establishment” in response to the 2002 Bioterrorism Act,<sup>69</sup> which required all food facilities to register with the FDA but exempted “retail food establishments.”<sup>70</sup> The amendment required the “FDA to clarify that ‘direct sales’ of food to consumers includes sales that occur other than where the food was manufactured, such as at a roadside stand or farmers’ market.”<sup>71</sup> Therefore, in section 102(c) of the FSMA, the Secretary is directed to amend the previously narrow definition of “retail food establishment” to specifically

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69. *The Bioterrorism Act of 2002*, WASH. ST. DEP’T OF AGRIC., <http://agr.wa.gov/FoodSecurity/TheBioterrorismAct.aspx> (last updated Aug. 2, 2004) (“The Public Health Security and Bioterrorism Preparedness and Response Act, commonly known as The Bioterrorism Act of 2002, is designed to protect the U.S. from bioterrorism. The law authorizes the U.S. Department of Health and Human Services (HHS) to take action to protect the nation’s food supply against the threat of intentional contamination. The Food and Drug Administration (FDA), as the food regulatory arm of HHS, is responsible for developing and implementing these food safety measures, including four major regulations.”); *see also* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, H.R. 3448, 107th Cong. (2002).

70. FDA defined the term “retail food establishments” at 21 C.F.R. § 1.227(b)(11) (2010):

*Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations.

71. *Summary of Tester Amendment*, U.S. SEN. JON TESTER, [http://tester.senate.gov/Legislation/upload/tester\\_amendment\\_agreement\\_summary.pdf](http://tester.senate.gov/Legislation/upload/tester_amendment_agreement_summary.pdf) (last visited Dec. 5, 2011) (emphasis omitted).

include the sale of food products or food directly to the consumer at a roadside stand or farmer's market, even if the stand or market is not located where the food is manufactured or processed, as well as to include the sale and distribution of food through a community supported agriculture program (CSA) and any other direct food sales platform as determined by the Secretary.<sup>72</sup>

The main thrust of the Tester-Hagan Amendment is contained in section 103 of the FSMA, the HARCP section, adding new FD&C section "418(l) Modified Requirements for Qualified Facilities."<sup>73</sup> Here, food facilities may qualify for an exemption from the HARCP requirements if they meet the following conditions: (1) the facility is a "very small business" (as defined by a study that the FDA is required to conduct within 18 months of the enactment of the FSMA; or (2) the average annual monetary value of all food sold by the facility during the previous three-year period was less than \$500,000 (adjusted for inflation), *and* during that three-year period the majority of the food sold by the facility was to "qualified end-users."<sup>74</sup> Section 103(a) (FD&C section 418(l)(4)(B)) defines a qualified end user as a direct consumer (which is not a business), restaurant, or retail food establishment (e.g., a grocery store) that was either in the same state of the facility or within 275 miles of the facility.<sup>75</sup>

Qualified facilities that are exempted from the HARCP requirements must still submit documentation to the FDA proving their status as qualified exempted facilities and demonstrating either that (1) they have identified potential hazards associated with their food production, are implementing preventative controls to address the hazards, and are monitoring the controls to ensure their efficacy, or (2) their facility is in compliance with state, local, county, or other applicable non-Federal food safety law.<sup>76</sup> If the facility chooses the second option (compliance with non-Federal food safety law), it must prominently and conspicuously provide the name and address of the facility that produced the food on a packaging label, or display the same

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72. FDA Food Safety Modernization Act, sec. 102(c)(1).

73. *Id.* sec. 103(a), § 418(l).

74. *Id.* sec. 103(a), § 418(l)(1)(B)-(C), § 418(n).

75. *Id.* sec. 103(a), § 418(l)(4)(B)-(C).

76. *Id.* sec. 103(a), § 418(l)(2).



information at the point of purchase.<sup>77</sup>

Small-scale, direct-marketing farms may also qualify for an exemption from the separate produce safety standards in section 105 of the FSMA, in which the FDA regulates growing and harvesting practices, provided that they meet the same requirements for exempted facilities under section 103(a).<sup>78</sup>

Additionally, the Tester-Hagan Amendment requires the FDA to conduct a study (mentioned above) of the food-processing sector to determine the definitions of the terms “small business” and “very small business.”<sup>79</sup> The study will focus on the distribution of food by type and size of operation, including the monetary value of food sold; the proportion of food produced by each type and size of operation; the number and types of food facilities co-located on farms; the incidence of foodborne illnesses originating from each size and type of operation (as well as which types have no reported or known hazards); and the effect on foodborne illness risk with respect to the scale of operation.<sup>80</sup> The definition of the terms required by section 103(a) of the FSMA requires the FDA to consider such factors as harvestable acres, income, number of employees, and the volume of food harvested.<sup>81</sup>

The exemption provided for qualified facilities in section 103(a) of the FSMA (amending section 418(l) of the FD&C) may be withdrawn at the FDA’s discretion if the Secretary determines that it is necessary to protect the public health.<sup>82</sup> Section 103(a), which amends FD&C section 418(l)(3), provides such discretion in the event of an active investigation of a foodborne illness outbreak that is directly linked to an exempted facility, or if the FDA finds it “necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food” at that facility.<sup>83</sup>

The FDA is required to provide, within 180 days of promulgating new regulations under FD&C section 418(n), a

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77. *Id.* sec. 103(a), § 418(l)(7).

78. *Id.* sec. 105(a), § 419(f).

79. *Id.* sec. 103(a), § 418(l)(5).

80. *Id.*

81. *Id.* sec. 103(a), § 418(l)(5)(B).

82. *Id.* sec. 103(a), § 418(l)(3).

83. *Id.*

small entity compliance policy guide to assist small entities that meet the definition of “small business” and “very small business” (to be determined by the study), explaining the FSMA’s hazard analysis compliance requirements in “plain language.”<sup>84</sup> Furthermore, the regulations must “provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses,” in establishing science-based minimum standards for HARCP under section 103<sup>85</sup> and for establishing science-based minimum standards for produce safety under section 105.<sup>86</sup>

### III. TOO LITTLE, TOO BROAD, TOO BAD

While the amendments and key provisions detailed in Part II provide the FDA with more authority and establish preventative measures to minimize the potential of foodborne illness outbreaks, the legislation is insufficient for tackling the problems posed by large-scale, industrialized food production, and unnecessarily burdens small and mid-sized facilities and farms that do not pose the same threats as larger operations. Additionally, many of the improvements established by the FSMA are dependent on agency discretion for their implementation and enforcement, and therefore the potential impact the law will have for food safety and its burden on small farms and facilities is dependent on the character and policies of the FDA.<sup>87</sup>

Before analyzing the drawbacks of the FSMA it is important to briefly discuss the assertion that large-scale, industrialized food production operations pose a greater threat to food safety than do smaller, local food production operations. Large-scale industrial

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84. *Id.* sec. 103(d).

85. *Id.* sec. 103(a), § 418(n).

86. *Id.* sec. 105(a), § 419(a)(1), (3).

87. Although the effect of the new legislation on imported food safety is debatably minimal, an in-depth examination of the pros and cons of this aspect of the FSMA is beyond the scope of this article. For further insight on the potential impact of the FSMA on imported food, see generally Liu, *supra* note 2 (discussing the potential drawbacks in protecting U.S. consumers by outsourcing regulatory power to China); Adam I. Muchmore, *Private Regulation and Foreign Conduct*, 47 SAN DIEGO L. REV. 371, 419 (2010) (discussing regulatory strategies with respect to imported food and concluding that the majority of proposals for imported-food-safety reform “try to do too much – and in the process risk doing too little”); but see Hoffmann & Harder, *supra* note 3, at 7 (discussing the advantages of global coordination of food safety management).

food production, often referred to as agribusiness, “relies upon heavy pesticide use, radiation, and other harsher interventions to kill germs in food grown in assembly line fashion.”<sup>88</sup> Large-scale food production involves “highly mechanized, monocultural, chemical-intensive methods” that transport raw materials to centralized processing facilities where they are mixed with production from other farms, and then packaged and shipped throughout the country.<sup>89</sup> The rate of foodborne illness incidents has increased in tandem with the growth of this industrial food system, and most cases of contaminated food “are the result of unsanitary conditions in the large-scale facilities that mass produce and process foods.”<sup>90</sup>

Conversely, small and mid-sized farming practices, and notably organic farming practices, focus on the health of the soil, plant, and food,<sup>91</sup> and are typically more accountable to consumers because of their proximity to the end-user. Local, sustainable food producers “use a systems approach that achieves greater safety and quality than any industrial producer using [Hazard Analysis and Critical Control Points] or [good agricultural practices], and are held accountable by the direct-to-consumer relationship, which creates greater transparency than any government regulation.”<sup>92</sup> Animals raised on small-scale, diverse farms, particularly organic, free-range farms, do not contribute the harmful pathogens that end up in other agricultural products because their varied diet, exercise, and exposure to good bacteria help them build resistance to the harmful pathogens.<sup>93</sup>

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88. Alison Rose Levy, *Food Safety: Why is the Food Safety Bill So Controversial?*, HUFFPOST HEALTH (Dec. 13, 2010, 4:30 PM), [http://www.huffingtonpost.com/alison-rose-levy/food-safety-why-food-safety-bi\\_b\\_795515.html](http://www.huffingtonpost.com/alison-rose-levy/food-safety-why-food-safety-bi_b_795515.html).

