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ADMINISTRATIVE LAW—ALL (FOOD) POLITICS IS LOCAL: COOPERATIVE FEDERALISM, NEW ENGLAND SMALL FARMS, AND THE FOOD SAFETY MODERNIZATION ACT

Laura Fisher

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ADMINISTRATIVE LAW—ALL (FOOD) POLITICS IS LOCAL:
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The family farm: it is way up there next to God and country, close to baseball and motherhood. . . . Family farming belongs to our secular theology.¹

Successive iterations of federal farm policy designed to maximize production have driven the romanticized Jeffersonian idea of the family farmer to the brink of extinction.²

INTRODUCTION

Gary Gemme and Davey Wojciechowski have been business partners since 1979 when they began farming eight acres (with one greenhouse) in Whately, Massachusetts.³ Since that time, their business, Harvest Farm, has grown and expanded to occupy over one hundred acres; Davey runs the greenhouses and Gary oversees the field production.⁴ They grow a variety of crops including vegetable and flower seedlings for sale on the wholesale market.⁵ Each day, Gary is able to oversee the work of field production, including harvest and post-harvest.⁶ In New England, it is very common for those who own farms to be involved as operators and be engaged directly in every aspect of the farm's production.⁷

1. RONALD JAGER, *THE FATE OF FAMILY FARMING: VARIATIONS ON AN AMERICAN IDEA* viii (2004).

2. Nicholas R. Johnson & A. Bryan Endres, *Small Producers, Big Hurdles: Barriers Facing Producers of "Local Foods,"* 33 *HAMLIN J. PUB. L. & POL'Y* 49, 49 (2012).

3. *History of Harvest Farm of Whately*, HARVEST FARM OF WHATELY, MASS., <http://www.harvestfarmofwhately.com/history.html> (last visited May 22, 2015).

4. *Id.*

5. *Id.*

6. *See Id.*

7. According to Mr. Gemme, "a small farm is of a size that allows the farmer the ability to closely inspect all of its crops in a given day . . . [and] manag[e] all aspects of the production operation and wor[k] directly with the labor force in the harvest and post-harvest processes, as well as the sales and shipping of the produce. This describes most farms in New England." Gary Gemme, *Gary Gemme: Food-Safety Rules a Threat to Small New England Farms*, *DAILY HAMPSHIRE GAZETTE* (Northampton, Mass.), Aug. 20, 2013, available at <http://www.gazettenet.com/home/8122078-95/gary-gemme-food-safety-rules-a-threat-to->

Despite a successful business model, long days on the farm, owner involvement and oversight of production at every level, and adoption of a consumer-based safety compliance program, Harvest Farm may cease to exist because the cost of compliance with new regulations could be preclusive.⁸ New federal food safety regulations will be fully implemented within the next few years,⁹ and because Harvest Farm will likely fall outside of any exemption, it could become a fatality of the Food Safety Modernization Act (“FSMA”).

In late 2010, Congress passed the FSMA, the first overhaul of food safety regulation in nearly seventy years.¹⁰ A variety of sweeping foodborne illnesses caused consumers and legislators alike to demand government action to ensure consumer safety.¹¹ Because several of the outbreaks stemmed from and were traced back to mainly industrial farming operations, agriculture – as an industry – was viewed as a part of the potential problem that required further oversight and regulation.¹²

small-new-england-farms. Mr. Gemme bases his opinions on his forty years of experience as a New England farmer. *Id.*

8. Mr. Gemme has further written that “these new regulations would force even small-scale growers such as myself to expend very limited financial and labor resources (in many cases beyond their means) in order to comply with the program.” *Id.* Much of the discussion herein examines the potential impact under the FDA’s initial set of proposed regulations. After significant outcry from farmers like Gemme, the FDA has since revised certain provisions. See FSMA Proposed Rule for Produce Safety, Standards for the Growing, Packing, and Holding of Produce for Human Consumption, *available at* <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>. This author contends that the underlying legislation will inevitably fail to create a fully workable system.

9. The implementation of multiple provisions of the FSMA have been continuously delayed, due in part to the government shutdown of late 2013 and also due to FDA concern regarding impacts on stakeholders to be affected across a vast realm of food producers and farmers. Ricardo Carvajal, *In Litigation, FDA Explains and Defends FSMA Efforts*, FDA LAW BLOG, (Dec. 11, 2012), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/12/in-litigation-fda-explains-and-defends-fsma-efforts.html. The FDA has agreed to set 2015 as the year in which the proposed rules must be finalized. See *Center for Food Safety v. Hamburg*, 954 F.Supp.2d 965 (N.D. Cal. 2013); *Center for Food Safety v. Hamburg*, No. C 12-4529 PJH (N. D. Cal. 2013) (order granting injunctive relief), *available at* http://www.centerforfoodsafety.org/files/fsma-remedy-order_52466.pdf.

10. The FSMA “overhaul[s] the nation’s food safety laws for the first time since the Great Depression.” Debra M. Strauss, *An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business*, 66 FOOD & DRUG L.J. 353, 354 (2011).

11. For example, a peanut butter outbreak in 2009 infected over seven hundred individuals with a strain of *Salmonella*; in 2006, tomatoes contaminated with a strain of *Salmonella* sickened over one hundred eighty individuals across twenty-one states and in 2006, bagged spinach contaminated with *E. coli* killed three and sickened nearly two hundred others. See generally, *List of Selected Multistate Foodborne Outbreak Investigations*, CTRS. FOR DISEASE CONTROL AND PREVENTION, *available at* <http://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html> (providing a chronological detailed listing of recent foodborne illness outbreaks).

12. *Overview and Background: What is the Food Safety Modernization Act (FSMA)?*, NAT’L SUSTAINABLE AGRIC. COALITION, *available at*

Federal regulation of agricultural activities has developed vis-à-vis the historical movement away from a society in which smaller agrarian pursuits have given way to a growth of a much more industrialized, national market.¹³ Regulation has been responsive to the various realities of such industrialization—as small family farms became fewer and further between, federal regulation responded to the proliferation and centralization of larger players.¹⁴

The FSMA, despite a well-intentioned exemption for “small” farmers and producers,¹⁵ merely pays lip service to the notion that retaining small agricultural entities is a worthy goal. Congress variously directs the Food and Drug Administration (“FDA”) to make subsequent regulations workable for smaller entities, but does little else to guide or control the development.¹⁶ Numerous individuals have criticized

<http://sustainableagriculture.net/fsma/overview-and-background/> (last visited May 22, 2015) (“Due to a rise in major outbreaks of foodborne illnesses and increasing bioterrorism concerns after 9/11, both Congress and the Obama Administration proposed new food safety measures in 2009 that expanded food safety regulations to the farm level.”).

13. See Peter Anderson, Comment, *Empowering Local and Sustainable Food: Does the Food Safety Modernization Act’s Tester-Hagan Amendment Remove Enough Barriers?*, 9 J.L. ECON. & POL’Y 145, 152-55 (2012) (describing briefly the vast changes to the American agriculture sector since the U.S. Department of Agriculture’s inception as a federal agency in 1862); See also Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L.J. 565, 565 (2003) (concluding that regulation attempts to address rapid changes in science and business, including centralization of the food industry.).

14. Anderson, *supra* note 13, at 152. “[I]n 1862, 48% of Americans lived on farms. By 2000, only 1% of Americans lived on farms. In the interim, the U.S. food economy has shifted towards specialization and globalization driven by new technologies. Only recently has the food economy shown some signs of ‘relocalization.’” Anderson, *supra* note 13 at 152.

15. The Tester-Hagan Amendment to the FSMA was included after many small and mid-sized farmers and producers decried the FSMA’s blanket regulation. See, e.g., *Action Alert: Protect Small Farmers and Food Producers from FSMA Regulations*, FARM AND RANCH FREEDOM ALLIANCE, (Nov. 5, 2014), available at <http://farmandranchfreedom.org/alert-protect-small-farmers-from-fsma-regulations/> (“We fought hard for the Tester-Hagan amendment to exempt small-scale, direct-marketing farms and artisan food producers from the most burdensome aspects of the Food Safety Modernization Act (FSMA). This exemption is essential to the continued vitality of the local foods movement.”). “Small” seems to have a subjective definition; frequently, it relies on gross income produced; however, small can also be defined by acreage or owner involvement in the operation, or some combination of these factors. See, e.g., Helen Dombalis, *Tester—Now More Than Ever*, NAT’L SUSTAINABLE AGRIC. COALITION, (Aug. 23, 2011), <http://sustainableagriculture.net/blog/tester-now-more-than-ever/> (“NSAC supported the Tester-Hagan amendment and advocated for its inclusion in the final legislation, for the very reason that it allows smaller farms that sell products locally to play to their natural strengths in terms of food safety.”). In effect, however, the Tester-Hagan Amendment functions more as a loophole by placing stringent caps based on revenue and average locality of sales. The exemption provisions at issue are codified at 21 U.S.C. § 350h(f) (2012) and 21 U.S.C. § 350g (2012).

