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Securing Food Justice, Sovereignty & Sustainability in the Face of the Food Safety Modernization Act (FSMA)

Eve Kerber*

I. INTRODUCTION

The laws we write, the goals we pursue, and the choices we make determine the health of the food system we create. Food sovereignty[1] and sustainability are not ideas that legislation enacts for us—they are ideas we must demand through processes that consider the public's opinions.

This article suggests that the public should utilize the Administrative Procedure Act's[2] notice and comment period to demand and effectuate a just food system—one that embraces food sovereignty and sustainability through promulgated regulations.

The Food Safety Modernization Act (FSMA) is one of the most significant food safety legislative actions Congress has enacted. It regulates all agricultural producers in an effort to prevent contamination of the US food supply, which considerably impacts our food system.[3] This sweeping legislation is reforming America's food safety laws; regulating all food

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* My most heart-felt thanks to my family, friends, and mentors, who have consistently encouraged and inspired me. A very special thank you to the most incredible woman I was blessed to be born with, and who, in return, was born with the burden of unconditionally loving me—my monozygotic twin, and love of my life, Sarah.

1 "Food sovereignty is the right of peoples to healthy and culturally appropriate food produced through sustainable methods and their right to define their own food and agriculture systems." *The International Peasant's Voice*, LA VIA CAMPESINA (Feb. 9, 2011, 2:16 PM), http://viacampesina.org/en/index.php/organisation-mainmenu-44.

2 5 U.S.C. § 551 (2011).

3 21 U.S.C. § 2201 (2010).

produced in industrial agriculture to food grown on small local farms.[4] The Food and Drug Administration (FDA) has yet to entirely promulgate the legislation's rules, therefore leaving opportunity for its regulations to be shaped by the demands of the public.[5] The written rules of FSMA must demonstrate the importance of small farms and facilities' sustainability in the face of FSMA legislation.

One of the central concerns about the legislation is its impact on local food producers, such as farmers' market vendors and community-supported agriculture (CSA) growers.[6] The law requires licensed food producers to pay fees to the FDA, and it sets traceability requirements and food safety standards.[7] Many local food producers fear that the costs of licensing, inspection, and implementation of FSMA's requirements will burden small food producers and will either drive them out of business, or discourage future small food production businesses.[8]

The history of this country has grown from the sweat and toil of farmers across the nation to feed our people. More recently, there has been a shift away from small, local food production to huge, industrial agriculture.[9]

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[4] See *FDA Food Safety Modernization Act: A Primer by FDA*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety/FSMA/ucm249243.htm (last updated Jan. 9, 2013), for a great tutorial to better understand FSMA.

[5] *The Food Safety Law and the Rulemaking Process: Putting FSMA to Work*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM277713.pdf (last updated Nov. 1, 2011).

[6] Laura Klein, *Turn Off the Alarm Bells . . .*, ORGANIC AUTHORITY (May 21, 2009), http://www.organicauthority.com/blog/organic/turn-off-the-alarm-bells%E2%80%A6/.

[7] *Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm (last updated Feb. 2, 2013).

[8] Shawn Stevens, *Food Safety Modernization Act: Are We Almost There Yet?*, DEFENDING FOOD SAFETY (Dec. 15, 2011), http://www.defendingfoodsafety.com/2011/12/articles/food-safety-news/the-food-safety-modernization-act-are-we-almost-there-yet/.

[9] What was once a "technological triumph" is now a "mistaken application to living systems." *Industrial Agriculture*, UNION OF CONCERNED SCIENTISTS, http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/industrial-agriculture/

Concomitant with this shift has been an increase in foodborne disease due to the capitalist nature of the industrial agriculture production process, which focuses on providing the highest quantity of food at the lowest prices.[10] Regulation of food produced by industrial agriculture is necessary to prevent increased risks of foodborne disease, yet FSMA's heavy regulation of small food production could potentially lead to the demise of small local farmers, leaving this nation with food grown solely by industrial agriculture. Simply put, regulation meant for industrial agriculture consequently favors industrial agriculture by promulgating rules to which only industrial agriculture can comply.

In response to the burdens imposed on small farms under FSMA, the Tester-Hagen Amendment (Tester Amendment) was included in FSMA's final legislation.[11] The Tester Amendment recognizes the importance of keeping small farms and food production facilities in business, and thus it exempts small farms and food production facilities from certain preventative aspects of FSMA.[12] This exemption allows a food system, other than industrial agriculture, to exist under the recent regulations. Nevertheless, how the rules and exceptions stemming from FSMA and the Tester Amendment are promulgated will determine whether a just food system will thrive.

The consistent theme from proponents for food sovereignty is that efforts to ensure food safety should not target or burden local farms that have a

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(last updated Aug. 30, 2012).

[10] *Public Health*, GRACE, http://www.gracelinks.org/270/public-health (last visited Feb. 10, 2013).

[11] Rebecca Gerenasy, *A Small Farmer's Viewpoint to the Tester Amendment*, HUFFINGTON POST FOOD BLOG (Jan. 13, 2011, 2:00 PM) http://www.huffingtonpost.com /rebecca-gerendasy/a-small-farmers-viewpoint_b_808605.html.

[12] Summary of Tester Amendment, Office of Senator John Tester (Nov. 18, 2010) *available at* http://files.meetup.com/1680824/tester_amendment_agreement_summary .pdf.

much better food safety record than large industrial agriculture.[13] Because the rules are still being written, no one is exactly sure how the federal rules will impact the states.[14] While FSMA includes the Tester Amendment, which exempts small farms and businesses from some of the regulations, the concern that the rules established to implement the new law will put new pressures on small local farms, continues to exist.[15] The threat to small farms regarding FSMA depends on its enforcement.[16]

This article addresses concepts of food justice, sovereignty, and sustainability. It also discusses how those concepts should inform the implementation of FSMA, and it recognizes that FSMA's implementation has a direct impact on our choices of food systems. First, this article begins by describing the shift of food production from small farms to industrial agriculture. Second, this article compares the two food systems that exist in our nation. Third, this article illustrates how small farms embrace concepts of food justice, sovereignty, and sustainability.

This article continues with a description of FSMA and its key authorities and mandates. It then introduces, and summarizes, the Tester Amendment to FSMA and discusses how it affects small food producers. This section further discusses critiques and endorsements of the Tester Amendment, and it addresses how the public is responding to those critiques.

Finally, this article describes the FDA's proposed rulemaking and comment process for FSMA, and it addresses how the rulemaking process can act as a vehicle for discourse for the public to demand that the government recognize the need, and support, for small farms when it comes to food justice, sovereignty, and sustainability.

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[13] Rich Hewitt, *Farmers Seek to Protect Locally Grown Foods*, BANGOR DAILY NEWS (Feb. 24, 2011, 9:15 PM), http://bangordailynews.com/2011/02/24/news/hancock/farmers-seek-to-protect-locally-grown-foods/.
[14] *Id.*
[15] *Id.*
[16] *Id.*

II. TWO FOOD SYSTEMS: INDUSTRIAL AGRICULTURE AND SMALL FARMS

A food system is best described as the entire set of activities and relationships that make up the various food pathways—from seed to table. It also influences the "how and why and what we eat."[17] It is important to remember that, despite any food system, there will always be food safety risks—at home, at a church supper, or on a small farm.

While there is no comfort in risk, the distinction is clear: there are two parallel food production and distribution systems in our country—industrial agriculture and small farms.[18] The incredible difference is the contained scope of a family farm compared to the large, industrial producers that affect hundreds of thousands of people in all fifty states.[19] Only one is inherently dangerous due to its scale, methodology, and distribution model, while the other depends on an intimate relationship between small local farmers who pride themselves on their work and their direct connection to consumers.[20]

The history of this nation's food production illustrates its shift from small farmers feeding their communities to industrial agriculture feeding the entirety of the nation. Understanding both food systems—industrial agriculture and small farms—is essential to build a foundation of knowledge about how small farms promote and prioritize food justice, food sovereignty, and sustainability.

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[17] ROBERT GOTTLIEB & ANUPAMA JOSHI, FOOD JUSTICE 5 (2010).

[18] *Will the Tester Amendment to S. 510 Help Small Farms and Processors, but Put More Kids at Risk?*, GRIST (Nov. 17, 2010, 7:26 AM), http://www.grist.org/article/food-2010-11-16-tester-amendment-to-s-510-help-small-farms [hereinafter *Kids at Risk*] (quoting Mark Kastel, co-founder of The Cornucopia Institute and director of its Organic Integrity Project).

[19] Press Release, Nat'l Sustainable Agric. Coal., Tester—Now More Than Ever, (Aug. 17, 2011), http://sustainableagriculture.net/blog/tester-now-more-than-ever/.