89. HELENA NORBERG-HODGE, TODD MERRIFIELD & STEVEN GORELICK, *BRINGING THE FOOD ECONOMY HOME: LOCAL ALTERNATIVES TO GLOBAL AGRIBUSINESS* 3-4 (2002).

90. *Id.* at 57-58.

91. Levy, *supra* note 88.

92. Judith McGeary, Comment to *Does the Food Safety Bill Give the FDA Too Much Power – Or Not Enough?*, GRIST (Nov. 17, 2010, 1:45 PM), <http://www.grist.org/article/food-2010-11-17-does-the-food-safety-bill-give-the-fda-too-much-power>.

93. NORBERG-HODGE, MERRIFIELD & GORELICK, *supra* note 89, at 59.

A. Too little: The FSMA does not adequately address the problems and health risks posed by large-scale, industrial food production operations.

The key provisions of the FSMA amending the FD&C to enhance food safety are the preventative measures established by the HARCP, the increased rate of inspections, the mandatory recall authority, and the whistleblower protections. On their face these additions to the FD&C appear to be improvements, but will not likely have the significant effect intended by the proponents of the legislation. This sub-section will discuss how the FSMA requires too little of large-scale food production operations.

### 1. *Hazard Analysis and Risk-Based Preventative Control Plans*

The HARCP requirement (for which small farms and facilities may be exempted)<sup>94</sup> is analogous to the HACCP programs, which were first developed within the food industry and later imposed through regulations, and “require companies to examine their production streams, identify points where pathogens or other hazards may enter the system, and take steps to make those processes safer.”<sup>95</sup> This systematic method of identifying foodborne hazards, assessing their criticality, and controlling weak points provides food production operations with a flexible approach capable of adapting to changing conditions rather than a specific mandate for the use of specific controls.<sup>96</sup> The meat, poultry, juice, and seafood industries are already required to have HACCP programs.<sup>97</sup> While some critics acknowledge that HACCP has made modest safety improvements within these industries,<sup>98</sup> it has received a mixed response from the food industry and consumers.<sup>99</sup> Because “HACCP requires relatively sophisticated

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94. See *supra* Parts II.A.1, II.B.

95. Gregory Conko, *More FDA Authority Won't Improve Food Safety*, FORBES (Dec. 2, 2010, 3:40 PM), [http://www.forbes.com/2010/12/02/fda-regulation-food-safety-opinions-contributors-gregory-conko\\_print.html](http://www.forbes.com/2010/12/02/fda-regulation-food-safety-opinions-contributors-gregory-conko_print.html).

96. Hoffmann & Harder, *supra* note 3, at 20-21.

97. See 9 C.F.R. § 417 (2011) (requiring meat and poultry establishments to implement HACCP programs); 21 C.F.R. §§ 120.1, 120.8 (2011) (requiring juice processors to implement HACCP programs); 21 C.F.R. §§ 123.6, 1240 (2011) (requiring seafood processors to implement HACCP programs).

98. See Conko, *supra* note 95.

99. Hoffmann & Harder, *supra* note 3, at 21.

administration and management,” it tends to work well for large companies that already have complicated “industrial engineering management practices,”<sup>100</sup> but “[a]s implemented by regulators . . . HACCP tends to smother [smaller companies] in paperwork and impose rigid, costly, and out-of-date practices that simply have not kept up with changes in the food industry.”<sup>101</sup> Thus, the requirements discourage innovation of new safety mechanisms, and compliance with HACCP is very expensive.<sup>102</sup> The HACCP requirements imposed by section 103 of the FSMA will do little to improve safety at large-scale food production facilities primarily because these facilities already have voluntary HACCP programs in place.<sup>103</sup>

## 2. *Increased Inspections*

The mandatory inspections provided for in section 201 of the FSMA, which are to increase in frequency depending on a facility’s risk-profile, do little to improve food safety in three reasons: (1) inspections are marginally useful for detecting harmful microbial pathogens that cause foodborne illness outbreaks; (2) increasing the frequency of inspections requires funding, which is not provided by the FSMA; and (3) the modest increase in frequency is not likely to make a significant difference. Inspections generally include visual observations of the premises and production, examination of records and safety plans, and written reports of the inspector’s findings after considering the many factors detailed in the FDA’s “Investigations Operations Manual.”<sup>104</sup> The FDA’s lofty goals for inspections are laudable, but the quality of an inspection is only as good as the inspector and is limited by what the inspector focuses on.<sup>105</sup> For example, even if a facility

100. *Id.*

101. Conko, *supra* note 95.

102. *Id.*

103. *Id.*; see also Josh Ozersky, *The Food-Safety Bill: Flawed, and Needed*, TIME (Dec. 8, 2010), <http://www.time.com/time/nation/article/0,8599,2035806,00.html>; Russell Libby, Comment to *Does the Food Safety Bill Give the FDA Too Much Power – Or Not Enough?*, GRIST (Nov. 17, 2010, 1:45 PM), <http://www.grist.org/article/food-2010-11-17-does-the-food-safety-bill-give-the-fda-too-much-power>.

104. See generally U.S. FOOD & DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL (2011), available at <http://www.fda.gov/ICECI/Inspections/IOM/default.htm>.

105. Erik Olson, director of chemical and food safety programs at the Pew

appears clean and is not listed as “high-risk,” it may still harbor harmful pathogens, while another facility that appears dirty and disorganized may indeed be sterile.<sup>106</sup> It is impractical for an inspector to visually determine whether or not a facility poses a safety risk, which is “the main reason why meat and poultry account for about half of all the food-borne illness outbreaks even though slaughterhouses may not legally operate without USDA inspectors on the premises at all times.”<sup>107</sup>

Furthermore, the costs associated with increasing the frequency of inspections are staggering, and doubling the current inspection rates would “account for most of the [FSMA’s] \$1.4 billion four-year cost.”<sup>108</sup> Section 401 authorizes the appropriation of funds from the FDA budget to increase the number of field staff; however, it remains to be seen whether Congress will make the necessary appropriations to fully fund the provisions of the FSMA. The FSMA is an authorizing bill and appropriations for it must still come from future Congressional legislation.<sup>109</sup> Even Deputy Commissioner of the FDA’s Office of Foods, Michael Taylor, publicly recognized the funding limitation of the FSMA when he noted that, “fulfilling the Congressional vision embedded in the new law . . . will require new resources and investment.”<sup>110</sup>

It is also difficult to contemplate how doubling the rate of inspections to once every three or five years (depending on the facility’s risk-profile) will seriously improve food safety. The salmonella outbreak originating from the PCA plant in Georgia

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Charitable Trust’s Health and Human Services Program has stated that “[t]he mere fact that there is an inspection isn’t enough . . . [y]ou’ve got to have the inspector properly trained and inspect frequently enough to detect problems. If any of this falls short, you can have a serious problem.” Kristin Choo, *Hungry For Change: The Feds Consider a Steady Diet of Stronger Regulation to Help Fix the U.S. Food Safety Network*, A.B.A. J., Sept. 2009, at 56, 60.

106. Conko, *supra* note 95.

107. *Id.*

108. *Id.*

109. Ferd Hoefner, Comment to *Will the Food Safety Modernization Act Better Protect Us From Contaminated Food?*, GRIST (Nov. 12, 2010, 6:30 AM), <http://www.grist.org/article/2010-11-11-food-fight-food-safety-modernization-act-better-protect-us>.

110. Michael R. Taylor, Deputy Comm’r for Foods, U.S. Food & Drug Admin., Address at the FDLI Food Safety Conference: The FDA Food Safety Modernization Act: Putting Ideas Into Action (Jan. 27, 2011), *available at* <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/ucm241192.htm>.