16. See, e.g., 21 U.S.C. § 305h(a)(3)(A) (2012) (directing that the rulemaking shall “provide sufficient flexibility to be applicable to various types of entities engaged in the

Congress, the FDA, and interested parties for a lack of creativity in developing a workable food safety regulatory system.¹⁷ The FSMA grants the FDA broad authority to develop a plethora of regulations with the further directive that the FDA define very small businesses,¹⁸ however, the very parameters of the Tester-Hagan Amendment delineating a basic rubric for the exemption framework illustrate a congressional tendency to view agriculture with no eye toward the intricacies that occur within the occupation.¹⁹

The Tester-Hagan amendment creates exemptions from two rules: the Produce Rule and the Hazard Analysis and Critical Control Point (HACCP) Rule.²⁰ In both instances, the exemption is available or partially available to entities with a gross income from sales of food less than \$500,000 and, additionally, the farm or facility must sell more than fifty percent of the food products directly to a qualified end user in the same state or within 275 miles of the facility.²¹

production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities”).

17. See, e.g., Helena Bottemiller, *Merrigan Expresses Worry About FSMA's Impact on Agriculture*, FOOD SAFETY NEWS (May 24, 2013), <http://www.foodsafetynews.com/2013/05/merrigan-expresses-worry-about-fsmas-impact-to-agriculture/#> (Kathleen Merrigan, former Deputy U.S. Secretary of Agriculture has stated that she is “worr[ie]d about the bureaucracy not always being as creative as they might be in achieving the same level of food safety at small and medium size operations”). Some have posited that the agendas of large-scale agricultural actors are actually aligned with the FSMA’s burdensome mandates:

Corporations depend on a global supply chain, and in doing so they are finding it increasingly difficult to deliver safe food. At the same time, they are losing market share to the local food systems that customers are demanding—witness the sharp increase in farmers markets, community—supported agriculture (CSAs), and restaurants offering “farm to fork” menus. To avoid legal liability, the corporations want to legitimize an industrial approach to sterilizing everything, without regard to the unnecessary and costly burden placed on local farmers. If your local farmer goes out of business trying to comply with the costs of hundreds of pages of new federal food safety regulations, well that just leaves more customers without a local alternative.

Michael Tabor & Nick Maravell, *Farm Markets Threatened by Food Safety Efforts*, LANCASTER FARMING, N. EDITION, Aug. 17, 2013, at A9, available at http://lfg.live.mediaspanonline.com/assets/9751540/A09LFWWE-081713_1.pdf.

18. 21 U.S.C. § 350g(1)(B)(i) (2012).

19. Mark Kastel, co-Founder of the Cornucopia Institute, commented that “[w]e are really talking about two parallel food production and distribution systems in this country. One is inherently dangerous due to its scale, methodology, and distribution model. The other depends on an intimate relationship between modest, local/regional owner operators. . . .” , *Will the Tester Amendment to S.510 help small farms and processors, put more kids at risk?*, FOOD FIGHT, (Nov. 17, 2010), <http://grist.org/article/food-2010-11-16-tester-amendment-to-s-510-help-small-farms/>.

20. See 21 U.S.C. § 350h(f) (2012); 21 U.S.C. § 350g (2012).

21. See 21 U.S.C. § 350h(f) (2012); 21 U.S.C. § 350g (2012).

Thus, there are several factors in determining whether an entity is exempt; however, arguably, there exist small and mid-sized farmers and producers who will not qualify in whole or in part. Additionally, the statutory requirement for FDA development of Hazard Analysis and Critical Control Point (HACCP) regulations²² falsely assumes that regulated entities will be able to absorb what have historically been high costs associated with similar types of preventive measures implemented elsewhere.²³

Nationwide, there has been a growth in new-entry farmers and an increased interest in small-scale sustainable and organic agriculture.²⁴ In New England, states are experiencing the effects of attempts at creating and bolstering local food economies through new farms, farmland preservation, and farmland tenure.²⁵ Small, sustainable, organic farms dedicated to invigorating local food systems are a growing trend, readily apparent in New England.²⁶ Consumers seek out locally-grown and produced items for a variety of reasons including perception of increased healthiness and freshness of product, inherent safety of the product, and a more direct form of accountability.²⁷ Supporting smaller, locally-based

22. 21 U.S.C. § 350g (2012).

23. See, e.g., Fortin, *supra* note 13, at 565 (stating that the most common grounds for opposition to HACCP preventive measures is cost).

24. See, e.g., Dan Charles, *Who Are the Young Farmers of Generation Organic?*, NPR, Dec. 12, 2011, available at <http://www.npr.org/blogs/thesalt/2011/12/12/143459793/who-are-the-young-farmers-of-generation-organic> (“[T]here’s a new surge of youthful vigor into American agriculture — at least in the corner of it devoted to organic, local food. Thousands of young people who’ve never farmed before are trying it out . . . [T]he overwhelming majority of [new] farmers . . . want to farm without chemical fertilizers or pesticides.”).

25. Various organizations are dedicated to preservation of small-scale agriculture in New England. See, e.g., FOREVER FARMLAND, <http://foreverfarmland.org/> (last visited May 22, 2015) (dedicated to preserving agricultural parcels in western Massachusetts through agricultural preservation restrictions); LAND FOR GOOD, <http://www.landforgood.org> (last visited May 22, 2015) (“Entire communities will benefit from increased farming opportunity, healthy lands and a more secure food supply.”); GROW FOOD NORTHAMPTON, *Our Mission, Goals, and Beliefs*, <http://www.growfoodnorthampton.com/about-us-2/our-mission/> (last visited May 22, 2015) (“We believe that successful agriculture looks to the past and the future: it studies lessons from our farming history, embraces new research into sustainable practices, critically examines current agricultural paradigms, and fosters farm-based and food-based learning in the entire community.”).

26. See generally U.S. DEPARTMENT OF AGRICULTURE/NATIONAL AGRICULTURAL STATISTICS SERVICE, NEW ENGLAND FIELD OFFICE, *Trends in New England Agriculture 2002-2007*, available at http://www.nass.usda.gov/Statistics_by_State/New_England/Publications/Presentations_and_Displays/TrendsInNewEnglandAgriculture.ppt (New England has experienced a growth spurt in organic agriculture, direct-market sales, and marketing through Community Supported Agriculture (CSA); this growth had outpaced the rest of the country as of 2007).

27. JAMES T. O'REILLY, A CONSUMER'S GUIDE TO FOOD REGULATION & SAFETY, 113 (2010) (“Food is produced more carefully by actual farmers—persons who either sell at a

farmers and producers infuses income into a local economy,²⁸ and local foods produced and grown sustainably create fewer adverse environmental impacts by virtue of the limited distance shipped and sustainable growing techniques.²⁹ As a whole, New England has historically and recently practiced a distinct type of agriculture.³⁰ Regional considerations alter the realities of agriculture as an industry across states and between regions,³¹ administering blanket regulations and exemptions in the agricultural industry are inherently problematic.

New England agriculture—because of considerations such as average level of on-farm diversification, weather, climate, costs of land and operation, and increased consumer demand for organic, sustainably-produced items³²—is a stark example of how the FSMA will be inadequately sensitive to regional and local agricultural considerations. This insensitivity is especially obvious in the provision providing an exemption for certain entities from the Produce Rule³³ and the HACCP

farmer's market or whose identities are known to repeat customers in their local community.”).

28. UNION OF CONCERNED SCIENTISTS, *Market Forces: Creating Jobs through Public Investment in Local and Regional Food Systems*, available at http://www.ucsusa.org/food_and_agriculture/solutions/expand-healthy-food-access/market-forces.html (last visited May 22, 2015) (“[Local food] creates jobs, keeps money in local economies, promotes community development, and can reduce the environmental and public health costs of the food we eat.”).

29. LOCAL HARVEST, *Why Buy Local?*, <http://www.localharvest.org/buylocal.jsp>, (last visited May 22, 2015) (“Most produce in the US is picked 4 to 7 days before being placed on supermarket shelves, and is shipped for an average of 1500 miles before being sold.”). See also MICHAEL POLLAN, *THE OMNIVORE’S DILEMMA: A NATURAL HISTORY OF FOUR MEALS* 261 (2006) (“I don’t believe it’s sustainable . . . to FedEx meat all around the country.”) Pollan further explains that there are “ethical implications” including the “expense [and] prodigious amounts of energy involved, the defiance of seasonality” *Id.* See also O’REILLY, *supra* note 27, at 113 (“Less energy is burned to move the crop from a distant area to the local consumer.”).