[20] *Id.*

A. Historical Shift of Food Production in the United States

This nation's production methods of produce have significantly changed since this nation's founding.[21] For example, before World War II, 24 percent of Americans were employed in agriculture—compared to 1.5 percent today.[22] In 1940, one farm worker supplied every eleven customers; today, it is one for every ninety.[23]

This historical shift in production is illustrated in politics. For example, President Obama's appointment of Tom Vilsack as the thirteenth Secretary of Agriculture was greeted with unhappiness by several food justice groups because of Vilsack's history of demonstrating preference for large industrial farms and genetically modified crops.[24] Change had seemed imperative, given the US Department of Agriculture's (USDA) history concerning key issues such as subsidies for commodity crops and support for genetically modified food technologies; its strong bias in favor of a chemically based agriculture; and its disregard of the conditions of farm labor.[25] Nevertheless, Obama appointed Vilsack despite Vilsacks's history of demonstrating preference for large industrial farms and genetically modified crops.[26]

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[21] 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, 59.

[22] MATTHEW SCULLY, DOMINION: THE POWER OF MAN, THE SUFFERING OF ANIMALS, AND THE CALL TO MERCY 29 (2002).

[23] *Id.*

[24] GOTTLIEB & JOSHI, *supra* note 17, at 75.

[25] *Id.*

[26] Mike Glover, Associated Press, *Vilsack, Gross Weigh in on Biotech Decision*, ORGANIC CONSUMER ASS'N (Oct. 24, 2002), http://www.organicconsumers.org /gefood/drugsincorn102302.cfm. As Iowa's governor, Vilsack originated a seed-preemption bill in 2005, effectively blocking local communities from regulating where genetically engineered crops would be grown. *Id.* Additionally, he was named Governor of the Year by the Biotechnology Industry Program, an industry lobbying group for genetically modified food. *BIO Thanks Agriculture Secretary Vilsack, Energy Secretary Chu for Biomass Program and R&D Grants*, BIOTECHNOLOGY INDUSTRY ORG. (May 5, 2011), http://www.bio.org/node/23.

Vilsack's appointment is just the latest chapter in the USDA's long history as a government entity—dating back to 1862 when President Lincoln established the Bureau of Agriculture (the Bureau), the predecessor of the USDA.[27] The Bureau was portrayed as the "People's Department," and it was "meant to serve the interests of the people who worked the land"— which is how President Obama characterized the USDA's origins at his press conference announcing Vilsack's appointment.[28]

Titling the Bureau as the People's Department accurately represented the laborers of the nation in the 1860s, with full-time farmers constituting as much as 48 percent of the population and with 90 percent of the population involved in farm-related activity.[29] The People's Department, at that time, was seen as representing a crucial segment of American politics.[30] In 1889, the Bureau was reorganized into a cabinet-level department and continued to expand its jurisdiction beyond its initial emphasis on services. Its dispensing of free seeds and crops was to become "the most dynamic portion of the national state," as one historian characterized it.[31] By the turn of the century, the USDA had become the third largest branch of the government, behind the Department of War and the Department of the Interior.[32]

The USDA's accumulation of responsibility at the turn of the century was a consequence of the Bureau of Chemistry being reorganized into the FDA in 1927.[33] The FDA was made responsible for protecting public health by

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[27] GOTTLIEB & JOSHI, *supra* note 17, at 75.
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.* at 75–76.
[32] *Id.* at 76.
[33] *Significant Dates in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm (last updated Nov. 6, 2012).

assuring that foods are safe, wholesome, sanitary, and properly labeled.[34] Despite reorganization, the USDA was given huge new social programs to administer from the late 1940s through the 1970s, and then again from the 1980s to the 1990s.[35]

None of these major food assistance programs challenged the primary orientation of the USDA, and the programs were embraced by the dominant large industrial agriculture and food industry as a way to expand market opportunities.[36] "Feed the poor and feed school children, but do it with the surplus commodity crops, surplus meat and dairy products," became part of the USDA's extended mission that combined large agriculture interests with the interests of social welfare programs.[37] In the end, concomitant with its growing social welfare focus, the USDA also reinforced its large agribusiness orientation.[38]

B. Food Production Today: Two Systems Compared

1. Industrial Agriculture as a Food System

The goals of industrial agriculture and its production processes are to increase yield and decrease costs of production.[39] Earl Butz, agribusiness revolutionary and Secretary of Agriculture appointed by President Nixon, exhorted farmers to plant their fields "fencerow to fencerow," and to "get

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[34] *About FDA: What Does the FDA Do?*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm (last updated Dec. 17, 2010).

[35] *See* GOTTLIEB & JOSHI, *supra* note 17, at 76–77. Examples of social programs the USDA was given to administer are the food stamp program, the National School Lunch Program, the Women, Infants, and Children program, and the Temporary Emergency Food Assistance Program. *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *The Costs and Benefits of Industrial Agriculture*, ALBERNI ENVTL. COALITION, http://www.portaec.net/library/food/costs_and_benefits_of_industrial.html (last visited Feb. 10, 2013).

big or get out."[40] His dream was to produce cheaper raw materials by vastly increasing the output of farmers.[41] Instead of produce coming from a single small farm and being sold directly to local consumers, industrial agriculture gathers produce from multiple farms and ships it all to central processing facilities where the produce is mixed and packaged for sale or sent for further processing.[42] However, this efficiency is not without risk; each additional process in the food production chain adds yet another opportunity for pathogens to contaminate the food supply—from contaminated water, to contact with infected animals, to mixing safe produce with tainted produce, to even exposure to ill farm or factory workers.[43]

2. Small Farms as a Food System

Small farms continue to have a large presence in society today. Small-scale farms make up over 71 percent of all farms; yet, they only produce approximately 7 percent of our food as measured by gross sales.[44] Some small family farms have been working their land for generations, while others view small farming as a new business opportunity.[45] Small farms can represent a principal means of economic support, yet, for others, small farming represents a lifestyle.[46] Despite their differences, small farms share

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[40] MICHAEL POLLEN, THE OMNIVORE'S DILEMMA: A NATURAL HISTORY OF FOUR MEALS 52 (2006).
[41] *Id.*
[42] Choo, *supra* note 21, at 59.
[43] *Id.* The industrial agriculture food production process has redefined foodborne illness outbreaks to the point where outbreaks caused by produce have surpassed outbreaks caused by tainted beef, poultry, or seafood. CSPI OUTBREAK ALERT DATA: INFO ON PRODUCE OUTBREAKS, CTR. FOR SCIENCE IN THE PUB. INT., http://cspinet.org/new/pdf/cspi_outbreak_alert.pdf.
[44] USDA NAT'L AGRIC. STATISTICS SERV., 2007 CENSUS OF AGRICULTURE—UNITED STATES DATA (2007), *available at* http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_1_US/st99_1_064_064.pdf.
[45] *Small Farms Overview*, U.S. DEP'T OF AGRIC., http://www.csrees.usda.gov/nea/ag_systems/in_focus/smallfarms_if_overview.html (last updated Mar. 18, 2009).
[46] *Id.*

valuable characteristics: a commitment to agriculture, strong links to local communities, and a need to love and care for the land.[47]

Small farms are becoming increasingly vulnerable to the combination of increased concentration among food processing companies, loss of competitive markets, and reduction of government price stabilizing tools, leaving them with less control over their economic security.[48] While some are profitable because of niche markets and proximity to urban centers, others continually watch their profit margins slowly erode.[49] The smallest farms suffer from a severe lack of resources, placing them below the poverty level, surviving only from their farm's income.[50] However, sometimes in these cases, quality of life and the desire to keep a farm in the family for future generations offset the lack of profitable production.[51]

a) Food Justice Through Small-Scale Farming

The food justice movement narrowly focuses on the relationship between a small-scale farmer, a consumer, and the environmental benefits of sustainable agriculture. The written rules of FSMA must demonstrate the importance of small farms' sustainability in the face of FSMA legislation, ensuring food justice despite regulation designed for industrial agriculture. Food justice ensures that the benefits and risks of where, what, and how food is grown, produced, transported, distributed, accessed, and eaten are fairly shared regardless of race, class, gender, ethnicity, citizenship, ability, religion, or community.[52]

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[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *What is Food Justice?*, FOOD JUSTICE BOOK (July 27, 2010), http://www.foodjusticebook.org/?page_id=6. See COMM. ALLIANCE FOR GLOBAL JUSTICE, OUR FOOD, OUR RIGHT: RECIPES FOR FOOD JUSTICE (2012), for some great recipes for food justice.