(mentioned in the introduction) occurred even though the facility was inspected nine times within a three-year period.<sup>111</sup> The PCA example is also indicative of the ineffectiveness of random sampling, as the sample of processed peanuts tested by inspectors there came up negative for salmonella.<sup>112</sup> However, the FSMA does incorporate a lesson learned from the PCA scandal. Section 307 incorporates a system for accrediting third-party auditors and includes a sub-section specifically addressing conflicts of interest as well as proscribing announced inspections by third-party auditors (both problematic in the PCA context where the third-party inspector of the Georgia plant was paid by PCA and not its customer Kellogg, and had pre-arranged a date for inspection with plant personnel).<sup>113</sup>

### 3. *Mandatory Recall Authority*

The mandatory recall authority provided by the FSMA has been characterized as “a solution in search of a problem.”<sup>114</sup> Previous recalls were strictly voluntary and the FDA relied on “the cooperation of food manufacturers, processors, wholesalers, and retailers to accomplish the arduous and expensive job of extracting contaminated food from commerce.”<sup>115</sup> Companies are usually willing to voluntarily recall tainted food.<sup>116</sup> While a voluntary system makes obvious sense in that companies have a vested interest in maintaining the public’s goodwill toward their products, a case can be made post-PCA scandal for greater government power to address “laz[y] or malfeasan[t]” manufacturers like PCA.<sup>117</sup> Nevertheless, this added authority is a mere formality because in reality it would be difficult “to identify a single case in which producers refused to honor a recall request based on evidence that a product was actually or likely to be tainted.”<sup>118</sup> Additionally, it is a power begging to be abused in the

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111. Steinzor, *supra* note 13, at 177.

112. *Id.*

113. *Id.* at 185-86.

114. Conko, *supra* note 95.

115. Steinzor, *supra* note 13, at 185.

116. Benson, *supra* note 11, at 517.

117. *See* Steinzor, *supra* note 13, at 185.

118. Conko, *supra* note 95; *see also* Benson, *supra* note 11, at 517 (“Most, if not all, firms that have been implicated in foodborne illness outbreaks associated with fresh produce are willing to recall their food in order to

face of public and media pressure over foodborne illness outbreaks.<sup>119</sup> However, section 206(a) of the FSMA does contemplate this to some extent by first providing a company with the opportunity to issue a voluntary recall before proceeding to section 206(a), whereby the FDA has the authority to require a cease distribution order.<sup>120</sup> Unfortunately, the mandatory recall authority does little to improve food safety overall because the real food safety threat occurs prior to the knowledge of that threat, which makes the recall essentially a last resort that rarely resolves the problem.<sup>121</sup>

#### 4. Whistleblower Protections

The employee protections provided by section 402 of the FSMA are an important aspect of the legislation intended to assist the FDA in preventing food safety issues. Like much of the FSMA, it is a noble addition to the FD&C, but one with few teeth in its practical application. Employees in the food industry, particularly those working for large-scale, industrial food operations, are not necessarily equipped with the knowledge and experience to recognize potential food safety risks. For example, like inspectors who cannot see the microbial pathogens through visual observation, employees are similarly situated in that they cannot with their eyes perceive potential threats that are likely microscopic. Furthermore, as with other similar legislation, the employees capable of “whistleblowing” (i.e. not management) are not likely to be aware of the protection afforded them by this legislation nor are they likely to have the confidence to take on their employers while already working at presumably low wage jobs. However, this component of the FSMA could prove quite

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protect consumers and preserve their reputations.”).

119. Conko, *supra* note 95; *see also* Benson, *supra* note 11, at 516.

120. FDA Food Safety Modernization Act, Pub. L. No. 111-353, sec. 206(a), § 423(a), 124 Stat. 3885, 3939-40 (2011).

121. “[E]ven in the best of circumstances, recalls are notoriously difficult to implement and are not an effective substitute for preventative regulation. Because products are relatively inexpensive and purchases are so numerous, retailers rarely have easy access to the names and contact information of individual customers. Even if such information is available, recalls involving millions of units are daunting to implement. The GAO reported in 2004 that ‘most recalled food is not recovered.’” Steinzor, *supra* note 13, at 186 (citation omitted).



effective for enhancing food safety with respect to a specific subset of employees, those involved in quality control, because they are acutely aware of health-risks and are privy to lab reports and other data that may reveal food safety hazards. Section 402 of the FSMA would allow them to report violations even when pressured by management to be complicit in misrepresenting data, or risk losing their jobs.

##### 5. *Missing from the FSMA*

Several elements missing from the FSMA would have provided consumers with enhanced food safety with respect to large-scale industrial food operations limitations on the use of chemical pesticides and fertilizers, a ban on sub-therapeutic antibiotics, and criminal penalties for knowingly violating and selling contaminated food. Section 105 of the FSMA purports to provide “science-based minimum standards” for produce safety and good agricultural practices for the “safe production and harvesting” of fruits and vegetables that are “raw agricultural commodities,”<sup>122</sup> but noticeably absent from the section is any reference to the use of chemical pesticides in growing these raw agricultural commodities. In the letter opening its 2008-2009 Annual Report, the President’s Cancer Panel “urge[d]” the President to “use the power of [his] office to remove the carcinogens and other toxins from our food, water, and air that needlessly increase health care costs, cripple our Nation’s productivity, and devastate American lives.”<sup>123</sup> The report advised that individuals could avoid “[e]xposure to pesticides” by choosing “food grown without pesticides or chemical fertilizers.”<sup>124</sup> The report was not conducted by “fringe” elements of the scientific community but by “the mission control of mainstream scientific and medical thinking,”<sup>125</sup> thus suggesting that the hazards and risks posed by chemical pesticides and fertilizers are apparent to

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122. See FDA Food Safety Modernization Act, sec. 105(a), § 419(a)(1)(A).

123. PRESIDENT’S CANCER PANEL, REDUCING ENVIRONMENTAL CANCER RISK: WHAT WE CAN DO NOW (2010), available at [http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP\\_Report\\_08-09\\_508.pdf](http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf)

124. *Id.* at 112.

125. Nicholas D. Kristof, *New Alarm Bells About Chemicals and Cancer*, N.Y. TIMES, May 6, 2010, at A33, available at <http://www.nytimes.com/2010/05/06/opinion/06kristof.html>.

the scientific community and should seriously be considered in determining “science-based minimum standards for the safe production and harvesting” of produce as well as for the publication of what constitute “good agricultural practices” under section 105 of the FSMA.<sup>126</sup>

Furthermore, section 104’s, “performance standards,” direct the FDA to “review and evaluate the relevant health data and other relevant information, including that from toxicological and epidemiological studies and analyses” in determining the most significant foodborne contaminants.<sup>127</sup> That the President’s Cancer Panel report was available to both Congress and the FDA prior to the final proposal of this legislation is indicative of its failure to adequately address serious health concerns posed by the dominant form of agricultural food production in the U.S. (i.e. the large-scale, centralized industrial food production operations).

Additionally, the report warned individuals against “exposure to antibiotics, growth hormones, and toxic run-off from livestock feed lots,” advising them to choose “free-range meat raised without these medications.”<sup>128</sup> Although meat and poultry products are beyond the purview of the FDA, the antibiotics and hormones used in factory farming is within its power to regulate, and should have been addressed in the FSMA by withdrawing approval for animal drug use. The movement from small, local, family farms to large, industrial factory farms mentioned *supra* Part I includes a similar transition within context of livestock farming.<sup>129</sup>

The only way for the modern system of industrialized, concentrated animal farms to be viable is through the use of antibiotics to prevent dangers of disease and death prevalent when animals are confined in the cramped quarters of concentrated animal feed operations (CAFOs).<sup>130</sup> “American farm policies and meat processing industries have sacrificed human health for the economic efficiency of industrialized livestock

126. FDA Food Safety Modernization Act, sec. 105(a), § 419(a)(1), (e)(1).

127. Food Safety Modernization Act, sec. 104, § 2201

128. PRESIDENT’S CANCER PANEL, *supra* note 123, at 112.

129. See Ariele Lessing, Note, *Killing Us Softly: How Sub-Therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. ENVTL. AFF. L. REV. 463, 463 (2010).

130. See *id.* at 467-69.

production.”<sup>131</sup> Sub-therapeutic doses of antibiotics (“low levels of antibiotics that are insufficient to kill an invading bacterial infection, but are effective in preventing bacterial infection from occurring”<sup>132</sup>) are particularly dangerous because they are responsible for creating strains of antibiotic-resistant bacteria that are “transferred to humans through the animal product, through human contact with livestock, and through environmental channels such as a contaminated water supply.”<sup>133</sup> Relevant to the FSMA and its goal of preventing foodborne illness outbreaks, the rise of drug resistant bacteria like salmonella and *E. coli* (the usual suspects in foodborne illness outbreaks), is largely a result of the use of antibiotics in raising livestock.<sup>134</sup> These drug resistant bacteria enter the agricultural food supply – and those fruits and vegetables regulated under produce safety standards section 105 of the FSMA – when manure from CAFOs is used as fertilizer in agricultural fields, and when it enters the groundwater used for irrigation in agricultural fields.<sup>135</sup> Given “the plethora of available data on the impact of the use of animal antibiotics to human health,”<sup>136</sup> the absence of this obvious food safety concern from the FSMA is remarkable and deplorable.