30. NEW ENGLAND FARMERS UNION, *FSMA and Structure of New England Agriculture*, www.newenglandfarmersunion.org/food-safety-modernization-act/fsma-and-structure-of-new-england-agriculture/ (last visited May 22, 2015) (“Because farms in New England are relatively small and our costs of production are higher than many other regions, we can expect to suffer more than our fair share of FSMA casualties.”).

31. Historically, FDA has concluded that because of the “diversity of agricultural practices and commodities, practices recommended to minimize microbial contamination will be most effective when adapted to specific operations.” U.S. FOOD AND DRUG ADMINISTRATION, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, 117 (Oct. 26, 1998), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlanProducts/ucm065474.htm>.

32. See, e.g., FAIR FOOD NETWORK, *Growing Good Food Enterprises Through Impact Investing*, (Jan. 3, 2012), available at <http://www.fairfoodnetwork.org/connect/blog/growing-good-food-enterprises-through-impact-investing> (promoting investment in sustainable New England farms in response to growing demand for local, sustainably produced food).

33. 21 U.S.C. § 350h (2012).

Rule.³⁴ It is problematic that many agricultural entities in New England will fall outside of the exemption and will be driven out of business or required to raise prices drastically because of the FSMA.³⁵ In turn, small to mid-sized owner-operated farms—especially those with the heightened operating costs associated with sustainable and organic agriculture—may disappear.³⁶ Our food supply would become inherently less safe³⁷ as further centralization and industrialization of agriculture would occur as larger businesses are able to more readily absorb the costs of compliance.³⁸

Blanket federal regulation of agriculture as an industry is fundamentally problematic due to these regional and state considerations. The FSMA, to the extent that it adequately addresses the issue of food safety, should be implemented in a way that recognizes each state's agricultural realities. To this end, revisiting the theory of cooperative federalism may prove insightful,³⁹ such an approach in implementation of a behemoth federal policy could be fruitful. The tenets of cooperative federalism represent an advocacy for heightened state and local involvement in implementation of federal policy objectives.⁴⁰ Over the past century, the concept of cooperative federalism has been interpreted and defined in various ways,⁴¹ and has most recently been associated with the national implementation of

34. 21 U.S.C. § 350g (2012).

35. U.S. FOOD AND DRUG ADMINISTRATION, *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, 317 (2013), available at www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf (“Small entities with above average costs of doing business will be at a competitive disadvantage. Some small entities might determine that their new expected costs are likely to exceed their revenues.”).

36. NEW ENGLAND FARMERS UNION, *FSMA and Structure of New England Agriculture*, www.newenglandfarmersunion.org/food-safety-modernization-act/fsma-and-structure-of-new-england-agriculture/ (last visited May 22, 2015).

37. The FSMA will have a direct bearing on the issue of increasing food security, especially for at-risk populations. Small and diversified farms function to provide an important alternative to massive supply chains and the monocultures from which much of our food stems.

38. NEW ENGLAND FARMERS UNION, *supra* note 36 (“FSMA favors larger scale operations that will be able to absorb the costs of FSMA compliance because they can spread the impact of the costs across more products.”).

39. Cooperative federalism is defined as “[d]istribution of power between the federal government and the states in which each recognizes the powers of the other while jointly engaging in certain governmental functions.” *Federalism*, Black’s Law Dictionary (9th ed. 2009).

40. See Symposium on Cooperative Federalism, *Foreword*, 23 IOWA L. REV. 455, 456 (1938).

41. *Id.* (cooperative federalism broadly defined as “the participation of several governments in cooperative legislation or administrative action.”).

federal natural resources and pollution control laws.⁴²

The basic principles of cooperative federalism include a collective approach to the implementation of laws—an approach in which state and local interests have a shared role in creating and implementing policies.⁴³ Rethinking and revisiting the tenets of cooperative federalism is a potential solution in reaching the important end of preserving state and regional autonomy in the face of overwhelming federal regulation such as the FSMA.

A more cooperative approach to food safety may afford the deference to states necessary to successful implementation of the FSMA. The FSMA will not be effective if it eliminates small owner-operated farms and producers; arguably, putting the smaller players out of business may actually further the ongoing food safety problems most often associated with large-scale industrial agriculture and food production.

This Note will analyze the FSMA exemption framework for small farmers and producers and the immense costs that compliance will place on those who are unable to qualify for the exemptions. Additionally, it will argue that New England, as a region, practices a distinct and beneficial type of agriculture, illustrating the need for exemptions that look beyond gross revenue caps and radial distances.

This Note will then argue that because the Tester-Hagan Amendment falls short of protecting small farmers, the FSMA will act as a disincentive to those wishing to practice small-scale sustainable agriculture and, in effect, will only further subsidize the growth of industrial agriculture, which is the main source of food safety concerns.

The argument portion of this Note will discuss potential solutions to problems created by the FSMA and its insufficient exemptions, including analysis of the tenets of cooperative federalism as a potential means to address the necessity of regional and state considerations in delineating exemptions.

I. FEDERAL FOOD SAFETY

This Section of the Note will briefly summarize the history of federal regulation of food safety in the United States; the development of a fragmented approach to food safety is contextually important to

42. See generally Robert L. Fischman, *Cooperative Federalism and Natural Resources Law*, 14 N.Y.U. ENVTL. L.J. 179 (2005) (providing historical and contemporary definitions and conceptions of cooperative federalism).

43. *Id.* at 192 (“[N]otwithstanding the stringency floor . . . cooperative federalism programs typically allow for significant customization of standards.”).

understanding some of the futility of a wholly federal approach to food safety. It will then discuss and analyze the depth and breadth of regulation of agricultural entities under the FSMA, including the provisions for partial or complete exemption from compliance for “small” entities.

Next is an examination of the facets of agriculture and food production in New England that render the region fundamentally different from other regions and states. Such regional and state-specific differences are an example of the inadequacy of the current federally-based approach. “[T]he definition of a small business, specifically with respect to farms, is relative to the geographic region in which it is located.”⁴⁴ Because the notion of *small* should be particular to the surrounding region, a blanket federal definition of what constitutes a “small farm” is problematic.⁴⁵

A. *A History of Fragmentation and Duplication*

The development of food safety regulation in the United States has been described by scholars as a “patchwork quilt.”⁴⁶ It has been implemented as a result of “ad hoc decision making arising from legislation designed to address the crisis *du jour* while appeasing an organized and active commodity production system, rather than the development of a comprehensive systematic program designed around the production of safe, nutritious food.”⁴⁷ In the early nineteenth century, Congress formed various committees and subcommittees centered on agriculture; interestingly, despite the fact that agriculture is integral to the nation’s food supply, not one of the committees had a hand in ensuring food safety.⁴⁸ The U.S. Department of Agriculture and the land-grant university system were established in 1862⁴⁹ and the Hatch Act of 1887 allotted funding for agricultural research in

44. Nicholas Obolensky, *The Food Safety Modernization Act of 2011: Too Little, Too Broad, Too Bad*, 17 ROGER WILLIAMS U. L. REV. 887, 914 (2012).

45. *Id.*

46. A. Bryan Endres & Nicholas R. Johnson, *Integrating Stakeholder Roles in Food Production, Marketing, and Safety Systems: An Evolving Multi-Jurisdictional Approach*, 26 J. ENVTL. L. & LITIG. 29, 39 (2011).

47. *Id.*

48. *Id.* This is not to say that food safety was not an issue in the early 1800s; interestingly, however, the percentage of individuals engaged in agrarian activities was historically more significant than at present. “Between 1974 and 1997, the number of farms with average sales over \$500,000 increased just over 600% while the total number of farms decreased approximately 17%.” Johnson and Endres, *supra*, note 2 at 51-52. In the 1800s, long supply chains were simply not everyday realities.

49. *Id.* First Morrill Act, ch. 130, 12 Stat. 503 (1862).

connection with each state's land-grant university.⁵⁰ "[I]n light of the jurisdiction of the congressional committees and the relatively localized nature of food production and consumption, these institutions focused on facilitating a system of agricultural production to feed the country's westward expansion and growing population, not the safety of the food supply chain."⁵¹ The U.S. Department of Agriculture has generally focused its policies on efficient maximization of dependable production of food.⁵²

This focus "remained steadfast despite the lengthening of the food supply system . . . and the potential for widespread food contamination due to consolidation of processing and distribution in the supply chain."⁵³ As demand for increased production grew, the theory of *successful* agriculture centered on maximizing land use, despite detriment to the environment.⁵⁴ The focus on "increased per-acre yields" additionally compromised integrity of the safety and nutrition of the end product.⁵⁵ The goal of increasing yields unfortunately places quality and safety standards on the back burner. The only aspect of food safety over which the U.S. Department of Agriculture retains jurisdiction is the slaughter and processing of meat products⁵⁶—this creates a problematic bifurcation of power between the FDA and the U.S. Department of Agriculture.⁵⁷

The initial instance of federal food safety legislation was the Pure Food Act of 1906,⁵⁸ followed by the 1938 Food, Drug, and Cosmetic Act.⁵⁹ Although jurisdiction under these acts initially rested with the U.S. Department of Agriculture, the FDA was transferred to the Federal Security Agency in 1940 as part of President Roosevelt's

50. Endres & Johnson, *supra* note 46, at 39; HATCH Act, ch. 314, 24 Stat. 440 (1887).

51. Endres & Johnson, *supra* note 46, at 40.

52. *Id.* at 44.