Food justice is also a powerful idea that resonates with many community groups and can be invoked to give rise to a different kind of food system.[53] The role of food justice is to open pathways for social and political action, and it helps establish a new language of social change in the food arena.[54] By recognizing and understanding the diverse participants in the food system, we can seek to advance knowledge about food justice dimensions of what, where, and how we eat—while describing opportunities for moving toward a more just, healthy, democratic, and community-based food system.[55]

b) Food Sovereignty and Sustainability Through Small-Scale Farming

The idea of food sovereignty is a potential answer for regulation that empowers industrial agriculture at the expense of small food farms. La Via Campesina coined the idea of "food sovereignty" in 1996.[56] This idea gave rise to a social movement focused on social sectors; such as urban-poor communities, associations, environmental groups, consumers, women's organizations, traditional fisherman and pastoralists, and many others.[57] Furthermore, many institutions and governments recognize food sovereignty.[58] The seven principles of food sovereignty are defined as:

> (1) **Food as a Basic Human Right**, that is, safe nutritious and culturally appropriate food in sufficient quantity and quality to sustain a healthy life with full human dignity; (2) **Agrarian Reform**, or ensuring that the land belongs to those who work it, especially women of color, who grow most of the world's food but rarely have ownership or control of the land; (3) **Protecting Natural Resources**, the sustainable care and use of natural

[53] GOTTLIEB & JOSHI, *supra* note 17, at 5.
[54] *Id.*
[55] *Id.* at 10.
[56] *The International Peasant's Voice*, *supra* note 1.
[57] *Id.*
[58] *Id.*

> resources, especially land, water, and seeds and livestock breeds; (4) **Reorganizing Food Trade** so that food is first and foremost a source of nutrition and only secondarily an item of trade; (5) **Ending the Globalization of Hunger** by multilateral institutions and by speculative capital . . . facilitated by the economic policies of multilateral organizations such as the WTO, World Bank and the IMF; (6) **Social Peace**, that is, freedom from violence, oppression of minorities and racism against peasant farmers, wherein food is never used as a weapon; and (7) **Democratic Control**, where everyone has the right to honest, accurate information and open and democratic decision-making.[59]

Simply put, "[f]ood sovereignty is the right of peoples to healthy and culturally appropriate food produced through sustainable methods and their right to define their own food and agriculture systems."[60] Sustainable agriculture describes farming systems that are "capable of maintaining their productivity and usefulness to society indefinitely."[61] Such systems must be "resource conserving, socially supportive, commercially competitive, and environmentally sound."[62]

Political systems have recognized the importance of food sovereignty. Congress addressed sustainable agriculture and food sovereignty in the 1990 Farm Bill.[63] The 1990 Farm Bill defines sustainable agriculture as an integrated system of plant and animal production practices that will satisfy human food needs; enhance environmental quality and the natural resource base upon which the agricultural economy depends; make efficient use of

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[59] Rebekah Wilce, *Local Ordinances and Land Grabs: Democracy Convention Panels Discuss Food Sovereignty*, PRWATCH (Sept. 8, 2011, 11:50 AM), http://www.prwatch.org/news/2011/09/10995/local-ordinances-and-land-grabs-democracy-convention-panels-discuss-food-sovereig.

[60] *The International Peasant's Voice*, *supra* note 1.

[61] Mary V. Gold, *What is Sustainable Agriculture?*, NAT'L AGRIC. LIBRARY, http://www.nal.usda.gov/afsic/pubs/agnic/susag.shtml (last updated July 18, 2012).

[62] *Id.*

[63] Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. No. 101-624, 104 Stat. 3359 (codified as amended in scattered sections of 7 U.S.C.).

nonrenewable resources and on-farm resources, and integrate natural biological cycles and controls; sustain the economic viability of farm operations; and enhance the quality of life for farmers and society.[64]

Directly related to the theme of this article, food sovereignty is people defining their own agriculture and food systems.[65] This places the idea of food sovereignty at the heart of political food systems and food aspirations, and at the center of the needs of livelihoods of farmers, producers, and consumers.[66] Food sovereignty is in direct conflict with the demands of industrial agriculture, which places its capitalist enterprise before concerns regarding local communities and the environment.

Food sovereignty gives priority to local production and local food consumption.[67] Most importantly, food sovereignty ensures that the right to use and manage land is in the hands of those who work the land and produce the food, not those who control the food industry. Food sovereignty further "develops a model of small scale sustainable production benefiting communities and their environment."[68]

III. THE FOOD SAFETY MODERNIZATION ACT (FSMA)

Every year, one in six Americans get sick from foodborne diseases.[69] According to recent data from the Centers for Disease Control and Prevention, of these forty-eight million sick from foodborne diseases,

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[64] Gold, *supra* note 61.
[65] *The International Peasant's Voice*, *supra* note 1.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Background on the FDA Food Safety Modernization Act (FSMA)*, U.S. FOOD & DRUG ADMIN., *available at* http://www.fda.gov/NewsEvents/PublicHealthFocus /ucm239907.htm (last updated Mar.18, 2013).

128,000 are hospitalized and 3,000 die.[70] This significant health burden is mostly preventable with adequate food safety measures.[71]

Acting in response to the growing casualties and preventability of foodborne disease, Congress enacted the FSMA in an effort to reform America's food safety laws.[72] On January 4, 2011, President Obama signed FSMA[73] into law. FSMA enables the FDA to better protect public health and prevent foodborne diseases by strengthening the food safety system.[74] The purpose of FSMA is to enable the FDA to focus on preventing food safety issues rather than on reacting to food safety issue occurrences.[75]

FSMA enables the FDA to enhance public health and prevent food safety issues with "new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur."[76] FSMA provides the FDA with the authority to increase risk-based inspections, to require mandatory recalls of tainted food, and to more effectively trace the source of foodborne illness outbreaks.[77] The FDA's deputy commissioner for foods, Michael R. Taylor, calls the new enforcement authorities critical for the success of FSMA, in part because it gives "the food companies strong additional incentives for keeping their products safe, and that helps us achieve the new law's goal, which is to protect consumers from unsafe food."[78]

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[70] *Id.*
[71] *Id.*
[72] *Id*.
[73] 21 U.S.C. § 2201 (2010).
[74] *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[75] *Id.*
[76] *Id.*
[77] *President Obama Signs Food Safety Modernization Act into Law*, NAT'L SUSTAINABLE AGRIC. COAL. (Jan. 7, 2011), http://sustainableagriculture.net/blog/obama-signs-food-safety-bill-2/.
[78] *The 'Teeth' of FDA's Food Safety Law*, U.S. FOOD & DRUG ADMIN. (Aug. 10, 2011), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM267486.pdf.

Consumer advocates have praised the new authority granted to the FDA by FSMA.[79] The Center for Science in the Public Interest has hailed the Act as a far-reaching improvement over previous food safety laws, and Kathy Means—vice president of the industry trade group Produce Marketing Association—said members of her organization "regard FSMA as a law that takes a good, comprehensive look at food safety. It sets the expectations for food safety measures by the industry, and it sets the priorities for the FDA—all of which is important for keeping our food safe."[80]

As an administrative agency, the next step for the FDA to implement FSMA is to allow the public to comment on the proposed legislative rules through the rulemaking process.[81] This process provides the public an opportunity to offer input and insight on how the Act will not only impact small farms and facilities, but also how its impact will affect our food systems. The FDA has established its objectives regarding rulemaking, though the FDA will not implement specific rules until six months to two years after the enactment of FSMA.[82]

A. The FDA's Key New Authorities and Mandates

1. Prevention

FSMA's purpose is to prevent foodborne disease.[83] For the first time, the FDA has a legislative mandate that requires comprehensive, scientific, and preventative controls for every step of the food production process.[84] First, FSMA requires food facilities to implement written preventative control plans that (1) evaluate the hazards that could affect food safety; (2) specify

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[79] *Id.*
[80] *Id.*
[81] *The Food Safety Law and the Rulemaking Process: Putting FSMA to Work*, *supra* note 5.
[82] *Id.*
[83] *See Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[84] *Id.*

what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards; (3) detail how the facility will monitor these controls to ensure they are working; (4) maintain routine records of the monitoring; and (5) list what actions the facility will take to correct problems that arise.[85]

Second, the FDA will establish standards for the safe production and harvesting of fruits and vegetables—which will consider soil amendments, such as compost being added to the soil, temperature controls, animals in the growing area and near the water source, and naturally occurring hazards.[86] Examples of naturally occurring hazards that cause food and crop contamination are: faulty employee hand washing and sanitation practices; handling of food by sick employees; contamination of irrigation water by human or animal feces flowing downhill; livestock in close proximity to food; and irregular application of and record keeping regarding composted manure treatment.[87]

Third, FSMA grants the FDA the authority to prevent intentional contamination.[88] Intentional contamination can be chemical, biological, radiological, or nuclear.[89] While intentional contamination typically refers to foreign terrorist threats, other threats of intentional contamination can arise from disgruntled employees and economic adulteration.[90]

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[85] *Id.*
[86] *Id.*
[87] Gretchen Goetz, *Bridging the GAP: Bringing Big Food Safety Regulations to Small Farms*, FOOD SAFETY NEWS (Oct. 24, 2011), http://www.foodsafetynews.com/2011/10/bridging-the-gaps-bringing-big-food-safety-regulations-to-small-farms/.
[88] *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[89] *Food Defense Mitigation Strategies Database*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm (last updated April 4, 2012).
[90] *Id.* Economic adulteration occurs where "less expensive ingredients are substituted or the proportion of more expensive ingredients are diminished so as to make the commonly identified article inferior to that which the consumer would expect to receive when purchasing it." 36A C.J.S. *Food* § 23 (2013).