Finally, the absence of severe criminal sanctions for violators that knowingly and intentionally put contaminated food into the stream of commerce,<sup>137</sup> is another example of the failure of the FSMA to adequately address the hazards posed by large-scale food production operations. Criminal penalties would provide a serious deterrent to reckless behavior endangering the health and lives of Americans. Under the current system, egregious violators like

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131. *Id.* at 463.

132. *Id.* at 469.

133. *Id.* at 490.

134. *See id.* at 472-74.

135. *See id.* at 475-76.

136. *Id.* at 488.

137. Although FD&C does provide for a criminal penalty of imprisonment for up to three years and a fine of not more than \$10,000 for committing a violation with the intent to defraud or mislead, or for committing a second violation, 21 U.S.C. § 333(a)(2) (2006), FDA “statistics reveal an extraordinary weak track record for criminal investigations” and enforcement. Steinzor, *supra* note 13, at 195-96. Additionally, a first violation committed without the intent to defraud or mislead is punishable only by a sentence of not more than one year and/or a fine of not more than \$1,000. 21 U.S.C. § 333(a)(1) (2006).

PCA chief executive officer Stewart Parnell, whose “[p]lant operators knowingly shipped peanut products” after they had tested positive for salmonella,<sup>138</sup> would merely receive misdemeanors, with little to no jail time and small fines.<sup>139</sup> As mentioned *supra* Part III.A.3, recalls are only minimally effective for protecting consumers, and thus, a deterrence mechanism beyond fines (that have relatively little impact on large businesses), is critical for enhancing food safety and was unfortunately left out of the FSMA.

B. Too Broad: The FSMA unnecessarily burdens small and mid-sized facilities and farms that do not pose the same threat as large-scale operations.

While many of the reforms enhanced the authority of the FDA, and heightened restrictions in the FSMA will have only a minimal effect on large food production operations, the one-size-fits-all legislation of the FSMA, which is barely discerning in its scope, may have a disproportionate and disastrous effect on small and midsized farms that do not fit within the exemption provided by the Tester-Hagan Amendment. This section will discuss how the FSMA overburdens small food production operations that do not qualify for an exemption from the preventative measures of section 103 as well as the positive and negative aspects of the Tester-Hagan Amendment as enacted.

### *1. The Regulatory Burden of the FSMA on Small and Mid-Sized Farms*

The extent of the regulatory burden of the FSMA is relative to the size and nature of the operation being regulated. For the most part, those facilities and farms selling a majority of their products directly, and grossing less than \$500,000 annually, will not be subject to the preventative measures, or HARCP, of section 103, and will not be subject to the produce safety standards and good

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138. Steinzor, *supra* note 13, at 176-78.

139. *Id.* at 179. Although the tort system functions, in part, as a deterrent, it is not sufficient for preventing serious violations. PCA may have been bankrupted by the civil justice system, but while financial risk is inherent in every business venture, a felony conviction is not, and serious criminal liability could deter the type of callous behavior demonstrated by Parnell.

agricultural practices of section 105.<sup>140</sup> Additionally, those businesses deemed “very small” following the study prescribed by section 103 will also be exempt from the regulatory burdens of sections 103 and 105.<sup>141</sup> While the discretionary aspects of this study’s determination will be addressed more fully below, it is noteworthy here that many small and mid-sized farms and facilities will not fall within the exemption and will thus be subject to these sections’ requirements. At the outset it is also important to point out that all businesses are subject to the remainder of the requirements and authority of the FDA provided by the FSMA. Finally, it should be noted that the definition of a small business, specifically with respect to farms, is relative to the geographic region where it is located. “[O]ne of the main tenets of local foods is [the recognition] that every area is different, based on its ecology and the community.”<sup>142</sup>

The first and most obvious burden on small and mid-sized facilities is the HARCP requirements in section 103. While they may not be overly burdensome on large facilities that have “capital-intensive, compliance department-managed, standardized, large-scale operations” (and likely already have voluntary HACCP programs in place), the reality for “low-input, owner-manned and -operated, diversified, small-scale operations” is distinctly different.<sup>143</sup> These smaller facilities would have to analyze the potential hazards of their operation, “identify and implement preventative controls” to mitigate the identified hazards, “monitor the performance of those controls,” and “maintain records of the monitoring as a matter of routine practice.”<sup>144</sup> As much of the HARCP requirements are highly technical and must be “science-based,”<sup>145</sup> in reality, this likely

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140. See FDA Food Safety Modernization Act, Pub. L. No. 111-353, sec. 103(a), 105(a), §§ 418(l), 419(f), 124 Stat. 3885, 3892-95, 3903-04 (2011).

141. *Id.*

142. Judith McGeary, Comment to *Will the Food Safety Modernization Act Harm Small Farms or Producers?*, GRIST (Nov 15, 2010, 6:46 PM), <http://www.grist.org/article/food-2010-11-15-food-fight-safety-modernization-act-harm-small-farms>.

143. See Roland McReynolds, *S.510 Opinion: Protect Small Farms*, FOOD SAFETY NEWS (Nov. 29, 2010), <http://www.foodsafetynews.com/2010/11/why-local-food-movement-opposes-large-scale-food-safety/>.

144. FDA Food Safety Modernization Act, Pub. L. No. 111-353, sec. 103(a), § 418(a), 124 Stat. 3885, 3889.

145. *Id.* sec.103(a), §418(n)(1)(A); sec.103(c)(1)(C).

involves hiring third-parties to assist in the initial analysis, specialists to assist in developing and implementing controls, and employees to handle the administrative task of monitoring and record-keeping.

Although the regulations imposed by the FDA under this section are supposed to “provide sufficient flexibility to be practicable for all sizes and types of facilities,”<sup>146</sup> and the FDA is required to provide “a small entity compliance guide setting forth in plain language the requirements,”<sup>147</sup> it is unclear whether such protective measures would actually minimize the costs for smaller facilities. For example, a recently published FDA guidance document for processing cut leafy greens, which many small and mid-sized farms that prepare salad mixes would be potentially subject to, “estimates that it would take a trained corporate team 100 hours to develop an appropriate safety plan, not to mention the cost of tests that such a plan would have to require.”<sup>148</sup> Simply reading guidance documents issued by the FDA is time-consuming and requires a level of sophistication beyond the “plain language” requirements.

HACCP, and here HARCP, compliance is “hugely expensive,” and forcing small and mid-sized facilities to absorb these costs could potentially drive them out of business.<sup>149</sup> Evidence of this effect can be found by looking at what the mandatory HACCP plans did to small and mid-sized slaughterhouses.<sup>150</sup> After USDA regulations requiring HACCP plans for slaughterhouses were

146. *Id.* sec.103(a), §418(n)(3)(A).

147. *Id.* sec.103(d).

148. McReynolds, *supra* note 143. McReynolds based this assertion on a proposed collection of information submitted to the Office of Management and Budget and published in the *Federal Register*. Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables, 75 Fed. Reg. 65491, 65494 (Oct. 25, 2010).

149. Conko, *supra* note 95; see also Tom Philpott, Patty Lovera, & Judith McGeary, Comment to *Will the Food Safety Modernization Act Harm Small Farms or Producers?*, GRIST (Nov 15, 2010, 6:46 PM), <http://www.grist.org/article/food-2010-11-15-food-fight-safety-modernization-act-harm-small-farms>.