53. *Id.* at 40.

54. *Id.* at 40-41.

55. *Id.* at 40.

56. *Id.* at 41-42. (An apt example of the absurdity of this bifurcation of powers between FDA and the USDA is that FDA's food safety jurisdiction oversees the manufacture of frozen cheese pizzas, while USDA oversees any pizzas with pepperoni.); Madaleine Drexler, *Foodborne Illness: Who Monitors Our Food?*, BRANDEIS UNIVERSITY SCHUSTER INSTITUTE FOR INVESTIGATIVE JOURNALISM, <https://www.brandeis.edu/investigate/food-health/foodborne-illness/who-monitors-food.html> (last visited May 22, 2015).

57. Endres & Johnson, *supra* note 46, at 41-42.

58. Pure Food & Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (June 30, 1906) (repealed 1938).

59. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-379(f) (2006). The FSMA, in effect, overhauls various portions of the Food, Drug and Cosmetic Act pertaining to food safety.

“Reorganization Plan Number Four.”⁶⁰ Food safety oversight expanded to include a majority of food products; somewhat strangely, jurisdiction over the slaughter and processing of meat and meat products remained within the purview of the U.S. Department of Agriculture, creating a peculiar split in authority.⁶¹ The FDA and the USDA remain the primary agencies sharing the responsibility of food safety oversight.⁶² “The result is a confused regulatory system in which different agencies exercise jurisdiction over a product depending upon the stage in production and the relative meat or poultry content in the end product.”⁶³

In addition to USDA and FDA oversight, the Environmental Protection Agency is tasked with overseeing the chemical aspects of agriculture including chemical inputs such as pesticides, herbicides, and fertilizers.⁶⁴ “The result of this longstanding federal policy ‘is a complicated, multi-agency system that is characterized by command-and-control regulations and jurisdictional silos.’ Today, fifteen agencies are responsible for implementing thirty different statutes having to do with food safety.”⁶⁵ Despite the massive overhaul of the FDA’s power brought about by the FSMA, demands for creation of a single food safety agency increase.⁶⁶

Against this background of multiple agency oversight, including state agencies, as well as voluntary, consumer-driven food safety programs, Congress reacted to consumer pressure in light of a growing number of serious, frequently deadly, foodborne illness outbreaks.⁶⁷ Constituent furor over the apparent inadequacy of food safety protections grew after incidents such as the E. coli outbreak of 2006

60. See Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 84 n.131 (2000).

61. Endres & Johnson, *supra* note 46, at 42.

62. *Id.*

63. *Id.*

64. *Id.*; Johnson & Endres, *supra* note 2 at 68 (“The fact is that the regulatory structure surrounding our food production system is labyrinthine, confusing, duplicative, and often bordering on draconian—and it applies to everyone.”).

65. Johnson & Endres, *supra* note 2, at 69.

66. “[The General Accountability Office] suggests Congress ask the National Academy of Science to study organizational structures the U.S. government might use for its food safety programs . . . [including] a single food safety agency, either housed within an existing agency or established as an independent entity, that assumes responsibility for all aspects of food safety at the federal level.” Dan Flynn, *GAO Report Calls for Single Food Safety Agency*, FOOD SAFETY NEWS, Mar. 2, 2011, available at <http://www.foodsafetynews.com/2011/03/call-for-one-food-safety-agency-leads-historic-gao-report/#.UnaeXiSw7CR>.

67. Johnson & Endres, *supra* note 2 at 71-72 “The Centers for Disease Control and Prevention . . . has estimated that there are more than 38.4 million illnesses, 71,500 hospitalizations, and 1,600 deaths per year associated with foodborne illnesses in the United States.” These statistics have, however, been criticized as inaccurate.

traced to bagged spinach,⁶⁸ the salmonella outbreak tentatively traced to jalapeno peppers in 2008,⁶⁹ and a severe salmonella outbreak traced to peanut butter processing plants in Georgia in 2008-2009, which caused at least nine deaths.⁷⁰

The regulatory scheme of the FSMA is aimed at the historical bad actors—namely, industrial agribusiness⁷¹—yet, the blanket, federal-level exemption based on gross revenue and radius of distance of sales⁷² is insufficient to protect the smaller entities. The FSMA drastically increases the powers of the FDA, shifting the locus of food safety regulation to the federal realm of oversight: “[I]n practice, the [FSMA] morphs cooperative federalism into a more centralized government. What results is a lessening of state independence.”⁷³ Congress has

68. The E. coli outbreak was traced to bagged Dole spinach processed at Natural Selection Foods, LLC in San Juan Bautista, California. U.S. FOOD AND DRUG ADMINISTRATION, *FDA Finalizes Report on 2006 Spinach Outbreak*, (Mar. 23, 2007) available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/2007/ucm108873.htm>. The Salinas Valley in California produces a majority of the fresh lettuce consumed in the United States: “in 2007, [the Salinas Valley] produced 84% of the head lettuce grown for U.S. consumption.” Johnson & Endres, *supra* note 2 at 52.

69. “Jalapeno peppers were traced back to distributors in the United States that received produce grown and packed in Mexico.” CENTERS FOR DISEASE CONTROL AND PREVENTION, *Investigation of Outbreak of Infections Caused by Salmonella Saintpaul*, (Aug. 28, 2008), available at <http://www.cdc.gov/salmonella/saintpaul/jalapeno/>.

70. Individuals associated with Peanut Corporation of America, the source of the outbreak, have since been indicted. Kate Brumback, *Feds Indict 4 In Peanut Butter Salmonella Outbreak*, WASHINGTON TIMES, Feb. 21, 2013, available at <http://www.washingtontimes.com/news/2013/feb/21/feds-indict-4-peanut-butter-salmonella-outbreak/?page=all> (“The Department of Justice will not hesitate to pursue any person whose criminal conduct risks the safety of Americans who have done nothing more than eat a peanut butter and jelly sandwich.”).

71. Representative Rosa DeLauro, who introduced the initial bill to Congress, stated “[t]he intent of the bill is to focus on the large, industrial processes such as the peanut processing plant in Georgia that was responsible for the salmonella outbreak that killed nine people.” Ryan Grim, *HR 875 Myth Sows Terror Among Organic Gardeners*, THE HUFFINGTON POST (May 10, 2009, 5:12 AM), http://www.huffingtonpost.com/2009/04/09/hr-875-myth-sows-terror-a_n_185230.html.

72. A farm is exempt from, for instance, full implementation of compliance measures in accordance with rules promulgated under the Standards for Produce Safety during any calendar year where more than fifty percent of the farm’s produce is sold directly to qualified end users for the previous three years and the average gross revenue stemming from all food sold during that same period was less than \$500,000.00. 21 U.S.C. § 350h(f) (2006). There is a nearly identical exemption to rules promulgated under the Hazard Analysis and Risk-Based Preventive Controls (known as HACCP) portion of the Food Safety Modernization Act, although such exemption is further qualified. 21 U.S.C. § 350g (2006).

73. Emily Walters, *The Food Safety Modernization Act’s True Implications for Sustainable Agriculture*, 4 WASH. & LEE ENERGY, CLIMATE & ENV’T. 391, 396 (2013). Of course, advocating for state independence in such matters does not preclude the potential downside that states will not rise to the occasion, eschewing the cost of developing programs closely tailored to their agricultural sector. In such an event, the FSMA could provide a satisfactory or workable plan to serve sufficiently.

generally framed food production in terms of economics “rather than one with broader health and cultural implications.”⁷⁴ The FSMA, as written, only further aligns federal policy with this historical rut.