2. Compliance

Despite the FDA's prevention measures, preventative control standards only improve food safety to the extent food producers comply with them. Therefore, FSMA authorizes the FDA to provide oversight, to ensure compliance with requirements, and to effectively respond to problems that emerge.[91] FSMA provides the FDA with new tools for inspection and compliance such as: mandating inspections of food facilities, basing the frequency of inspections on risk, and requiring the immediate increase of the frequency of food facility inspections.[92] The FDA will also have access to records, including industry food safety plans.[93] These industry food safety plans will most likely replicate the retail food industry, where food safety is enhanced by managers assessing their food safety systems, implementing appropriate procedures and training, and actively monitoring compliance to reduce risk in retail operations.[94] Further, FSMA requires food testing to be conducted by accredited laboratories and requires the FDA to establish accreditation for US food testing that meets high-quality standards.[95] Mirroring regulation of the retail industry, the FDA will likely work with its partners to assess the effectiveness of managerial control strategies, to identify and share best practices, and to verify implementation to broaden the use of effective tools throughout the industry.[96]

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[91] *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[92] *Id.*
[93] *Id.*
[94] *Backgrounder: FDA Retail Food Safety Initiative*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm230315.htm (last updated Oct. 22, 2010).
[95] *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[96] *Backgrounder: FDA Retail Food Safety Initiative*, *supra* note 94.

3. Response Mechanisms

FSMA provides the FDA with authoritative tools to effectively respond to problems that occur despite preventative controls.[97] Some of these tools include the authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after notification by the FDA; establish a product-tracing system in order to rapidly identify recipients of contaminated food and prevent a foodborne illness outbreak; suspend registration of a facility if it determines that its food poses a reasonable probability of serious adverse health consequences or death; and propose rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the secretary of the Department of Health and Human Services (Secretary) designates as high-risk foods.[98]

4. Partnerships

FSMA also enhances partnerships by building a system of collaboration with all food safety government agencies so that public health goals are achieved.[99] For example, FSMA provides the FDA with new grants to facilitate investment in state and local agencies to achieve food safety goals.[100] In addition, the FDA is authorized to rely on inspections conducted by other federal, state, and local agencies to help meet its increased inspection mandate.[101]

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[97] *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*

IV. THE TESTER AMENDMENT: RECONCILING FOOD SAFETY CONCERNS WHILE PROTECTING SMALL FARMS AND PRESERVING FOOD SOVEREIGNTY

The Tester Amendment was included in the final legislation of FSMA to address concerns regarding the new regulations and their impact on small, local food producers.[102] Because FSMA was originally written to treat all food farms and facilities the same, Montana Senator Jon Tester introduced the Tester Amendment to FSMA in order to exempt small farms and facilities from its preventative control provisions.[103] Food farms and facilities qualify for the exemption if, during the previous three-year period, the average monthly value of food sold was less than $500,000.[104] However, those sales must be to consumers, restaurants, or grocery stores, as opposed to third-party food brokers.[105] Additionally, those sales must have been made in the same state where the facility sold the food, where the farm harvested or produced the food, or within 275 miles of the farm or facility.[106]

In addition to local requirements, all farms and facilities eligible for the exemption from preventative control provisions must also comply with FSMA—either by demonstrating to the FDA that potential hazards have been identified and that preventative controls are currently being implemented to address those hazards, or by demonstrating to the FDA that they are in compliance with state or local safety laws.[107] If a farm or facility chooses to comply with the latter requirement, that farm or facility must

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[102] *Id.*
[103] S. 510, 111th Cong. § 103 (2010); Summary of Tester Amendment, *supra* note 12. See *supra* notes 82–89 and accompanying text for more information on specific preventative control measures.
[104] Summary of Tester Amendment, *supra* note 12.
[105] *Id.*
[106] *Id.*
[107] *Id.*

prominently display on all of its food labels information linking food distributed from that farm or facility.[108]

The exemption is limited in the event of an active investigation of a foodborne illness outbreak directly linked to the farm or facility.[109] The exemption is also limited if the Secretary determines, based on conduct or conditions associated with the farm or facility, that it is necessary to protect public health and prevent or mitigate a foodborne illness outbreak.[110] Under this limitation, the Secretary may withdraw the exemption provided to a farm or facility.[111]

Without the Tester Amendment, FSMA would unnecessarily burden small, local food producers that provide an alternative to the industrialized food supply. Should any problems arise, these small-scale farmers and processors have a direct relationship with their customers—ensuring traceability.[112] Furthermore, FSMA would unnecessarily burden small-scale food producers that are already regulated by local and state authorities by adding an additional layer of compliance. Additional compliance is excessive given that their size and limited food production processes inherently limit the potential risks of their products.[113]

Even with the Tester Amendment, small farms and facilities are subject to increased regulations and compliance requirements.[114] Additional licensing fees and costs for inspections cut profits from small farms and

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[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] Letter in Support of Tester Amendment, Support Fresh, Safe Local Food in the Food Safety Bill (Nov. 6, 2010), *available at* http://mainstreetinsider.org/pdf/Group%20letter%20-%20Tester%20Amendment.pdf.
[113] *Id.*
[114] Gretchen Goetz, *Bridging the GAP: Bringing Big Food Safety Regulations to Small Farms*, FOOD SAFETY NEWS, Oct. 24, 2011, http://www.foodsafetynews.com/2011/10/bridging-the-gaps-bringing-big-food-safety-regulations-to-small-farms/.

facilities that already struggle with minute profit margins.[115] FSMA regulations illustrate the theme of regulating the poor in order to promote commercialization, industrial agriculture, and a capitalistic food system. This demands the public's participation in the rulemaking process and promulgation of FSMA's rules to demonstrate the public's concern for the sustainability of small farms and food sovereignty.

A. Tester Amendment Assessments

1. Criticism of the Tester Amendment

Not everyone welcomed the Tester Amendment as an addition to FSMA. In a letter—sponsored by the United Fresh Produce Association, along with fifteen other associations ranging in size—critics asserted that "the Tester [A]mendment utterly fails to protect consumers by including blanket exemptions from the rest of the bill's strong safety net, without regard to risk."[116] The represented associations are appalled by Senator Tester saying that small producers do not raise a commodity, but raise food, while industrial agriculture takes people out of the equation.[117]

Furthermore, even ardent supporters of the local food movement have concerns with the Tester Amendment. First, the Tester Amendment allows preventative regulations to be dictated by state law.[118] Because laws can vary significantly from state to state, the adoption of the Tester Amendment means that the federal government essentially lacks an opportunity to adopt

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[115] Rebecca Gerenasy, *A Small Farmer's Viewpoint to the Tester Amendment*, HUFFINGTON POST (Jan. 13, 2011, 2:00 PM), http://www.huffingtonpost.com /rebecca-gerendasy/a-small-farmers-viewpoint_b_808605.html.

[116] Letter in Opposition to Tester Amendment (Nov. 18, 2010), *available at* http://www.unitedfresh.org/assets/files/Letter%20on%20Passage%20of%20S%20%20510%20and%20Tester%20Amendment.pdf.

[117] *Id.*

[118] Alex Ferguson, *What's Wrong with the Tester Amendments*, FOOD SAFETY NEWS (May 4, 2010), http://www.foodsafetynews.com/2010/05/whats-wrong-with-the-tester-amendments/#.UQsyFUqs3C4.

national standards for hazard analysis and risk-based preventative controls.[119] The resulting risk is that a consumer at a grocery store will not know whether they are purchasing food from a state with safe preventative controls or from a state without.[120] While some will argue that this will encourage shopping at farmers' markets, the reality is that the majority of this nation's citizens buy their food from supermarkets, and those citizens deserve assurance of the safety of their food.[121]

Another problematic provision of the Tester Amendment is the limit on recordkeeping requirements for facilities that have an average annual adjusted gross income—for the previous three-year period—of less than $500,000.[122] Because the Tester Amendment only requires records to be kept for immediate suppliers and recipients, the result is a huge hindrance in the push for national traceability requirements.[123] The $500,000 limit exempts nearly 95 percent of all small farms from FSMA's strict traceability standards, which nearly eliminates the effectiveness of the national requirements.[124] Any delay in traceability can lead to more foodborne illnesses and deaths when an outbreak occurs.[125]

Finally, small food facilities are exempt from produce safety requirements "if the qualifying facility's annual value of sales of food directly to consumers, hotels, restaurants, or institutions exceeds the annual value of sales of food to all other buyers."[126] This specific provision requires proposed rulemaking "to establish science-based minimum standards for the safe production and harvesting of those types of fruits and

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[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *Id.* I would argue that national traceability requirements are not needed for food exclusively sold locally.
[124] *Id.*
[125] *Id.*
[126] *Id.*

vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."[127] Because of how uncomplicated, yet important, produce safety measures are, critics do not believe small farms should be exempt from this provision.[128]

However, because this provision is subject to the rulemaking process—small farms, proponents of food justice, sustainability and sovereignty, and the public will be able to offer input on how these standards for production and harvesting would be measured.