150. See A. Bryan Endres & Michaela Tarr, *United States Food Law Update: Initial Food Safety Restructuring Efforts, Poultry Production Contract Reforms and Genetically Engineered Rice Litigation*, 6 J. FOOD L. & POL'Y 103, 117 (2010); Judith McGeary, Comment to *Will the Food Safety Modernization Act Harm Small Farms or Producers?*, *supra* note 142.

promulgated in 1996, many slaughterhouses went out of business because of the high costs involved in implementing the programs.<sup>151</sup> It has been argued that small slaughterhouses were already in decline,<sup>152</sup> but small, local farms<sup>153</sup> are actually becoming more prevalent, and it cannot be argued that hiring safety consultants, identifying, implementing, monitoring controls, maintaining records, and training employees does not add expenses. In fact, an analysis conducted by a farm operator at Rivendelle Farm in North Carolina estimated that “a typical small farm doing on-farm processing would need 150 hours to create, implement and monitor the [HARCP] plan, and [would] spend \$9,500 per year on consulting and testing costs. If the farm hired a consultant to create the plan, the first year costs [would] be to \$20,000.”<sup>154</sup> This analysis is “consistent with the concerns of local and organic farming advocates across the country” as evidenced by the findings of a small California farm that estimated that “it would cost their operation 100 hours to develop and implement a HARPC plan, plus two hours per day to maintain it, and \$15,000

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151. See Judith McGeary, Comment to *Will the Food Safety Modernization Act Harm Small Farms or Producers?*, *supra* note 142. In this Grist forum discussion (relied on here because this is an area of evolving policy not covered in depth by traditional sources) discussing the impact that the FSMA will have on small farms and producers with experts from consumer organizations, victim-advocacy groups, and sustainable farming advocates, Judith McGeary (founder and executive director of the Farm and Ranch Freedom Alliance), Russell Libby (executive director of the Maine Organic Farmers and Gardeners Association) and Patty Lovera (assistant director of Food & Water Watch), among others in the field, commented on the decline of small and mid-sized slaughterhouses after the USDA mandated HACCP programs and noted the high costs of hiring consultants to write food safety plans. *Id.*

152. Michael Bulger, Comment to *Will the Food Safety Modernization Act Harm Small Farms or Producers?*, *supra* note 142 (arguing that “small slaughterhouses had been rapidly declining in numbers for half a century, the USDA sa[id].”).

153. Small, local farms often incorporate some form of processing which would categorize them as facilities and thus be subject to the HARCP requirements. See Russell Libby, Comment to *Will the Food Safety Modernization Act Better Protect Us From Contaminated Food?*, *supra* note 109.

154. Roland McReynolds, HURTING NC'S LOCAL FOOD HARVEST: THE UNINTENDED CONSEQUENCES OF FEDERAL FOOD SAFETY LEGISLATION ON NORTH CAROLINA'S SMALL AGRICULTURAL ENTERPRISES, CAROLINA FARM STEWARDSHIP ASS'N 7 (2010), [http://www.carolinafarmstewards.org/docs/Hurting\\_NC's\\_Local\\_Food\\_Harvest042010.PDF](http://www.carolinafarmstewards.org/docs/Hurting_NC's_Local_Food_Harvest042010.PDF).

in annual testing fees.”<sup>155</sup>

The second disadvantage to small and mid-sized facilities is that the provision disincentives growth by making profitability a potential liability. Setting the qualification for exemption at \$500,000 constrains small and mid-sized farms and facilities that may be close to that threshold. Considering that it is a gross revenue threshold or “value of all food sold by such facility,”<sup>156</sup> not accounting for expenses and overhead, a farm or facility may not be turning a profit, yet would still have to comply with the expensive HARCP requirements. One farmer interviewed by Mike Adams, Natural News Editor, said “that’s so un-American to say hey, you’re going to stay in this box, and you can never grow your business bigger than that. \$500,000 [in revenue] is your cap.”<sup>157</sup> He told Mr. Adams that his farm was actually halting plans for expansion as a result of the FSMA “because we don’t want to get too successful.”<sup>158</sup>

An example of a small, local food facility (packer and distributor) that has gross revenues just above \$500,000 is the Appalachian Harvest Network, which brings local farms together under a common brand and into a distribution system with major retailers and grocers in the region.<sup>159</sup> With total revenue at

155. *Id.*

156. FDA Food Safety Modernization Act, Pub. L. No. 111-353, sec. 103(a), § 418(l)(1)(C)(ii)(II), 124 Stat. 3885, 3892 (2011).

157. Mike Adams, *How the Food Safety Modernization Act will Destroy American Jobs, Farms and Local Foods*, NATURALNEWS.COM (Jan. 12, 2011), [http://www.naturalnews.com/z030986\\_food\\_safety\\_farmers.html](http://www.naturalnews.com/z030986_food_safety_farmers.html).

158. *Id.*

159. Michael Shuman, et. al., APPALACHIAN HARVEST NETWORK, COMMUNITY FOOD ENTERPRISE 44 (2009), [http://www.communityfoodenterpriseprose.org/book-pdfs/CFE%20-%20appalachian-harvest-network\\_view.pdf](http://www.communityfoodenterpriseprose.org/book-pdfs/CFE%20-%20appalachian-harvest-network_view.pdf).

At the heart of [Appalachian Harvest Network’s] business model is . . . a “buyers’ matrix”—independent health food stores, local grocers, and regional chains that are the main purchasers of AHN’s produce. This weekly process of assessing demand begins in the late fall and carries through the winter. Every week AHN “plans and pools production to meet demand”: it assembles a list of buyers’ requests, shares the information with its growers, and then recruits local growers to meet these demands. Wherever necessary, it offers direct technical support and training to growers so that they get the proper seeds, plant their fields properly, get organic certification, and fulfill the buyers’ requirements for high quality. Participating farmers then bring their harvest to the AHN certified organic packing and grading facility, where the produce is washed, packaged and readied



\$515,000, and over half of its sales to wholesalers and distributors, Appalachian Harvest Network does not fall within the Tester-Hagan Amendment's exemption but is "operat[ing] on a tight budget with slim margins, leaving them especially vulnerable to periods of economic downturn," or to burdensome regulations that would require allocating time, money, and energy to paperwork, equipment upgrades, and creating HARCP plans.<sup>160</sup> It is unfortunate that an enterprise that has created a system to assist small, local farmers while providing good, healthy food in an environmentally sustainable manner will be threatened by the over-burdensome requirements of the FSMA.

## 2. *Tester-Hagan Pros & Cons*

The Tester-Hagan Amendment adopted in the final legislation of the FSMA, as detailed in Part II.B, is an important protection for small-scale food producers. It insulates qualifying facilities and farms from the HARCP requirements and produce safety standards, but does not go far enough to mitigate the effects of legislation that otherwise does not differentiate in regard to scale. The significant achievements of the Tester-Hagan Amendment are that it provides an exemption for small facilities and farms; it clarifies the definition of "retail food establishments," specifically stating that "direct sales" include roadside stands, farmer's markets, and CSAs; it includes flexibility and guidance for small entities; and it requires the FDA to "conduct a study of the food processing sector" by evaluating food production and health risks in relation to size, type, product value, and scale and to use the results of that study to ultimately define the terms "small business" and "very small business."<sup>161</sup> The drawbacks of the Tester-Hagan Amendment are its limited threshold for qualification; the discretionary nature of the withdrawal provision; and its failure to address geographical differences in

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for sale. AHN goes back to the buyers to let them know what is available and when. Once the orders are finalized, it delivers the fresh produce directly to the retailers' centralized delivery docks. Some of the retailers redistribute the product to their own sites via their own networks.

*Id.*

160. *See id.* at 44, 47.

161. FDA Food Safety Modernization Act, sec. 103(a), § 418(l).

scale.<sup>162</sup>

Once ubiquitous in American society, small farms serving local needs are having a renaissance in American culture that the Tester-Hagan Amendment protects. “The growing trend toward healthy, fresh, locally sourced vegetables, fruit, dairy, and value-added products improves food safety by providing the opportunity for consumers to know their farmers and processors, to choose products on the basis of that relationship, and to readily trace any problems should they occur.”<sup>163</sup> Consumers choosing local food often buy it directly from the farm, at roadside stands, at farmer’s markets, or participate in CSA programs. Local and state authorities (not to mention existing federal laws) already regulate these local methods of supplying consumers with food.<sup>164</sup> Sparing them from further federal oversight and regulations, which translates into higher costs, not only protects their financial viability but allows them to be more responsive to local and community needs, which can differ from region to region. The study of the food processing sector that the FDA is mandated to conduct and report is a unique achievement because it will “foster the development of multiple climate-, scale- and market-appropriate models for promoting safe and healthy food in a sector of the farm economy largely ignored heretofore by research institutions.”<sup>165</sup> Researchers conducting the study will have an opportunity to closely examine the “unique conditions of small and diversified farming operations” while enabling the FDA to define the terms “small business” and “very small business.”<sup>166</sup> It is hoped that the government will recognize the impact and safety aspects of small, local farms provided it has the opportunity *and funding* to conduct a meaningful study.

Unfortunately the Tester-Hagan Amendment did not go far enough. The \$500,000 threshold leaves out many farms and facilities that would consider themselves “small” and does not recognize offsetting factors such as expenditures and types of commodities. While it appears Congress recognized the need to add the words “adjusted for inflation,” it did not add wording that

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162. *Id.* sec. 103(a), § 418(l)(1)-(3).