B. *The Food Safety Modernization Act: Regulation in Depth and Breadth*

The FDA now oversees and regulates approximately eighty percent of the nation’s food supply.⁷⁵ Most of the expansive reach of the FSMA is beyond the scope of this Note; instead, the focus here is on two particular sections of the law, both of which will directly regulate farmers and agriculture. In particular, new regulatory power is created in the FDA to create and implement food safety measures for vegetable and fruit farms⁷⁶ and to mandate Hazard Analysis and Critical Control Points (HACCPs) for all non-meat food processing facilities.⁷⁷ Congress was motivated in particular by recent illnesses and deaths caused by foodborne contamination; in this sense, passage of the FSMA was reactive.⁷⁸ The general intent of the FSMA, however, is to realign the FDA’s powers to create a more preventive approach to food safety, as opposed to a historically reactive approach.⁷⁹

74. Johnson & Endres, *supra* note 2, at 68.

75. Strauss, *supra* note 10, at 354.

76. 21 U.S.C. § 350h (2006).

77. 21 U.S.C. § 350g (2006). The USDA, which oversees the safety of meat and poultry, instituted HACCP measures for meat and poultry processors in the late 1990s, with costs of compliance arguably contributing to the loss of small slaughterhouses and the centralization and industrialization of larger meat processing facilities thereafter. “One problem developing for the last thirty years . . . is the consolidation of meat processors and therefore USDA-approved inspection sites . . . [s]ince 1981, the number of slaughterhouses and . . . inspectors have each declined by 10%. During the same period, however, meat and poultry production doubled.” Anderson, *supra* note 13, at 154. A study by Michael Ollinger and Danna Moore examined the ability to absorb costs of compliance with HACCP-type regulations in the meat processing industry: “large plants may have lower per-unit regulatory costs because they can spread fixed regulatory costs over more volume . . . ‘Economies of scale in food-safety process control give the very largest plants a substantial cost advantage over their smaller competitors.’” Anderson, *supra* note 13, at 161-62 (quoting Michael Ollinger & Danna L. Moore, *The Direct and Indirect Costs of Food-Safety Regulation*, 31 REV. AGRIC. ECON 247 (2009)).

78. Sarah K. Baker, *The Food Safety Modernization Act: Keeping Dinner Safe and Farmers in the Fields*, 3 KY. J. EQUINE, AGRIC. & NAT. RESOURCES L. 247, 253 (2011) (citing the public reaction to the 2009 salmonella outbreak linked to peanut butter as setting the stage for the FSMA).

79. “Developing and implementing the new prevention standards mandated by Congress is the FDA’s most critical activity in the initial phase of its implementation of FSMA . . . [it] requires a sea change in the standards . . . for assuring safe food production.” Kathleen Sebelius, U.S. Dep’t of Health and Human Services, *Report to Congress on Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)* 6 (2013),

While most consumers laud the objective of making food safe for consumption,⁸⁰ there are questions about the efficacy of such expansive preventive regulation.⁸¹ Additionally, the implementation of expanded inspection power will require immense amounts of funding.⁸² Initially, and still, small and mid-sized farmers and producers have decried the attempts at blanket regulation of agriculture.⁸³ The Tester-Hagan Amendment was adopted as a means to create a scalable system, one in which the small producers were not excessively burdened by regulatory schema aimed at industrial agriculture.⁸⁴

A closer look at the Tester-Hagan Amendment betrays its futility in achieving the goal of preserving small, owner-operated farms. The Amendment places the burden of proof of exemption on the agricultural entity; additionally, to qualify, the entity must prove multiple elements with documented evidence based on several years' worth of records.⁸⁵ Exemption from one regulation does not necessarily imply exemption from the other; for instance, those entities that are fully exempt from the Produce Rule may still be subject to the Hazard Prevention Rule. In any event, most producers will not achieve a full exemption and will instead need to fulfill various compliance requirements.⁸⁶ For example:

available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM351876.pdf>.

80. Strauss, *supra* note 10, at 357.

81. Baylen J. Linnekin, *The Food Safety Fallacy: More Regulation Doesn't Necessarily Make Food Safer*, 4 NORTHEASTERN UNIVERSITY LAW JOURNAL, 89, 91 (2012) ("In hindsight, the FDA's own record—and those of other federal agencies—shows that food—safety regulations often rest on factually erroneous premises and, consequently, can sometimes . . . make consumers *less safe*." (emphasis in original)).

82. See Kathleen Sebelius, U.S. Dep't of Health and Human Services, *Report to Congress on Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)* 59 (2013), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM351876.pdf>. ("FSMA places broad new demands on FDA . . . FSMA cannot be fully implemented in a timely and effective manner without additional resources.") The FSMA's grant of extensive inspection authority is, however, beyond the scope of this note.

83. See Richie Davis, *Valley Farms Again Decry Food-Safety Rules They Call Onerous, Unnecessary*, DAILY HAMPSHIRE GAZETTE (Northampton, Mass.), Aug. 24, 2013, available at <http://www.gazettenet.com/home/819689-95/valley-farmers-again-decry-food-safety-rules-they-call-onerous-unnecessary>.

84. See Baker, *supra* note 78, at 259.

85. See 21 U.S.C. 350h(f)(1) (2006): "A farm shall be exempt . . . if . . . during the previous 3-year period, the average annual monetary value of the food sold by such farm directly to *qualified end users* during such period exceeded the average annual monetary value of the food sold by such farm to all other buyers . . . and . . . the average annual monetary value of all food sold during such period was less than \$500,000.00." (emphasis added).

86. See generally NEW ENGLAND FARMERS UNION, *The Food Safety Modernization Act: What Do the New Laws Mean for Small Farms and Food Producers?*, (last visited May 22, 2015), available at <http://www.newenglandfarmersunion.org/wp-content/uploads/2012/05/FoodSafety.pdf>.

If a farm processes or manufactures food products and sells less than half of its products to individual consumers but more than half to a combination of those customers, local restaurants and stores, and the gross sales are less than \$500,000, the farm is still required to register with the FDA under the Bioterrorism Act of 2002 . . . The farm operators also must also demonstrate that they have identified potential hazards and are implementing preventive controls, OR demonstrate to FDA that they are in compliance with state or local food safety laws.⁸⁷

In short, even those farms or producers with qualified exemptions will be subject to compliance mechanisms, which will likely be duplicative in light of state and local policies, as well as consumer-driven food safety policies.⁸⁸

C. *Agriculture in New England: Moving Toward a Sustainable, Self-Reliant Region.*

Agriculture in New England is undeniably shaped by seasonal realities which lengthen or shorten growing seasons, more so than in some other regions.⁸⁹ Farmers and producers in New England must contend with seasonal oddities, such as a recent freeze that destroyed most of the annual apple crop.⁹⁰ Because of unpredictable weather events, annual gross income has an ability to fluctuate significantly: for instance, an orchard that loses most of its crop one year may have a successful season the next.⁹¹ Many farms and food producers will likely find the \$500,000.00 average revenue cap element of the exemption unrealistic because of seasonal fluctuations.

Because of the foregoing realities, many farms in New England choose to diversify their crops and additionally sell value-added items to

87. *Id.*

88. Many New England farms have already adopted safety policies; many are driven by consumer demand. *See, e.g.,* Gemme, *supra* note 7. (“As a vegetable grower in the Connecticut River valley, I have been involved in a customer-required food safety audit program on my farm for the past three years This now takes about four hours a day.”).

89. Abigail Curtis, *Apple Growers Struggling With Tough Season*, BANGOR DAILY NEWS, Sept. 9, 2012, <http://bangordailynews.com/2012/09/08/business/apple-growers-struggling-with-tough-season/>. Unseasonable weather events are becoming more frequent, possibly as a result of climate change: “We’re definitely running into a pattern of earlier hot spells and very erratic weather It’s not the real normal kind of patterns that we’re used to, or the trees are used to. It’s a real indication that things are changing.” Crop failure, while common, could make or break the gross sales revenue facet of the exemption requirement – by setting the cap for exemption at \$500,000 gross sales revenue from sales of food, the FSMA fails in its sensitivity thereto.

90. *Id.*

91. *Id.*

bolster their profits.⁹² By diversifying produce and selling value-added products—such as pickles, frozen vegetables, or jam—farmers are able to increase their sources of revenue and capitalize on the value that some degree of processing can impart.⁹³ Under the FSMA, however, farms and producers must be very careful if they wish to work around the “trip wires” that will cause them to fall outside of the exemption. Virginia Nickerson of the University of Vermont’s Center for Sustainable Agriculture commented on the difficulty of utilizing these strategies for generating income under the FSMA:

[W]e’ve been encouraging farms to diversify, to process some of their products and to create value-added products. And when farms do that, depending upon gross sales levels, that may put a lot of farms into the preventative controls category, and if that happens, that’s going to mean they’re going to have a lot more record keeping. They might have to put in more infrastructure.⁹⁴

Some farms, who simply offer a modest roadside farmstand stocked only with an occasional bumper crop of seasonal produce, may not qualify for an exemption despite the fact that most of their income is based in, for example, animal feed, such as silage or feed hay.⁹⁵

Many diversified farms will not qualify for the exemption even though their produce or value-added operations are relatively small. They will be faced with two options: comply with the costs of FSMA, or exit their produce or value-added operations (which often provide an essential income diversification strategy). Both options may well destroy the financial viability for these diversified farms.⁹⁶

92. NEW ENGLAND FARMERS UNION, *FSMA and Structure of New England Agriculture* (last visited May 22, 2015), <http://www.newenglandfarmersunion.org/food-safety-modernization-act/fsma-and-structure-of-new-england-agriculture/>. (“New England, with its preponderance of small but growing and diversified farms, will be disproportionately affected by FSMA.”).