2. Support for the Tester Amendment

Supporters for the Tester Amendment argue that it ensures that small farms and facilities thrive under regulation designed for industrial agriculture.[129] While the bill is far from perfect, some believe the backing of the Amendment by the National Sustainable Agriculture Coalition (NSAC) assures "protections and size-appropriate alternatives from cumbersome, one-size-fits-all regulations for smaller farms and processors and for local and regional food systems."[130] The NSAC serves as an alliance of grassroots organizations that advocates for federal policy reform to promote sustainability of agriculture, food systems, natural resources, and rural communities.[131]

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[127] *Id.*
[128] *Id.*
[129] The Carnegie-Knight News21 Program, *Powerful Coalition Gains Exemption for Small Farmers*, FOOD SAFETY NEWS (Nov. 18, 2011),http://www.foodsafetynews.com/2011/11/powerful-coalition-gains-exemption-for-small-farmers/#.URCC46U0rap.
[130] *President Obama Signs Food Safety Modernization Act into Law*, *supra* note 77.
[131] *About Us*, NAT'L SUSTAINABLE AGRIC. COALITION, http://sustainableagriculture.net/about-us/ (last visited Feb. 11, 2013). Member groups of the NSAC work to advance support of small and mid-size farms. *Id.* Through their work the NSAC is able to bring grassroots perspectives to policy reform typically dominated by big business and give voice to sustainable and organic farmers. *Id.*

Because FSMA was originally written to treat all farms and facilities the same, it adds responsibilities that small farmers and facilities will find onerous or unduly cumbersome.[132] The possible imposition of these burdens united many small farmers who were willing to have the entirety of FSMA struck from legislation if the Tester Amendment was not included.[133] Small farmers felt that since they were not part of the problem, due to their direct sales to local consumers, they should not have to suffer an undue burden to be part of the solution.[134]

FSMA mandates steps to address contamination problems that still espouse the exemptions made under the Tester Amendment. First, FSMA provides the FDA competitive grants to achieve food safety goals.[135] These goals can be achieved through FSMA's National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program, which will propose solutions to common contamination problems.[136] This program will provide food safety training to small farms, small food processors, and small fruit and vegetable merchant wholesalers.[137] Second, FSMA limits the exemption in the event of an active investigation of a foodborne illness outbreak directly linked to the small farm or facility, allowing the Secretary to withdraw the exemption.[138]

Accomplished Seattle food safety lawyer Bill Marler welcomes FSMA.[139] However, one of Marler's main critiques of FSMA is that

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[132] Ezra Klein, *Michael Pollan on the Food Safety Bill*, WASH. POST (Nov. 18, 2010, 4:36 PM), http://voices.washingtonpost.com/ezra-klein/2010/11/michael_pollan_on_the_food_saf.html.
[133] *Id.*
[134] *Id.*
[135] *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.
[136] *FDA FSMA and Small Business*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety/FSMA/ucm268229.htm (last updated Mar. 1, 2012); Press Release, Nat'l Sustainable Agric. Coal., *supra* note 19.
[137] Press Release, Nat'l Sustainable Agric. Coal., *supra* note 19.
[138] Summary of Tester Amendment, *supra* note 12.
[139] Choo, *supra* note 21, at 61.

registration fees and hazard control plans will drive up the costs for small farmers and producers.[140] Marler says that he has "never had an outbreak linked to a farmers' market."[141] Further, he thinks "local farmers have a point that they haven't been linked to outbreaks, so why put an added burden on them?"[142]

Because of the Tester Amendment, the FDA will study the incidence of foodborne illness, in relation to the size of food operations, for the first time.[143] Small and local farm advocates predict the findings will support their assertion that small-scale growers produce safer food, in part because fewer people handle it.[144] Also, due to the direct-sales relationship between small-scale producers and their customers, if an outbreak does occur, it can be quickly traced.[145]

Despite statistics that speak to the contrary, consumer groups continue to argue against the Tester Amendment because they assert there are risks to food safety no matter the scale of the operation.[146] For example, some national produce industry groups are exploiting a recent outbreak of the E. coli bacteria, believed to have originated in strawberries from an Oregon farm, to discredit and even repeal the Tester Amendment.[147]

In reality, the Tester Amendment exemptions will not jeopardize the safety of our nation's food supply because it includes transparency and traceability measures, including specific notifications to consumers about the origin of the food they are purchasing.[148] Once the Tester Amendment is implemented, all food purchased from a small farm or facility that is

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[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] The Carnegie-Knight News21 Program, *supra* note 129.
[144] *Id.*
[145] *Id.*
[146] Choo, *supra* note 21, at 59.
[147] Press Release, Nat'l Sustainable Agric. Coal., *supra* note 19.
[148] *Id.*

exempted by the Tester Amendment will have the farm or facility from which it was produced prominently displayed on the food label.[149] The limited scale of production and distribution between a small farm or facility and a shopper inherently allows for an easily traceable loop because the identity of the farm or facility is preserved.[150] Thus, while there are lessons to be learned from the Oregon outbreak, the problems it presented will be easily resolved by the Tester Amendment.[151]

B. FDA Response to the Financial Strains FSMA Imposes on Small Farms

Reacting to the increased strain on small farms and facilities from having to comply with FSMA, the FDA has taken steps to relieve small farms of their increased burden. First, the FDA has stated it will partner with small farmers and facilities to educate and train them through guidance documents that address the real-world issues that they, as small farmers and facilities, face in attempting to abide by, and comply with, the new rules.[152]

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[149] Summary of Tester Amendment, *supra* note 12.

[150] *Id.* In fact, in the specific case of the Oregon strawberry outbreak, the foodborne illnesses caused by the strawberries from the Oregon farm were traced with speed and accuracy because of the farm's small size. Press Release, Nat'l Sustainable Agric. Coal., *supra* note 19. The only significant hindrance was the fact that some resellers of the tainted berries failed to declare where they received the berries. *Id.*

[151] Press Release, Nat'l Sustainable Agric. Coal., *supra* note 19. It should be further noted that groups attempting to use the strawberry E. coli incident as leverage to repeal the Tester Amendment are likely politically motivated to shift the focus away from the inherently risky large-scale production process toward a naturally occurring hazard on small farms. Groups representing these large-scale operations are concerned about any regulation that levels the playing field for small-scale producers that compete with industrial agriculture in the food market. The current theory regarding the tainted strawberries is that infected deer may have wandered into the strawberry field, contaminating the strawberries—a risk that cannot be avoided by the FSMA regulations devoid of the Tester exemption. Health officials have emphasized that the farm in question acted accordingly, and that the same farm may not even be eligible for the Tester Amendment provisions to begin with. *Id.*

[152] Margaret A. Hamburg, Comm'r of Food & Drugs, Remarks at the 34th Annual National Food Policy Conference (Oct. 4, 2011), http://www.fda.gov/NewsEvents/Speeches/ucm274449.htm.

Additionally, the FDA has committed itself to educate and train its own work force to inspect facilities with an eye toward prevention and problem solving, and to avoid simply citing small farms and processors for every possible infraction.[153] Not only has the FDA clarified that it needs to stay up to date on the science of produce and innovative industry technologies and practice, it has also stated that it needs to invest more to train, educate, inspect, and research.[154] However, the FDA admits it cannot live up to the promise of food safety reform envisioned by FSMA without a significant infusion of funds.[155] Meanwhile, the legislation, which is estimated to cost $1.4 billion over five years, faces considerable opposition by a budget-conscious Congress.[156] Without the appropriate budget, the FDA will be less likely to address the concerns of financial burdens imposed on small farms and processors when facing financial concerns for the legislation itself.