163. MacDonald & McGeary, *supra* note 19.

164. *Id.*

165. McReynolds, *supra* note 143.

166. *See id.*

considered offsetting factors that may belie the size of a farm or facility with sales over \$500,000.<sup>167</sup> Ideally this shortcoming will be resolved after the FDA conducts the required study.<sup>168</sup> Even though qualifying facilities are theoretically exempt from the HARCP requirements, they must still prove to the FDA, with documentation, that they have identified hazards associated with their food production, are implementing controls to address the hazards, and are monitoring the controls.<sup>169</sup> This additional requirement to establish exemptions seems contradictory because it essentially requires them to have an informal HARCP system. While they may opt out of this requirement by submitting documentation proving compliance with non-federal food safety laws, both options nonetheless impose requirements that could be burdensome for very small operations, and the second option leaves some discretion to the FDA as to which evidence of compliance will be acceptable.<sup>170</sup> As with the \$500,000 threshold, this hurdle might also be minimized after the FDA defines the terms “small business” and “very small business.”<sup>171</sup>

The discretionary withdrawal provision that allows the FDA to withdraw an exemption in the event of an active investigation directly linked to the exempted facility or a determination by the FDA that it is necessary to protect the public health leaves quite a bit of room for the FDA to choose to withdraw an exemption if its analysis of the type of operation leads it to consider the facility a threat to public health.<sup>172</sup> Therefore, as discussed further *infra* Part III.C, a small facility otherwise meeting the qualifications for exemption may still not be exempted if it is not in accord with FDA policies for food safety.

Finally, the Tester-Hagan Amendment does not accommodate differences in scale related to geography and market availability. “[A] small farm in California is a massive farm in New England, and \$200,000 worth of cabbage comes from a much different-sized operation than \$200,000 of artisanal cheese.”<sup>173</sup> Additionally, a

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167. FDA Food Safety Modernization Act, sec. 103(a), § 418(l)(1)(C)(ii)(II).

168. *Id.* sec. 103(a), § 418(l)(5).

169. *Id.* sec. 103(a), § 418(l)(2)(B)(i)(I).

170. *Id.* sec. 103(a), § 418(l)(2)(B)(i)(II).

171. *Id.* sec. 103(a), § 418(l)(5)(B).

172. *Id.* sec. 103(a), § 418(l)(3)(A).

173. Patty Lovera, Comment to *Will the Food Safety Modernization Act Harm Small Farms or Producers?*, *supra* note 142.

small facility located in a remote region may have little opportunity for direct sales and have to sell more than half of its products through a third-party or at a distance greater than 275 miles, thus curtailing its opportunity for exemption under section 103.<sup>174</sup> Both sections 103 and 105 do direct the FDA to provide “flexibility” for “small businesses,”<sup>175</sup> but the long list of “highly prescriptive and specific requirements . . . contradict the ‘flexibility.’”<sup>176</sup>

Overall, the Tester-Hagan Amendment is a positive addition to the FSMA and much of its practical application for preserving small farms will depend on the outcome of the mandated study.<sup>177</sup>

### C. Too Bad: Agency Discretion

The notion of agency discretion has been alluded to throughout this article and is a subject for further analysis because the realities of this new legislation have not yet been realized, and the inherent speculation of its impact on food safety is largely dependent on one’s perspective of government decision-making. However, as this section further explores, after considering the FDA’s history of persecution of alternative food producers, skewed priorities, revolving-door hiring policy, and lack of understanding of the specific needs of small farmers, it is apparent that the FSMA grants too much discretion to an unreliable and untrustworthy agency. This section will focus on the discretionary aspects of the FSMA, a brief history of the FDA’s use of its discretion, and the policies and goals the FDA intends to pursue.

Throughout the FSMA there are numerous provisions that leave key decisions to the discretion of the FDA. Part of the trouble with analyzing the legislation, as well as the controversy

174. FDA Food Safety Modernization Act, sec. 103(a), § 418(l)(4)(B).

175. *Id.* sec. 103(a), § 418(n)(3)(A); sec. 105(a), 419(a)(3)(A).

176. MacDonald & McGeary, *supra* note 19 (discussing a specific example of an FDA regulation that is not flexible and does not protect small business and diversified farms by requiring vegetation-free buffer zones and protections against wildlife that are not scientifically proven to increase food safety and that contradict sustainable practices of these diversified farms).

177. The FSMA requires the FDA to submit the results of this study to Congress within 18 months of the act’s enactment. FDA Food Safety Modernization Act, Pub. L. No. 111-353, sec. 103(a), § 418(l)(5), 124 Stat. 3885, 3894 (2011).

surrounding its passage through Congress,<sup>178</sup> is that much of the language is vague, many of its effects depend on its interpretation and implementation, and many of the standards have yet to be defined or promulgated. Citizen concern over agency discretion is not without merit. Because federal agency's decisions are given great deference and reviewed using the *Chevron* standard,<sup>179</sup> there is little recourse for challenging a decision so long as it was based in reason. For the purposes of this article, this section will briefly discuss several instances of vague, discretionary language within the FSMA to illustrate the wide latitude granted to the FDA that may disproportionately impact small and mid-sized farms.

The ultimate determination of the definition of the terms "small business" and "very small business" rests with the FDA after it receives the results of the study described in section 103(a), creating section 418(l)(5)(A). While the FDA is constrained by the language requiring it to consider "harvestable acres, income, the number of employees, and the volume of food harvested,"<sup>180</sup> the weight given to each factor, and whether to consider other factors when actually defining those terms, is left to the FDA. This is a significant power because this determines which facilities must comply with the HARCP requirements and which ones may qualify for an exemption without having to meet the threshold standards in section 103(a).

The change to section 207 is an example of intentionally providing the FDA with additional discretionary authority for the administrative detention of food by replacing a stricter standard

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178. See *Bill Summary & Status 111th Congress (2009 - 2010) H.R.2751CRS Summary*, LIBR. CONGRESS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR02751:@@D&summ1&> (last visited May 21, 2012) (offering a neutral view of the passage of the FSMA); see also *The "Food Safety" Saga: Our Job Is Just Beginning*, ALLIANCE FOR NATURAL HEALTH (Jan. 4, 2011, 3:00 PM), <http://www.anh-usa.org/the-food-safety-saga-our-job-is-just-beginning/> (offering a somewhat biased view of the complicated passage of the FSMA).

179. Agency interpretations on an ambiguous statute that the agency has been charged with administering are given deference by reviewing courts. See *Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984) (holding that if a "statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute").

180. FDA Food Safety Modernization Act, sec. 103(a), § 418(l)(5)(B).

for quarantine of “credible evidence” with a looser one: “reason to believe.”<sup>181</sup> The FDA may now impound food based on a hunch that it may be dangerous. This relaxed standard may be helpful in situations where food was intentionally poisoned but could easily be abused for reasons other than food safety. Similarly, the potential for abuse is inherent in the articulated standard for the mandatory recall authority of section 206, which allows the FDA to offer the responsible party an “opportunity to cease distribution and recall such article” based on a “reasonable probability that an article of food . . . is adulterated . . . or misbranded . . . and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals.”<sup>182</sup> Relatively benign labeling issues, like the one that prompted kombucha producers to voluntarily recall their beverages from stores nationwide during the summer of 2010 because of potential disparities in the actual alcohol content and that labeled, may now be strictly enforced by the FDA.<sup>183</sup>

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181. See *supra* Part II.A.4.

182. FDA Food Safety Modernization Act, sec. 206(a), § 423(a).

183. To consider the substance of the following news report to constitute a risk of “serious adverse health consequences or death” is patently ridiculous, and even more so when considering that the kombucha sold in stores was not even the same home-brewed kombucha that the FDA was worried about. Furthermore, it is an example of the FDA imposing mainstream beliefs about what does and does not have health benefits:

“Kombucha is not currently regulated by the U.S. Food and Drug Administration, except for alcohol content. However, the Treasury Department issued a statement when the product was pulled saying that the alcohol levels found in certain products were high enough for it to be taxed as an alcoholic beverage and require new labeling.”

Mitch Lipka, *Kombucha Tea After the Recall: It's Back and Still Controversial*, DAILY FINANCE (Aug. 5, 2010, 3:45 PM), <http://www.dailyfinance.com/2010/08/05/kombucha-tea-after-the-recall-its-back-and-still-controversial/>.

“[T]he mainstream health community does not embrace Kombucha tea. Quite the opposite. Mayo Clinic internist Dr. Brent Bauer warns on the Mayo Clinic web site that ‘it’s prudent to avoid it’ given the lack [sic] evidence to support health claims and more evidence to suggest it can cause ‘harm.’ ‘The Food and Drug Administration cautions that the risk of contamination is high because Kombucha tea is often brewed in homes under nonsterile conditions,’ Bauer writes. ‘Lead poisoning also may be a risk if ceramic pots are used for brewing – the acids in the tea may leach lead from the ceramic glaze.’”