93. See Melissa Matthewson, *Exploring Value Added Agriculture*, OR. S. U. SMALL FARM NEWS, Vol. II, No. 2, Summer 2007, available at <http://smallfarms.oregonstate.edu/sfn/su07valueadded> (last visited May 22, 2015).

94. Bob Nuner, *Battling the Goliath of Federal Regulations— Small Vermont Farms and the Food Safety and Modernization Act*, THE BRIDGE, Sept. 8, 2013, <http://www.montpelierbridge.com/2013/09/battling-the-goliath-of-federal-regulations-small-vermont-farms-and-the-food-safety-and-modernization-act/>.

95. Rosemary Fifield, *Food Safety Modernization Act in New England*, CO-OP FOOD STORES, Aug. 23, 2013, <http://www.coopfoodstore.coop/news/food-safety-modernization-act-new-england> (“‘Food sales’ include all food sold for human or animal consumption – hay, milk, syrup, and produce . . . If a farm’s gross food sales (of all farm or feed production) exceed the limit OR if their direct sales just are a small portion of their total sales, a farm is not exempt. Many diversified farms will not qualify for the exemption even though their produce or value-added operations are relatively small.”).

96. NEW ENGLAND FARMERS UNION, *supra* note 92.

New England is also known for a recent growth spurt in its sustainable and organic farming practices.⁹⁷ Market demand for sustainably grown and organic produce and other food has created a massive influx of new and old farms embracing the practices.⁹⁸ These methods, however, are often costly to implement and may require additional certification.⁹⁹ Organic certification is time consuming, costly, and requires a heft of administrative tasks in addition to the costly practices.¹⁰⁰

Because sustainable and organic agriculture often costs more in terms of startup and continuing production, those farmers must, in turn, charge more to recoup these expenses.¹⁰¹ An example of an environmental enhancement cost not captured by conventional farming methods is the cost of maintaining buffer strips, also known as conservation buffers—these areas of permanent vegetation prevent various types of contamination.¹⁰² They prevent runoff and erosion, increase biodiversity, and provide habitat.¹⁰³

This singular example means that farmers utilizing this sustainable, organic method cannot utilize every square inch of their arable land. Thus, the prices of any resulting products tend to be higher, reflective of

97. NEW ENGLAND FARMERS UNION, *See Number of Farms on Rise in New England*, <http://www.newenglandfarmersunion.org/number-of-farms-on-the-rise-in-new-england/> (last visited May 22, 2015); see also Steve Grant, *Let it Grow: Connecticut Leads Farm Growth in New England*, HARTFORD COURANT, Mar. 23, 2014, http://articles.courant.com/2014-03-23/news/hc-farm-survey-results-ct-20140322_1_new-farmers-agriculture-census-andy-billipp.

98. Jo Anne Shatkin, *Financing a Growing Appetite for Sustainable Food*, CONSERVATION LAW FOUNDATION BLOG (Feb. 27, 2013), <http://www.clf.org/blog/clf-ventures/financing-a-growing-appetite-for-sustainable-food/>.

99. The high purchase cost of organic foods and produce more accurately reflect the true growing and processing costs than other products because organic producers “substitut[e] labor and intensive management for chemicals, the health and environmental costs of which are borne by society.” ORGANIC FARMING RESEARCH FOUNDATION, *Organic FAQs: What is organic farming?*, <http://offr.org/organic-faqs> (last visited May 22, 2015).

100. For organic certification through an entity accredited by the U.S. Department of Agriculture, there is a three-year transitional period during which the land for which certification is sought is free of non-organic amendments or inputs. The cost of certification can range from a few hundred to several thousand dollars, depending on the size of the operation. U.S. DEP’T OF AGRIC., *National Organic Program FAQ: Becoming a Certified Operation* (last modified Jan. 28, 2014), <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&topNav=&leftNav=NationalOrganicProgram&page=NOPFAQsHowCertified&description=FAQ:%20%20Becoming%20a%20Certified%20Operation>.

101. FOOD AND AGRIC. ORG. OF THE UNITED NATIONS, *Organic Agriculture FAQ*, <http://www.fao.org/organicag/oa-faq/oa-faq5/en/> (last visited May 22, 2015).

102. See generally, U.S. DEPT. OF AGRIC., NATURAL RES. CONSERVATION CENTER, *Buffer Strips: Common Sense Conservation*, http://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/newsroom/features/?cid=nrcs143_023568 (last visited May 22, 2015).

103. *Id.*

the tradeoff for use of that portion of the land for agriculture.¹⁰⁴ Based on the growth and demand for locally-sourced, organic produce and food, one can infer that consumers in New England are willing to, in turn, pay more for the knowledge that the agricultural practices at hand are environmentally friendly.¹⁰⁵ By capping the gross revenue at \$500,000.00, the exemption would tend to offer a disincentive to the sustainable, organic model.¹⁰⁶ Because costs for organic and sustainable production tend to be higher, gross revenue must also be higher to reflect that difference.

Additionally, New England as a region boasts large price tags on real estate—the high cost of land and living in New England is reflected in the cost of farmland.¹⁰⁷ Realistically, a New England farmer or producer with a gross income of \$500,000.00 may only have a net profit of ten percent of that income, or \$50,000.00.¹⁰⁸ The FSMA's exemption provided by 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

104. “Prices of organic foods include not only the cost of the food production itself, but also a range of other factors that are not captured in the price of conventional food, such as: [e]nvironmental enhancement and protection (and avoidance of future expenses to mitigate pollution). For example, higher prices of organic cash crops compensate for low financial returns of rotation periods which are necessary to build soil fertility.” FOOD AND AGRIC. ORG. OF THE UNITED NATIONS, *supra* note 101.

105. See, e.g., FOREVER FARMLAND, <http://foreverfarmland.org/> (last visited May 22, 2015) (dedicated to preserving agricultural parcels in western Massachusetts through agricultural preservation restrictions); LAND FOR GOOD, <http://www.landforgood.org> (last visited May 22, 2015) (“Entire communities will benefit from increased farming opportunity, healthy lands and a more secure food supply.”); GROW FOOD NORTHAMPTON, *Our Mission, Goals, and Beliefs*, <http://www.growfoodnorthampton.com/about-us-2/our-mission/> (last visited May 22, 2015).

106. “[S]etting a revenue ceiling for exemption from the FSMA’s costly compliance requirements creates a disincentive for local direct-to-consumer producers to expand production and may discourage new entrants in local farming.” Anderson, *supra* note 13, at 164.

107. “In the Northeast, which boasts 7 out of the 10 states with the most expensive farmland, and particularly in tiny Rhode Island, farms cost more because land is scarce.” Maya Roney, *Green Acres*, BLOOMBERGBUSINESSWEEK, (Apr. 11, 2007), <http://www.businessweek.com/stories/2007-04-11/green-acresbusinessweek-business-news-stock-market-and-financial-advice>.

108. “Costs will be significant for farmers of all sizes but most acutely felt by small and mid-size growers – FDA’s numbers show that growers with sales up to \$500,000 will spend 4-6% of their gross revenue to comply with proposed on-farm regulations. . . . The average net income for farmers nationally was 10% of sales in 2011; so for small farms subject to the rules, FSMA could consume more than half of those modest profits.” NATIONAL SUSTAINABLE AGRIC. COALITION, *Top 10 Reasons for Farmers, Consumers, and Organizations to Weigh in on Proposed Food Safety Rules*, (Oct. 11, 2013) <http://sustainableagriculture.net/blog/food-safety-comments-top-10/>. (emphasis added).

than \$200,000 of artisanal cheese.”¹⁰⁹ New England small-scale agriculture is a prime example of how the FSMA will fail to achieve effective, workable, scalable, and importantly, place-oriented regulation.

D. *Falling Outside of the Exemption: Will Compliance Make our Regional Food Supply Safer?*

This section of the Note will examine how compliance with the FSMA will hurt New England agriculture and, in effect, make our food system more dependent on industrial agriculture, and thus less safe. Additionally it will argue that local food is safer than product associated with industrial agriculture.