Needless to say, all involved in the debate and critique of the Tester Amendment share compassion for those who have suffered serious illness caused by contaminated food.[157] Nonetheless, no matter what procedures and protocols are incorporated in small farm or industrial agriculture food systems, neither will be completely safe.[158]

Recognizing the inherent risks of eating, consumers have the right to choose between two food systems. Without the Tester Amendment, the resurgence of small farms and local food will be stifled by undue burdens in the name of public health under FSMA, and the United States will lose an attractive alternative to the distinctly risky, highly industrialized food

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[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] *President Obama Signs Food Safety Modernization Act into Law*, *supra* note 77.
[157] *Kids at Risk*, *supra* note 18.
[158] *Id.*

system.[159] Yet, even if FSMA is implemented with the Tester Amendment, some small farm activists do not believe that the Tester Amendment reaches far enough to encourage small farms to thrive and conduct business in their local communities, as the following section illustrates. Since neither food production system is 100 percent safe, consumers should be given the prerogative to weigh risks, and select the food system they prefer.[160]

C. Public Response to the Financial Strains FSMA Imposes on Small Farms

1. Constitutional Commerce Discourse as a Response to FSMA Regulations

In Maine, small-scale farms' rallying cry, "from farm to table," represents their fight against what they consider to be burdensome state and federal regulations, such as those found in FSMA.[161] "From farm to table" represents local farmers' determination to align food policy and regulations with their food philosophy.[162] Through their fight, small farms are laying the foundation for a food sovereignty movement aimed at restoring the direct relationship between food producers and consumers while reducing government interference with local food systems.[163] FSMA, as detailed above, expands the regulatory powers of the FDA.[164] But while the bill "aims to ensure the U.S. food supply is safe by shifting the focus of federal

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[159] Press Release, Nat'l Sustainable Agric. Coal., *supra* note 19.
[160] *Kids at Risk*, *supra* note 18.
[161] Deirdre Fulton, *Free Our Food*: *Small Farmers Demand Independence From Agrobusiness Industry Rules*, THE PORTLAND PHOENIX (May 4, 2011), http://portland.thephoenix.com/news/120146-free-our-food/?page=1#TOPCONTENT. Blue Hill peninsula, a tiny cluster of rural, coastal towns just north of Portland, Maine, is leading the movement. *Id.*
[162] *Id.*
[163] *Id.*
[164] *See Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 69.

regulators from responding to contamination to preventing it," it has united political groups that feel the bill overreaches.[165]

"I think we've been colonized by a global economy that doesn't recognize the value of local communities," says Bob St. Peter, a farmer in Sedgwick, Maine, and director of Food for Maine's Future, a local-food advocacy organization.[166] St. Peter asserts that the rules and regulations that have evolved over generations have created a situation where, even if people wanted to feed themselves locally, they cannot.[167] Thus, St. Peter underscores a current two-option strategy: "[W]e can buy into the industrial system, or we can create our own rules."[168] People in Maine are choosing the latter route.[169] The Farm-to-Consumer Legal Defense Fund[170] claims that the "FDA has used its existing power to benefit the pharmaceutical and

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[165] *Id.*
[166] *Id.*
[167] *Id*.
[168] *Id.*
[169] *Id.*
[170] *See Our Mission*, FARM-TO-CONSUMER LEGAL DEF. FUND, http://www.farmtoconsumer.org/mission-statement.html (last visited Feb. 20, 2013).

> The Farm-to-Consumer Legal Defense Fund (FTCLDF) is a 501(c)(4) non-profit organization whose members are joining together and pooling resources to:
>
> - Protect the constitutional right of the nation's family farms and artisan food producers to provide processed and unprocessed farm foods directly to consumers through any legal means.
> - Protect the constitutional right of consumers to obtain unprocessed and processed foods directly from family farms and artisan food producers.
> - Protect the nation's family farms and artisan food producers from harassment by federal, state, and local government interference with food production and/or food processing.

Id.

biotechnology industries at the expense of public health."[171] This parallels the FDA designing legislation for industrial agriculture at the expense of small farmers.

Activists interested in the food sovereignty movement are attempting to gather a political foothold by challenging the Constitution's Commerce Clause. The food sovereignty movement and philosophy applies broadly: it is knowing the hand that feeds you.[172] Activists interested in introducing state regulations against the federal government's right to regulate through the Constitution's Commerce Clause [173] have contacted the Tenth Amendment Center to explore what would make the food sovereignty movement law.[174]

The Tenth Amendment Center is a national think tank that "works to preserve and protect the principles of strictly limited government . . . , [and] it serves as a forum for the study and exploration of state and individual sovereignty issues, focusing primarily on the decentralization of federal government power as required by the Constitution."[175] In situations such as this, the Tenth Amendment Center promotes its model legislation, the Intrastate Commerce Act, which specifically focuses on goods produced and sold within state boundaries.[176] Thus, in lieu of the Tester Amendment, and under the Intrastate Commerce Act, if a small farm grows and sells its

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[171] Pete Kennedy, *Food Safety–Can FDA Be Trusted*, FARM-TO-CONSUMER LEGAL DEF. FUND, http://www.farmtoconsumer.org/news/news-29jan2010-food_safety.html (last updated Feb. 2, 2010).
[172] *Id.*
[173] U.S. CONST. art. 1, § 8, cl. 3.
[174] H.R. 870, 125th Leg., 1st Reg. Sess. §§ 1409(5), 1410(1) (Me. 2011), *available at* http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0870&item=1&snum=125.
[175] *About the Tenth Amendment Center*, TENTH AMENDMENT CENTER, http://www.tenthamendmentcenter.com /about/ (last visited Feb. 20, 2013).
[176] *Intrastate Commerce Act: Summary*, TENTH AMENDMENT CTR., http://www.tenthamendmentcenter.com/legislation/intrastate-commerce-act/ (last visited Feb. 20, 2013).

food within state boundaries it would not be subject to FSMA's regulation.[177]

A summary of the Intrastate Commerce Act, presented by Republican representative Melvin Newendyke of Litchfield, Maine, reads:

> The power to regulate intrastate commerce is reserved to the states or the people . . . . A person may not enforce or attempt to enforce a federal law that regulates . . . goods grown, manufactured or made in this State . . . when those goods or services are sold . . . exclusively in this state.[178]

However, legislation introduced to amend a state's constitution in an attempt to fight against federal regulation may "almost certainly be unconstitutional," says H. Cabanne Howard, an assistant professor of law and public policy at the University of Maine School of Law.[179] Howard asserts that federal commerce interpretations are very broad and include regulation of intrastate commerce.[180]

This is illustrated in the Supreme Court's significant decision in *Wickard v. Filburn.*[181] Filburn owned a small dairy farm in Ohio and grew wheat primarily for home consumption and to feed his livestock.[182] Under the Agricultural Adjustment Act, the Secretary of Agriculture set a quota for wheat production and each farmer was given an allotment.[183] Filburn claimed that the federal law could not constitutionally apply to him because the wheat that he grew in excess of his specific allotment was for home

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[177] H.R. 870, 125th Leg., 1st Reg. Sess. §§ 1409(5), 1410(1) (Me. 2011), *available at* http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0870&item=1&snum=125.
[178] *Id.*
[179] Fulton, *supra* note 161.
[180] *Id.*
[181] Wickard v. Filburn, 317 U.S. 111 (1942).
[182] *Id.* at 114.
[183] *Id.* at 113.

consumption, and, as a result, was not a part of interstate commerce.[184] Despite Filburn's argument, the Court upheld the application of the federal law to home grown wheat because of the aggregate effect of the wheat on the national market.[185] The Court noted that even though Filburn's "own contribution to the demand for wheat may be trivial by itself, [it] is not enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial."[186]

Despite the Court's broad interpretation regarding the constitutional breadth of the Commerce Clause, small-scale food production activists consistently insist that FSMA increases small farmers' regulatory burdens and limitations to a level that is unconstitutional.[187] Furthermore, the fear of those burdens resulting in the loss of many small farmers drives the introduction of initiatives, such as the Intrastate Commerce Act, to establish a precedent allowing small-scale food farmers and producers to realize their potential, stimulate the economy, and allow for a food system that embraces food sovereignty in our country.[188]

2. Local Ordinance Discourse as a Response to FSMA Regulations

Due to the increasing state and federal regulations, such as FSMA, not only are small local farmers threatened, but also are local residents and their rights to buy local food.[189] One possible solution is the local ordinance movement, which embraces the willing seller and willing buyer philosophy and declares that people have the right to produce, sell, and consume local

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[184] *Id.* at 115–16, 119.
[185] *Id.* at 127–28.
[186] *Id.*
[187] Fulton, *supra* note 161.
[188] Hewitt, *supra* note 13.
[189] *Id.*

foods without the intervention of state licensing or inspections.[190] The local ordinances would exempt small farms from new state licensing and inspection requirements as long as farm products are sold directly to a consumer for home consumption.[191]

Local ordinance proponents argue that the best way to ensure food safety is to provide food raised and prepared close to where consumers purchase and consume it.[192] "If someone comes up my driveway, and can look around and inspect the operation, they can decide whether our food is right for them," said a small farm farmer in Penobscot, Maine.[193] "They don't need the government to decide for them."[194]