Another example of FDA discretion embedded in the FSMA is the “sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses” that the FDA is required to provide in promulgating “science-based minimum standards for conducting [the] hazard analysis, documenting hazards, implementing preventative controls, and documenting the implementation of the preventative controls” in section 103.<sup>184</sup> Further factors that shape this rulemaking are contained in section 103(a), such as acknowledging differences in risk, minimizing the separate standards applied to separate foods, and not forcing companies to hire consultants, but again, these rules will ultimately be determined by the FDA with few enforceable limitations.<sup>185</sup> There is, as with most agency rulemaking, a public comment period, but an agency is not required, unless specifically required by statute, to change its regulations or adopt any portion of the public’s comments.<sup>186</sup> For example, the “FDA has repeatedly approved genetically modified foods without labeling despite significant public opposition.”<sup>187</sup>

In fact, as the FSMA provides the FDA with quite a bit of expanded authority to inspect records upon a “reasonable belie[f]” of a “reasonable probability” of serious risk under section 101 and to establish science-based minimum produce safety standards and good agricultural practices based under section 105, the remaining questions are, who is the FDA and what food safety goals does it wish to pursue?

The FDA is a federal agency within the executive branch of the U.S. government. The commissioner, Dr. Margaret Hamburg,

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*Id.*

184. FDA Food Safety Modernization Act, sec. 103(a), § 418(n).

185. *Id.*

186. See Administrative Procedure Act, 5 U.S.C. § 553(c) (2006) (directing an agency to provide a public comment period but not requiring an agency to adopt those comments); see also *Reytblatt v. U.S. Nuclear Regulatory Comm'n* 105 F.3d 715, 722 (D.C. Cir. 1997) (“An agency need not address every comment, but it must respond in a reasoned manner to those that raise significant problems.”); *Athens Cmty. Hosp. v. Heckler*, 565 F. Supp. 695, 699 (E.D. Tenn. 1983) (an agency “need not respond to all specific issues raised in comments on a proposed rule,” but the response “must be sufficient for [a court] to determine whether the [agency] considered the relevant factors in reaching the final decision”).

187. Judith McGeary, Comment to *Does the Food Safety Bill Give the FDA Too Much Power—or Not Enough?*, *supra* note 92.

was nominated by President Obama and confirmed by the Senate on May 18, 2009.<sup>188</sup> “[S]he is an experienced medical doctor, scientist, and public health executive.”<sup>189</sup> More relevant is the Deputy Commissioner for Foods, Michael R. Taylor, who Dr. Hamburg appointed to a new position that she created in August 2009 to “develop and carry out a prevention-based strategy for food safety” and “plan for new food safety legislation”<sup>190</sup>:

The new Office of Foods is responsible, on behalf of the Commissioner, for providing all elements of FDA’s Foods Program leadership, guidance, and support to achieve the Agency’s public health goals. The Office is also the focal point for planning implementation of the recommendations of the President’s Food Safety Working Group and the new food safety authorities being considered by Congress.<sup>191</sup>

Therefore, Mr. Taylor, former vice president for public policy of Monsanto, former administrator of USDA’s Food Safety and Inspection Service and acting under secretary for food safety at USDA, former partner at King & Spalding law firm, and former staff attorney at the FDA,<sup>192</sup> is the authority whose discretion matters. The point of highlighting Mr. Taylor’s career is to illustrate the inherent industry bias of this top official tasked with the final determination of discretionary agency decisions.<sup>193</sup>

188. See *Commissioner’s Page*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CommissionersPage/default.htm> (last updated July 19, 2011).

189. *Id.*

190. *Meet Michael R. Taylor, J.D., Deputy Commissioner for Foods*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm196721.htm> (last updated Apr. 23, 2010).

191. *Office of Foods: Overview and Mission*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm196720.htm> (last updated Jan. 11, 2010).

192. *Meet Michael R. Taylor, J.D., Deputy Commissioner for Foods*, *supra* note 190.

193. Of course his appointment also reflects the “revolving door” policy so prevalent in federal agencies that permits leaders of industry to occupy prominent roles at the very agencies regulating their industry. This prime example of a “fox watching the henhouse,” has generated a good deal of controversy and has culminated in a petition for his removal with more than 430,000 signatures. See Elizabeth Flock, *Monsanto Petition Tells Obama: ‘Cease FDA Ties to Monsanto’*, BLOGPOST (Jan. 30, 2012, 11:27 AM),



Although some of the discretionary decisions highlighted below were pursued by the FDA prior to his appointment, Mr. Taylor nevertheless represents the agency's adherence to the current mainstream, one-size-fits-all, industrial approach to food production, and therefore its approach to food safety.<sup>194</sup>

An examination of some recent instances in which the FDA has exercised its authority reveals its preferences and policies for controlling food safety. The current trend of enforcement by the FDA against farmstead dairies is an ominous indicator of where the FDA wants to go. For example, on April 20, 2010, two FDA agents, two federal marshals, and one state trooper went to the Rainbow Acres farm in Pennsylvania at 5 a.m. "to execute an administrative search warrant," ultimately fining the farm-owner for violating a law against selling raw milk.<sup>195</sup> The FDA has targeted twenty different buying clubs in Chicago suspected of obtaining raw milk from out-of-state sources and "has a similar strategy for the states, with the plan being to pressure one state at a time to ban raw milk sales."<sup>196</sup> Morningland Dairy, a farmstead raw milk cheese operation in Missouri, has been involved in litigation for over a year, and has had approximately 29,000 pounds of its cheese impounded since August 26, 2010, even though there have been no reported illnesses from consumption of its products throughout the thirty years it has

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[http://www.washingtonpost.com/blogs/blogpost/post/monsanto-petition-tells-obama-cease-fda-ties-to-monsanto/2012/01/30/gIQAA9dZcQ\\_blog.html](http://www.washingtonpost.com/blogs/blogpost/post/monsanto-petition-tells-obama-cease-fda-ties-to-monsanto/2012/01/30/gIQAA9dZcQ_blog.html); Frederick Ravid, *Tell Obama to Cease FDA Ties to Monsanto*, SIGNON.ORG (last visited Apr. 1, 2012), [http://signon.org/sign/tell-obama-to-cease-fda.fb1?source=s.fb&r\\_by=2105328](http://signon.org/sign/tell-obama-to-cease-fda.fb1?source=s.fb&r_by=2105328).

194. See Endres & Tarr, *supra* note 150 ("Critics fear [Taylor] will institute policies that indirectly harm small business by failing to take into account the unique needs of such entities in favor of adopting a one-size-fits-all (and that one-size is big business) approach."); McReynolds, *supra* note 143 ("[T]he corporate giants that dominate the fresh produce industry . . . cannot conceive of the means for managing contamination issues in the local food sector. Those agribusiness behemoths' only frames of reference are their own capital-intensive, compliance department-managed, standardized, large-scale operations. From their perspective, the realities of low-input, owner-manned and-operated, diversified, small-scale operations are unfathomable.").

195. Pete Kennedy, *FDA Steps Up Enforcement Against Raw Milk*, THE WESTON A. PRICE FOUNDATION (April 28, 2010, 6:28 PM), <http://www.westonaprice.org/action-alerts/2010-alerts/1929-fda-steps-up-enforcement-against-raw-milk.html>.

196. *Id.*

been in business.<sup>197</sup> The list of recalls, suspensions, and enforcement actions against raw milk products goes on and on even though there is not yet a federal prohibition of raw milk.<sup>198</sup> The zero tolerance policy on *Listeria monocytogenes*, a foodborne pathogen that can sometimes be virulent, threatens to eliminate raw milk artisanal cheese production, and thus cut out a significant high-value niche for small and mid-sized farming operations.<sup>199</sup>

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197. Pete Kennedy, *Morningland Cheese Trial*, FARM-TO-CONSUMER LEGAL DEFENSE FUND (Feb. 4, 2011), <http://www.farmtoconsumer.org/morningland-cheese-trial-kennedy.htm>.

Recently, the United States Food and Drug Administration (FDA) has pressured farmstead cheesemakers in Washington state and Missouri into recalling thousands of pounds of cheese due to samples testing positive for L-mono even though in neither case was there a single report of foodborne illness blamed on the farmstead operations. Compared to the raw milk incidents . . . , the stakes are much higher [for cheesemakers]. Unlike the raw milk producers who can only sell in their own states due to the federal interstate ban, raw milk cheese aged at least sixty days can be sold anywhere in the U.S. and has a longer shelf life, meaning a great deal more money can be lost due to a recall.

Pete Kennedy, *FDA's Ace in the Hole*, FARM-TO-CONSUMER LEGAL DEFENSE FUND (Oct. 13, 2010), <http://www.farmtoconsumer.org/fda-ace-in-the-hole-kennedy.htm>.