Small and mid-sized New England farms that fall outside of the scope of complete exemption will face many tough choices going forward. Cost of compliance with the FSMA may force some small farms out of business, and may still force others to lower the costs of their agricultural practices—by, for example, utilizing cheaper synthetic pesticides and herbicides in place of more labor-intensive sustainable practices that cost more to implement.¹¹⁰

Assuming some farmers are able to bear the costs of compliance, the result would not be that our regional food supply is made any safer.¹¹¹ The overwhelming majority of large-scale foodborne illnesses can be traced back to industrial agriculture and its subsequent lengthy supply chains and extensive handling of product.¹¹² Conversely, for small, local producers, any outbreaks of foodborne illness would be much more limited in scope, both quantitatively and geographically.¹¹³

109. Obolensky, *supra* note 44, at 920 (internal citation omitted).

110. FOOD AND AGRIC. ORG. OF THE UNITED NATIONS, *supra* note 101 (explaining that organic food is costlier because it requires “greater labour [sic] inputs per unit of output and because greater diversity of enterprises means economies of scale cannot be achieved.”).

111. “There is no food safety issue on our small farms here in New England. Richard Bonano, a vegetable specialist at the University of Massachusetts Extension, recently wondered how we would measure the success of implementing a major food safety program on New England farms, given that there is no problem in the first place.” Gemme, *supra* note 7.

112. Endres & Johnson, *supra* note 46, at 54 (“[T]he long transportation chains needed to move fresh-cut greens from field to processing plant to retail outlets are an especially important area of potential bacterial contamination.”).

113. “The argument typically goes like this: big food producers are the source of most bacterial contamination because they grow vast amounts of raw agricultural commodities, which are shipped to central processing plants, handled by many people, commingled with other produce, and stripped of natural protective barriers They are then treated to preserve shelf life and shipped thousands of miles away This long chain of processing and supply introduces countless opportunities for contamination.” Johnson & Endres, *supra* note 2, at 91. Unfortunately, there has been no extensive study empirically indicating the *inherent* safety of locally-grown produce and locally-sourced products.

Historical evidence illustrates the fact that high costs of compliance, especially those associated with stringent preventive rules, tend to drive smaller businesses out.¹¹⁴ For example, in the late 1990s, when the USDA mandated HACCP-type rules for slaughterhouses and meat processors, the result was that many smaller-scale slaughterhouses and meat producers ceased to exist and the industry became further industrialized and centralized.¹¹⁵ Larger, industrial facilities were able to absorb the costs more readily.¹¹⁶

Even the FDA has predicted that the FSMA's strict preventive approach will have a similar effect on small agricultural entities.¹¹⁷ In effect, the large industry players that are generally the sources of the majority of the problems prompting the passage of the FSMA will be left standing. Subsequently, some small entities, which were never the source of the problem, may cease to exist.

II. COOPERATIVE FEDERALISM

There is no question that agriculture is a vast and diverse industry with regional particularities involving various types of entities, practices, crops, levels of on-farm diversification, costs of production and overhead, and levels of owner involvement in production. Because these facets consistently vary from state to state and region to region, serious care should be taken to increase *all* stakeholder roles in repairing food safety in the United States. Any federal food safety or agricultural regulation should take especial care to preserve the identities and functionality of small and mid-sized growers and producers. Realistically, because agriculture is so diverse, as described above, even the FDA has recognized this fact.¹¹⁸ Any type of blanket regulation thereof will be inadequate, and no unilateral rules for exemption will serve as an effective safety net for the small players in what is an increasingly large-scale food system. Despite the well-intentioned

114. Anderson, *supra* note 13, at 161-62.

115. Obolensky, *supra* note 44, at 915-17.

116. Anderson, *supra* note 13, at 161-62.

117. FOOD AND DRUG ADMIN., ANALYSIS OF ECONOMIC IMPACTS – STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION, 317 (2013), available at www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf.

118. U.S. FOOD AND DRUG ADMINISTRATION, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, 117 (Oct. 26, 1998), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlanProducts/ucm065474.htm> (noting, in part, that agricultural practices and commodities differ vastly, and that food safety practices should be tailored to each individual entity).

Tester-Hagan Amendment, many small and mid-sized farmers and producers across the nation will either fall outside of the exemption or will be forced to significantly alter their business practices while continuously taking great care to keep their revenue from sales of their product beneath the gross revenue cap.

To the extent that we feel that the federal government should be regulating food safety all the way back to the fields, such federal regulation must somehow be reflective of the place-based identity inherent in this industry.¹¹⁹ To that end, an examination of the historical tenets of a cooperative federalism approach to implementation of federal regulation at a state level reveals the ability of such an approach to achieve the goal of protecting the individuality inherent in each state and region's agriculture.

An inquiry into the theories supporting cooperative federalism highlights valid concerns for state sovereignty and regionalism in similar scenarios. Historically, and recently, cooperative federalism has been most often associated with the state implementation of environmental laws, including pollution control and natural resource conservation.

An examination of the potentialities of such an approach in the environmental law realm illustrates that justifications for such an approach are appropriately translated and translatable to the regulation of the food safety implications of agricultural practices.

The FSMA, as currently written, does not adequately address the inherent certainty of state and regional agricultural variability; revisiting the tenets of cooperative federalism as a means to increase state and local tailoring and creative implementation of federal law may give rise to a solution that better balances all of the interests at stake. At minimum, each state should have the opportunity to shape the implementation of such law to fit its own needs while also respecting the intent of federal food safety legislation.

A. *The Roots of Cooperative Federalism: Shared Power*

Cooperative, or collaborative, federalism can be defined as the sharing of responsibilities for given functions by the federal and state governments. In this sense it is conceived to be the opposite of dual federalism which implies a division of functions between

119. “[C]ommonalities in localities or regions form natural foodsheds. . . . The idea is that a foodshed is embedded in a geographic region, and that this allows people to become more concerned with their immediate environment and how food production affects it.” Margaret Sova McCabe, *Foodshed Foundations: Law's Role in Shaping Our Food System's Future*, 22 *FORDHAM ENVTL. LAW REV.* 563, 569-70 (2011).

governments as well as a division of governmental structures Even during the nineteenth century, when the ethos of the times called forth a theory of dualism that was based on a functional demarcation between governments, *the actual exigencies of the operation of the system of necessity demanded cooperation.*¹²⁰

Cooperative federalism stems from the very “roots of federalism itself” namely, “a federalist theory of government, a dual governmental structure, some specific cooperative programs, and some administrative techniques for intergovernmental collaboration.”¹²¹ The Constitution “provides for dual institutions, some cooperative programs, and a wide range of concurrent powers which can either be divided between the federal government and the states or shared by them in various cooperative programs.”¹²² Indeed, the Supreme Court has “characterized our federalism as requiring that Congress treat the States in a manner consistent with their status as residuary sovereigns and joint participants . . . federalism entails neither blind deference to States’ Rights nor centralization of control over every important issue in our National Government and its courts.”¹²³

Without delving into a lengthy examination of hundreds of years of the historical development of American federalism, it is important to note how a cooperative approach to implementation of federal policy has been construed within the past century or so. Examining the initial theories behind cooperative federalism sheds light on the way in which a more cooperative approach to food safety could achieve the preservation of federal and state (and, thereby, local) objectives and considerations. This Note’s criticism of the FSMA centers around its insensitivity to state and regional agricultural differences in its blanket regulation and exemption provisions. Congress could “pursue its objectives without running roughshod over state sovereignty [by] enlist[ing] the assistance of state governments in the pursuit of federal goals and to allow the states to pursue supplementary or alternative goals, as long as such state efforts do not frustrate achievement of the federal purposes.”¹²⁴ Although the FSMA directs the FDA to work with other federal agencies and state actors to implement the eventual regulations, no real recourse is

120. Daniel J. Elazar, *Federal-State Collaboration in the Nineteenth-Century United States*, in COOPERATION AND CONFLICT, READINGS IN AMERICAN FEDERALISM, 107 (Daniel J. Elazar et al., eds., 1969).

121. *Id.* at 85.

122. *Id.* at 85-86.

123. Robert L. Glicksman, *From Cooperative to Inoperative Federalism: The Perverse Mutation of Environmental Law and Policy*, 41 WAKE FOREST L. REV. 719, 722 (2006) citing *Younger v. Harris*, 401 U.S. 37, 44 (1971) (internal formatting and citations removed).

124. *Id.* at 723.

left to the states themselves to tailor regulations to fit each state's individual needs.