The local ordinance movement is illustrated by a bill cosponsored by Maine Representative Walter Kumiega[195] that was presented to and defeated by both legislative committees in both the House and the Senate.[196] The ordinance focuses on concerns regarding small farms viability because of the growing number of requirements under FSMA to build and maintain facilities that are designed for industrial agriculture operations.[197] Supporters of the ordinance assert that the state rules, which are based on federal regulations introduced by FSMA, are too complicated, restrictive, and costly for small local farmers.[198] Farmers that want to protect locally grown food assert that "[b]ackers of the local food ordinance movement

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[190] *Id.*
[191] Hewitt, *supra* note 13.
[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] H.R. 870, 125th Leg., 1st Reg. Sess. (Me. 2011), *available at* http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0870&item=1&snum=125.
[196] *Actions for LD 722*, STATE OF MAINE LEGISLATURE, http://www.mainelegislature.org/LawMakerWeb/dockets.asp?ID=280040711.
[197] Hewitt, *supra* note 13.
[198] *Id.*

argue that so long as there is a willing seller and a willing buyer, there is no need for a small farm operation to be licensed or inspected by the state."[199]

However, questions remain regarding "whether the ordinances would supersede state and federal law."[200] Advocates insist "that the authority to enforce local ordinances is rooted in the principles of local control and self-government," and that those principles are "backed by the Declaration of Independence and the Maine Constitution as well as by Maine law."[201] Here, Maine law grants municipalities "all powers necessary to protect the health, safety and welfare of residents of the town."[202] Proponents also cite to a separate Maine law that declares, "it is the policy of the state to encourage food self-sufficiency for the state."[203] While the proposed ordinance is the first to directly relate to food and farming, the "rights-based" ordinance "is similar to ordinances enacted in other Maine towns relating to large-scale water extraction . . . , genetically modified organisms and corporate personhood."[204]

The largest issue surrounding the enforceability of the local ordinance is that the federal funding, which the state depends on for its inspection programs, is linked to adopting federal rules and regulations.[205] With the threat of the USDA and the FDA withholding funds unless the state enforces the regulations, any local ordinance within any state must carefully balance its principles and priorities and work within the framework of federal regulations.[206]

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[199] *Id.*
[200] *Id.*
[201] *Id.*
[202] *Id.*
[203] *Id.*
[204] *Id.*
[205] *Id.*
[206] *Id.*

V. RULEMAKING AS A PROCESS TO EFFECTUATE A JUST FOOD SYSTEM THAT PROMOTES FOOD SOVEREIGNTY AND SUSTAINABILITY

During the rulemaking process, interested persons are provided an opportunity to submit written data, views, or arguments about a proposed rule.[207] The FDA is charged with preparing more than fifty rules, guidance documents, reports, and studies within specific timeframes under FSMA.[208] The FDA is seeking public comments on proposed rules and regulations to consider in its implementation of FSMA; because FSMA is put into action through the rulemaking process, which requires a period for consideration of input from interested persons, the public has an opportunity to demand regulations that permit small farms to thrive.

For instance, on the open docket of the Federal Register is the FDA's *Burden of Food and Drug Administration Food Safety Modernization Act Fee Amounts on Small Business*, which allows interested persons to offer input on FSMA's economic implications for small farms.[209] FSMA provides the FDA with authority under the Food, Drug, and Cosmetic Act to assess and collect user fees, including costs for domestic reinspection and failure to comply with a recall order.[210] The FDA is seeking public comments on what burdens these fees should impose on small businesses, and whether and how the FDA should alleviate those burdens with respect to the fee issue.[211] Specifically, the FDA is seeking opinions on whether a reduction of fees is appropriate for small businesses, and in the event that a reduction

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[207] Administrative Procedure Act, 5 U.S.C. § 553(c) (1946).
[208] *See FSMA Implementation Management Structure*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodSafety/FSMA/ucm249297.htm (last updated Jan. 11, 2012).
[209] *See* Request for Comments, Burden of Food and Drug Administration Food Safety Modernization Act Fee Amounts on Small Business; 76 Fed. Reg. 45818 (Aug. 1, 2011), http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0001.
[210] *Id.*
[211] *Id.*

is called for, what factors should be considered.[212] Additionally, the FDA is seeking public comments on how small business should be defined.[213]

To clarify, the imposed fees provide for the recovery of costs associated with small businesses in the food industry whose noncompliance requires the FDA to conduct additional follow-up activities.[214] There are two instances where the FDA could assess fees in regard to noncompliance with small, local food farmers and processors: (1) facility reinspections to determine whether compliance has been achieved after finding a violation materially related to food safety requirements during a previous inspection, and (2) food recall activities conducted by the FDA as a result of noncompliance with a recall order.[215]

The FDA has stated that it recognizes that the full cost of reinspection or recall oversight on small business may cause severe economic hardship.[216] Based on that severe hardship, the FDA announced it would consider a waiver of some or all invoiced fees during the 2012 fiscal year on a case-by-case basis,[217] and that it would consider the waiver based on the nature of the underlying violation and other relevant factors.[218]

A. Comments from Interested Persons Illustrating Concerns of Regulating Industrial Agriculture at the Expense of Small Farms

Comments from interested persons regarding fee amounts imposed on small food farmers and producers are a direct representation of the burdens

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[212] *Id.* Some factors that could be considered are the number of employees, the gross revenue, net income, net assets, market liquidity, or other financial measures or ratios, and whether the business has a subsidiary or is a subsidiary of a parent company. *Id.*
[213] *Id.*
[214] Jeff Farrar, Letter to the Editor, *Fee Schedule Story Needs Clarification for Readers*, THE PACKER (Sept. 2, 2011, 8:58:32 AM), http://www.thepacker.com/opinion/fresh-produce-opinion/Letter-to-the-Editor--129070833.html.
[215] *Id.*
[216] *Id.*
[217] *Id.*
[218] *Id.*

Congress imposed on small farms in an effort to regulate food safety in industrial agriculture. It is important to consider the perspectives of these interested persons, regarding this narrow issue, because the submitted comments represent the sentiments of small food farmers and producers regarding the breadth of the FSMA legislation.

While there have been varying comments to this notice and request for comments from the FDA on the burden of fees on small businesses, many interested persons have suggested that small businesses cannot absorb the new costs.[219] These persons have noted that the FDA's published intention to charge $224 per hour for a range of activities, such as agents' driving time to rural farms for reinspection, could easily add up to tens of thousands of dollars, quickly driving small food farmers and processers out of business.[220]

Arguments highlight the contradiction of Congress' debates on how to reduce regulatory burdens on small businesses while at the same time creating fee structures that could make it impossible for small businesses to survive a simple reinspection.[221] Small business owners argue that fee provisions under FSMA should not be applied in a way that favor large businesses over small, especially because a large business is more capable of absorbing additional costs due to its economies of scale.[222]

Further, interested persons assert that the imposition of fees based on travel time unfairly penalizes rural businesses because many small food producers are located in remote rural areas that are many hours from the

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[219] Public Comment by Farm & Ranch Freedom Alliance, Farm-to-Consumer Legal Def. Fund, and Weston A. Price Found., 76 Fed. Reg. 45818-01 (Aug. 1, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0016 [hereinafter Comment by Farm & Ranch].
[220] *Id.*
[221] *Id.*
[222] *Id.*

nearest FDA offices.[223] Thus, small food producers argue that the imposition of fees based on the travel time of FDA agents to a remote rural farm could easily require those farms to face thousands of dollars in fees simply because of where they are located.[224]

Interested persons have suggested other methods for keeping costs down. Some argue that all food producers, with a net worth less than one hundred thousand dollars, should be exempt from all fees due to the significant hardships that small businesses currently face to remain in business.[225] Others speak to the incredibly low profit margins in the food industry because of high overhead associated with keeping perishable inventory safe.[226] Some opine that the FDA should consider what segment of the food industry the business falls in and correlate fees according to the risk of the food.[227] Furthermore, interested persons suggest incentives where clean track records of food safety could result in lower fees; while businesses that cause outbreaks or that do not abide by imposed food safety regulations should have to face penalties, therefore bearing the burden of funding food safety implementation and discouraging reinspections or recalls from happening again.[228]

Interested persons also express serious concern that the additional costs will deter entrepreneurs from starting businesses, or will cause small business to close because large businesses have a much greater advantage with legal and regulatory issues due to accessibility of resources and greater

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[223] *Id.*
[224] *Id.*
[225] Public Comment by Anonymous, 76 Fed. Reg. 45818-01 (Oct. 5, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0005.
[226] Public Comment by Tricia Q. Morris, 76 Fed. Reg. 45818-01 (Oct. 5, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0003.
[227] *Id.* This argument asserts that those who have the most ability to prevent foodborne illness should be the ones burdened with increased regulation. *Id.*
[228] *Id.*

revenues.[229] In response, interested persons suggest that small businesses should not be exempt from the imposition of fees, but rather should be assisted by the FDA to comply with FSMA regulations through grants offered to small businesses for the purpose of compliance.[230]