198. See e.g., Pete Kennedy, *Summary of Raw Milk Statutes and Administrative Codes*, A CAMPAIGN FOR REAL MILK, (Dec. 1, 2004) <http://www.realmilk.com/milk-laws-1.html> (compiling a summary of state laws on raw milk). For further information and numerous articles regarding FDA enforcement and litigation over raw milk products, see generally FARM-TO-CONSUMER LEGAL DEFENSE FUND, <http://www.farmtoconsumer.org> (last visited Sept. 12, 2011); FOOD SAFETY NEWS PRESENTED BY MARLER CLARK LLP, PS, <http://www.foodsafetynews.com> (last visited Sept. 12, 2011); FOOD FREEDOM, <http://foodfreedom.wordpress.com> (last visited Sept. 12, 2011); A CAMPAIGN FOR REAL MILK, <http://www.realmilk.com> (last visited Sept. 12, 2011); THE WESTON A. PRICE FOUNDATION, <http://www.westonaprice.org> (last visited Sept. 12, 2011).

199. It should be noted that

There are many subtypes of *Listeria monocytogenes*; many of these subtypes have not been implicated in human illness. There are laboratories in the U.S. that have the capability to identify the subtype of L-mono in a food after the initial test for that bacteria is positive. What is happening is that FDA and state agencies are just relying on the initial positive test for L-mono without doing further testing to determine if the subtype is one that has actually caused illness in humans. If the L-mono subtype found in a food has not caused illness in humans, then the food is not adulterated and there

Even seemingly innocuous products, like walnuts and cherries, are not immune from being targeted by the FDA for making “false” health claims.<sup>200</sup> In 2006, the FDA demanded that twenty-nine cherry producers stop making claims that their products were healthy, and in 2010, the FDA threatened an attack against a large walnut producer to remove health claims on their website and marketing materials.<sup>201</sup> Even though both claims were backed up by scientific evidence, the FDA does not allow health claims about treating or preventing disease without its prior approval, because such claims would categorize the product as a “drug.”<sup>202</sup> However, health claims made on Frito-Lay’s website have not received the same, if any, attention from the FDA.<sup>203</sup>

Furthermore, the FDA has not banned chemical pesticides and fertilizers known to cause cancer,<sup>204</sup> nor did the FSMA include regulations on the use of bisphenol-A (commonly used in plastic beverage containers and known as BPA), a well-known health risk that Senator Diane Feinstein pushed to be banned.<sup>205</sup> The priorities of the FDA seem to be askew. When the President’s Cancer Panel advises changing the paradigm from presuming chemicals are safe until strong evidence emerges to the contrary,

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should be no product recall since the detected L-mono poses no risk of illness or injury. . . .

Even if the subtype of L-mono is virulent, it still needs to be determined whether the amount of bacteria in the food is enough to cause illness in humans. FDA has a “zero” tolerance policy for L-mono, a standard widely rejected by the scientific community throughout the world. The European Union (EU) allows up to 100 organisms per gram in food at the end of its shelf life.

*FDA’s Ace in the Hole*, *supra* note 197.

200. Mike Adams, *Health Products Under Fire as FDA Attacks Walnuts, Cherries and More*, FOOD FREEDOM (May 27, 2010), <http://foodfreedom.wordpress.com/2010/05/27/health-products-under-fire-as-fda-attacks-walnuts-cherries-and-more/>.

201. *Id.*

202. *Id.*

203. *Id.*

204. *See supra* part III.A.5.

205. *See* PRESIDENT’S CANCER PANEL, *supra* note 123, at 18; Kristof, *supra* note 125; *see also* Marla Cone, *President’s Cancer Panel: Environmentally Caused Cancers Are ‘Grossly Underestimated’ and ‘Needlessly Devastate American Lives,’* ENVIRONMENTAL HEALTH NEWS (May 6, 2010), <http://www.environmentalhealthnews.org/ehs/news/presidents-cancer-panel>.

to presuming they are dangerous until proven safe,<sup>206</sup> the FDA, charged with protecting food safety and setting agricultural standards, ought to pay attention. It is especially irresponsible and indicative of the heavy influence of big industry that the President's Cancer Panel report was released nine months before the enactment of the FSMA. Thus, it is reasonable to be afraid of the discretionary authority afforded to the FDA by the FSMA. When the FDA states in a legal brief on public record that "there is no generalized right to bodily and physical health" and "there is no absolute right to consume or feed children any particular food,"<sup>207</sup> its food safety and health policies become highly suspicious.

Congress was correct to recognize that U.S. food safety regulations were in dire need of a massive overhaul. However, both Congress and the President missed the mark by enlisting personnel like Michael R. Taylor, who represent the very industry creating the greatest risks and in need of the most stringent regulations, to set forth the guidelines and criteria for a revised food-safety regime. Instead of writing legislation with a one-size-fits-all approach, Congress ought to have focused its efforts on the large agribusinesses creating the risks and left small and mid-sized operations to state regulations.

#### IV. CONCLUSION

We are what we eat, and our health and nutrition depend on the consumption of nutritious, high-vitamin foods. Food is human sustenance and is the fundamental prerequisite to life. Its production must be transparent and its producers held accountable. What is truly needed is a paradigm shift from our

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206. See PRESIDENT'S CANCER PANEL, *supra* note 123, at 103.

207. Brief in Support of United States' Motion to Dismiss Plaintiff's Amended Complaint at 25-26, *Farm-to-Consumer Legal Defense Fund v. Sebelius, Secretary*, No. C 10-4018-MWB (N.D. Iowa Apr. 26, 2010) ECF No. 11-1. Admittedly, these statements were made as part of a legal argument attempting to lower the level of judicial scrutiny over challenged FDA regulations, which prohibited the sale or distribution in interstate commerce of unpasteurized milk and milk products for human consumption. Nevertheless, it is disconcerting that the entity charged with protecting Americans' "bodily and physical health" can even make a legal argument suggesting we have no right to choose our food, nor have a fundamental right to "bodily and physical health." *Id.*

dependence on industrialized food to an increased reliance on local and sustainably grown food rather than further government regulation. Local food can be defined by the proximal relationship between production and consumption<sup>208</sup> but is better understood by examining the “producer’s and consumer’s motivations for buying and selling local food: ‘1) a sense of connection, 2) quality, 3) environmental impact, and 4) political and social support for a particular type of agriculture.’”<sup>209</sup> Local food may be safer because it is sold fresh and therefore does not require preservatives, or storage and transportation.<sup>210</sup> “[I]t is usually sold unprocessed [and] has come in contact with fewer hands and mechanization.”<sup>211</sup> The local producer is directly accountable to its local consumer because the local consumer knows exactly where and when he purchased a particular product from the local producer, and can easily express any dissatisfaction directly to the producer or to the surrounding community.

It is not coincidental that the rise in food-related illnesses has accompanied the “rise of industrial agriculture and food production,”<sup>212</sup> and the current rate of outbreaks reflects our over-dependence on an increasingly concentrated food production system.<sup>213</sup> The resulting concern for food safety has led us to adopting “‘clean farming’ practices, which ironically run directly counter to farming practices developed by sustainable farmers with human health and the larger healthy functioning of the food production system in mind.”<sup>214</sup> Our definition of what is a health risk must be re-examined. For example, raw milk cheese may pose a serious health risk if produced by a large, industrial

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208. While it is clear that the proximal relationship must be a relatively short distance between the producer and the consumer, there is no specific definition for local food, and no specific geographic requirement. Any specific requirement would be problematic because of the inherent differences and relativity of size and scale within the United States.

209. Nathan M. Trexler, Note, “Market” Regulation: Confronting Industrial Agriculture’s Food Safety Failures, 17 WIDENER L. REV. 311, 337-38 (2011).

210. *Id.* at 338.

211. *Id.*

212. *Id.* at 337.

213. Mrill Ingram, *Keeping up with the E. Coli: Considering Human-Nonhuman Relationships in Natural Resources Policy*, 50 NAT. RESOURCES J. 371, 374-75 (2010).

214. *Id.* at 375.

facility, while it may be nutritionally advantageous<sup>215</sup> and perfectly safe if it is produced by a small, local facility. Congress must recognize that broad, sweeping legislation like the FSMA does not account for the different risks posed by varying sized food production facilities – namely that it does too little to be effective in mitigating risks posed by larger facilities, it is too broad to accommodate the needs of smaller facilities, and in reality, it does little to actually protect consumers. Consumers would be better served by more stringent regulations of large business, defined by market share, and government funded compliance for those businesses that occupy only a minor share of the market. The government’s role with respect to food safety, health, and nutrition should be to regulate large-scale food production operations while leaving consumers the choice to determine for themselves what is healthy and safe when buying from their local farm.

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215. The live enzymes in raw milk aid human digestion of sugars, fats, and minerals. *Id.* at 379.