Finally, interested persons have argued that high reinspection fees for small farms could seriously impact small farms' ability to comply with food safety regulations, especially as the reinspection process is implemented.[231] Interested persons anticipate that there will likely be a higher failure rate during the implementation stage of FSMA until producers have a chance to learn how the rules will be implemented and what is required to meet the expectations of the first inspection.[232] Thus, interested persons are urging the FDA not to impose fees for inspection or reinspection until FSMA has been in place for at least one year.[233]

Most of the submitted comments illustrate the widespread concern that FSMA will promote commercialization, industrial agriculture, and a capitalistic market food system at the expense of the small farm and farmer.[234] However, the comments submitted also demonstrate strategies that promote small farms and farmers despite necessary regulations to

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[229] Public Comment by Dennis Paul Higginbotham, 76 Fed. Reg. 45818-01 (Oct. 5, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0002.
[230] *Id.*
[231] Public Comment by Jim Sluyter, 76 Fed. Reg. 45818-01 (Oct. 14, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0009.
[232] *Id.*
[233] *Id.*
[234] Comment by Farm & Ranch, *supra* note 219; Public Comment by Anonymous, 76 Fed. Reg. 45818-01 (Oct. 5, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0005; Public Comment by Tricia Q. Morris, 76 Fed. Reg. 45818-01 (Oct. 5, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0003; Public Comment by Dennis Paul Higginbotham, 76 Fed. Reg. 45818-01 (Oct. 5, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0002; Public Comment by Jim Sluyter, 76 Fed. Reg. 45818-01 (Oct. 14, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0529-0009.

address the increase of foodborne illness since the rise of industrial agriculture.[235] If the FDA addresses these concerns, and integrates ideas generated by people in reaction to the regulations of FSMA, then the rulemaking process might be used to promote a food system that supports food justice, sovereignty, and sustainability.

B. Recommendations That Embrace Food Sovereignty and Sustainability in the Face of FSMA Through the Rulemaking Process

As the FSMA rulemaking process is underway, one way for proponents of small food farmers and producers to embrace food sovereignty and sustainability is to participate in rulemaking. Proponents of food sovereignty and sustainability that participate in the rulemaking process will require the FDA to consider their concerns of burdens faced by small-scale food producers and distributors.[236]

The National Sustainable Agriculture Coalition's (NSAC) Food Safety Task Force submitted a memo to the FDA that provided how to address wildlife and environment provisions in FSMA that conflict with conservation concerns.[237] Some key points made by the NSAC include (1) resolving conflicts of interest between rules and farming practices that were installed pursuant to conservation programs or environmental regulations;[238] (2) shifting the burden of reconciling agency differences from farmers by providing them with financial assistance through federal conservation

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[235] *Id*.
[236] *NSAC Submits Comments to FDA on Co-Management*, NAT'L SUSTAINABLE AGRIC. COAL. (Oct. 7, 2011), http://sustainableagriculture.net/blog/nsac-co-management-comments/.
[237] Memoranda from Nat'l Sustainable Agric. Coal. Food Safety Taskforce to Don Kraemer and Prevention Standards Team (Oct. 5, 2011), *available at* http://sustainableagriculture.net/wp-content/uploads/2011/10/NSAC-Memo-to-FDA-on-Co-Management-Rulemaking-Issues.pdf.
[238] *Id.*

programs if the need to comply to federal regulations arises;[239] (3) continuing to decrease the risk of pathogens;[240] and (4) implementing new food safety rules that allow farmers to continue conservation efforts.[241] Another key point raised by the NSAC that should be seriously considered by the FDA as FSMA is implemented includes protecting, caring for, and sustaining natural resources, particularly concerning land, water, seeds, and livestock.[242] These key points underscore the definition of food sovereignty by asserting that it is the role of the government to uphold the rights of all people to food sovereignty, and adopt and implement policies that promote sustainable, family-based production rather than industry-led, high-input and export orientation production. In order to accomplish those goals, the FDA must address food safety and establish food quality standards that reflect the culture and value of its people and establish quality control measures to comply with environmental, social, and health quality standards.

FSMA's leverage to promote prevention and food safety should not be at the expense of small farmers, small food processors, or small food distributors—such as CSAs and farmers' markets. Rural communities are already struggling, and small local food producers are vital to the economies of their areas.[243] Furthermore, allowing farmers a choice between participating in large-scale or small-scale food production is essential for small farmers to thrive in our nation. It also offers consumers a choice between available agricultural products. To regulate small farmers identically to industrial agriculture, when the disparity of financial

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[239] *Id.*

[240] *Id.* Examples of pathogen reduction efforts include (1) increasing non-crop vegetation; (2) implementing rules to promote the planting of hedgerows and grass water strips, cover cropping, and composting; (3) prioritizing the control of livestock on farms over the control of wildlife; and (4) integrating crop and livestock systems. *Id.*

[241] *Id.* For example, proper composting in accordance with National Organic Program standards. *Id.*

[242] *Id.*

[243] Public Comment by Farm & Ranch Freedom Alliance, *supra* note 219.

resources are obvious, is to regulate the poor (i.e., small farmers and food producers) in order to promote commercialization, industrial agriculture, and a capitalistic market system.

The written rules of FSMA must demonstrate the importance of the success of small farms, processors, producers, and distributors. FDA agents need to recognize the exemptions of small food producers under the Tester Amendment. Small farms and food producers connected to reinspections, or to food recalls, should qualify for a reduction in fees. Further, the promulgated rules need to clarify how small farms and food producers qualify for such reduced fees.

A small farm's, or small food processor's, net income is the most direct way to understand how many financial resources a small food entity has to implement the current legislation and rules to meet FSMA's purpose of prevention. Thus, a small farm or food producer's net income should be considered on a sliding scale in order to calculate fee reductions. Furthermore, while the $500,000 maximum value of produce sold by a small farm to consumers seems large enough to support many small farmers by exempting them from the preventative control conditions of FSMA, it still is not large enough to promote small farms and food producers growth and expansion in the face of FSMA regulation. In order to promote small farms and food producers, the maximum value of produce sold by a farm in order to continue to be eligible for the exemption under the Tester Amendment should be increased to allow small farmers economic security.

Furthermore, small farmers and food producers should be supported through the implementation of written preventative control plans. This could be done through the education and training component offered through FSMA. The FDA will establish a competitive grant program within the National Institute for Food and Agriculture (Institute) to provide food safety training, education, extension, outreach, and technical assistance to

farmers, small food processors, and small fruit and vegetable merchant wholesalers.[244] The Institute, through its competitive grant program, should address the implementation of written preventative control plans.[245]Agents for the FDA should also help implement records monitoring protocol at local farmers' markets so that local farmers and food producers may learn together and support one another through the process of implementing new procedures in compliance with the new regulations. This would result in small farms working to meet food safety goals in a way that supports and promotes the sustainability of a food system other than industrial agriculture.

These proposals—reducing fees and assisting in implementing preventative control plans, and taking into consideration the financial resources a small-scale food producer has available to implement FSMA rules and regulations—help ensure safe food consumption in our nation. Furthermore, these proposals would allow a small farmer or producer the ability to continue being a sustainable business, despite new regulations, therefore embracing the concept of food sovereignty and the right of people to define their own agriculture and food systems.

VI. CONCLUSION

The implementation of FSMA and the Tester Amendment exemptions will no doubt affect small farmers' and food producers' sustainability. The forces underlying the rulemaking, in regard to the implementation of FSMA and the Tester Amendment, most notably the fee schedules and the monitoring requirements of people in farming, significantly impact the parallel food industry to industrial agribusiness—small-scale food production. The interest and desire of consumers for local food drives the food sovereignty movement; the movement for local food is rejecting faceless transactions, or buying convenience in exchange for E. coli

[244] *FDA FSMA and Small Business*, *supra* note 136.
[245] *Id.*

infections. This reflects opportunities for individuals, communities, businesses, and the nation to impact FSMA legislation.

There should be choices within this nation's food system. In the years ahead, as legislation such as FSMA is implemented, it is imperative to consider critically which farming and food systems are promoted. The food system and its functions need to be influenced by our actions as citizens, workers of the land, and business people. Our actions and voices need to be heard through the implementation of legislation that shapes and supports a sustainable small-scale food system, one that embraces the concept of food sovereignty so that it serves the needs of individuals and of society.

Again, food justice, sovereignty, and sustainability are concepts that offer a new discourse for the public to demand support of small farms despite legislation in the name of food safety. How FSMA's rules are promulgated has a direct impact on whether small farms and food producers will continue to thrive, allowing for a food system that embraces the concepts of food justice, sovereignty, and sustainability. Proponents of small farms must take action and require thoughtful regulations instead of promoting commercialization, industrial agriculture, and a capitalistic food system at the expense of small farms and farmers.