In 1938, an Iowa Law Review symposium examined and explained the idea of cooperative legislation; the articles therein focused on the relationship of state and federal regulatory authority, including commentary on the national objective of providing safe food.¹²⁵ An entire article posited the “influence of federal legislation on state efforts to engage in natural resource conservation and planning.”¹²⁶ Overall, the symposium pieces saw cooperative federalism as an experimental but meaningful facet in what amounted to an ongoing effort to define American federalism by parsing out various iterations of the scope of state and federal regulatory power.¹²⁷

The federal government has clear authority to regulate pollution under the commerce clause¹²⁸ and under its ability to manage federally-owned lands, including protection of those lands from damage by adjacent properties.¹²⁹ In the latter half of the twentieth century, the predictions made in 1938 about the suitability of cooperative federalism in addressing national issues such as environmental and natural resources concerns came to fruition.

Beginning in the 1970s, environmental law and policy embraced a cooperative approach to implementation of pollution control law through the Clean Air Act¹³⁰ and the Clean Water Act,¹³¹ among other environmental and health-based statutes adopting a cooperative approach.¹³² These federal enactments aimed at nationwide environmental protection and pollution control “did not completely divest states and localities of their preexisting regulatory authority. Instead, many of the statutes . . . created cooperative partnerships

125. See generally Frank R. Strong, *Cooperative Federalism*, 23 IOWA L. REV. 459 (1938).

126. Glicksman, *supra* note 123 at 724, citing William E. Warne, *The Drainage Basin Studies: Cooperative Federalism in Practice*, 23 IOWA L. REV. 565 (1938).

127. “[F]ederalism is still in flux . . . no balance has yet been struck between state and nation.’ The same statement clearly still holds true.” Glicksman, *supra* note 123, at 719 (internal citations removed).

128. U.S. CONST. art. I, § 8, cl. 3. See also *N.Y. v. United States*, 505 U.S. 144, 167 (1992) (noting that, despite Congressional power to regulate private activity, in some instances, Congress has offered States a choice to adopt regulations in accordance with federal programs).

129. U.S. CONST. art IV, § 3, cl. 2.

130. Clean Air Act, 42 U.S.C. §§ 7401-671q (2000).

131. Clean Water Act, 33 U.S.C. §§ 1251-1387 (2000).

132. Another ground for federal regulation regarding environmental pollutants stemmed from the “inability of the states to provide effective constraints on transboundary pollution—pollution with interstate or international effects.” Glicksman, *supra* note 123, at 735.

between federal and state governments.”¹³³

Both sets of regulations explicitly spell out the Congressional intent that state and local governments retain a role in implementing rules and regulations aimed at achieving the ends of a national policy.¹³⁴ The Clean Air Act promotes state programs designed to “prevent and control air pollution” through federal funding.¹³⁵ The Clean Water Act similarly encourages federal financial assistance in state development of programs to eliminate and control pollution in connection with water sources.¹³⁶ In both cases, the federal government essentially remains “unquestionably . . . in the driver’s seat” because the stringent floor standards to which state programs must essentially conform their programs remains under the Congressionally delegated regulatory purview of the Environmental Protection Agency.¹³⁷

The Clean Air Act gave states the ability to create and adopt state implementation plans (SIPs)¹³⁸ to achieve national ambient air quality standards (NAAQS).¹³⁹ The EPA maintains the ability to promulgate NAAQS at a federal level; these NAAQS create a “maximum permissible concentration;” states are then allowed to create and implement plans centered on the federal model.¹⁴⁰ The Clean Water Act similarly vests power in the EPA to promulgate technology-based standards to control pollution point source discharges into waters of the United States.¹⁴¹

Under this approach, one author has noted that there are two key elements necessary to this type of cooperative federalism: “the fostering of state administrative programs, and . . . the delegation of tailored standard-setting.”¹⁴² The Clean Water Act and the Clean Air Act are apt demonstrations of the ability of the federal and state governments to enter into cooperative agreements concerning regulatory realms where specific input and output of identifiable substances into the environment

133. *Id.* at 728-29.

134. *Id.* at 738-39.

135. *Id.* at 738-39.

136. 33 U.S.C. § 1251(g) (2000).

137. Glicksman, *supra* note 123, at 740.

138. “As the Supreme Court has recognized, Congress initially intended to afford each state the liberty to adopt whatever mix of emission limitations it deems best suited to its particular situation.” Glicksman, *supra* note 123, at 741, citing *Train v. Natural Res. Def. Council, Inc.*, 421 U.S. 60, 79 (1975) (internal quotations removed).

139. Glicksman, *supra* note 123, at 740-41.

140. *Id.*

141. 33 U.S.C. § 1311(b) (2000).

142. Fischman, *supra* note 42, at 190 (“Both . . . elements operate under oversight by the federal government. In practice, this oversight is generally less strict than legislation suggests because of political considerations and fiscal limitations.”).

facilitates permitting and enforcement schemes. Such constructions of cooperative federal-state approaches are generally characterized by federal funding (in whole or in part) of the state program, as well as a federal allowance for some measure of state customization of substantive standards.¹⁴³ Such customization can be based on local, state, and regional considerations¹⁴⁴—such considerations as exist in the agricultural industry. Normally, however, because the scientific inquiries behind the federal legislation are expensive, states are generally unable or unwilling to pay for comparable studies to significantly tailor the state’s version of the regulations in such schemes.¹⁴⁵

While cooperative federalism is most frequently associated with state implementation of such pollution control scenarios, other types of cooperative agreements between federal and state agencies have arisen, and have arguably been executed successfully.¹⁴⁶ One author describes cooperative federalism in both narrow and broad conceptions, stating that most scholars only focus on environmental programs within the “aegis of the EPA.”¹⁴⁷ Through a deeper and broader understanding of cooperative federalism—an understanding that makes room for many forms of federal-state integration and coordination—we may glean a solution to the problems inherent in blanket regulation of agriculture.

A broader conception of cooperative federalism may offer workable solutions to the problems small and mid-sized farmers and producers are facing under the FSMA. If we are to retain a conception of cooperative federalism that only provides for state implementation of, as another author put it, pollution control mechanisms “within the aegis of the EPA,”¹⁴⁸ the result is limiting. A broader conception of cooperative federalism, combined with the tenets of state customization accompanying the implementation of the Clean Water Act and the Clean Air Act, offers a plausible framework in which the intent of the legislation can be achieved without indiscriminately putting many smaller entities out of business.

143. Fischman, *supra* note 42, at 192-93. This author additionally notes that despite stringency floors set by federal agency, “cooperative federalism programs typically allow for significant customization of standards. For instance, under the CWA, states have a great deal of discretion in determining water quality standards by defining designated uses and their applications to particular bodies of water.” Similarly, under the Clean Air Act, states have “wide latitude to choose among air pollution abatement and reduction strategies.”

144. “[S]tates may tailor their standards to . . . economic and social priorities . . . [and] must justify deviations from the elaborate federal models.” Fischman, *supra* note 42, at 193.

145. *Id.* at 193.

146. *Id.* at 194.

147. *Id.*

148. *Id.*

As one author noted, “[f]ew scholars of cooperative federalism have considered the broad conception [of cooperative federalism].”¹⁴⁹ Additional instances of state-federal and regional coordination of implementation of natural resources laws “distill[] principles that deepen our understanding of cooperative federalism.”¹⁵⁰ Federal oversight of public lands is a prime example of this conception of cooperative federalism that is much broader than the type exhibited in the pollution control mechanisms.¹⁵¹ The Sagebrush Rebellion of the 1970s and 1980s¹⁵² gave rise to increased “willingness of the federal government to work with states as well as an increased capacity of the states to offer substantive expertise and clearly articulated policies supporting the rise of this informal, administrative federalism.”¹⁵³ Although these types of cooperative agreements center on federal jurisdiction based in the Constitution’s property clause,¹⁵⁴ arguably, such ends could be reached in any instance where the federal government has some jurisdiction in which it may legislate.

A prime example of this broadened conception of cooperative federalism is evinced in federal resource planning for federally-owned multiple-use designated lands; the federal government in essence invites the states to participate through a planning process wherein states may assert their objectives and interests.¹⁵⁵

A particular breed of this type of cooperative federalism is place-based collaboration.¹⁵⁶ It is responsive to the specific needs of one location as a type of “system of decision-making . . . that is unique to a particular site or region.”¹⁵⁷ Such collaborations grow out of a particular

149. *Id.*

150. *Id.*

151. *Id.*

152. The Sagebrush Rebellion argued for increased state and private activity (including mineral extraction and grazing) on large quantities of federally-owned lands in western states. While the ends sought (mineral extraction, privatization) are often maligned, the Sagebrush Rebellion did give rise to the broad conception of cooperative federalism noted herein. For more information on the Sagebrush Rebellion, *see generally* R. MCGREGOR CAWLEY, *FEDERAL LAND, WESTERN ANGER: THE SAGEBRUSH REBELLION AND ENVIRONMENT POLITICS* (1993).

153. Fischman, *supra* note 42, at 194 (“The[se] informal, ad-hoc, complex arrangements facilitating greater state leverage over federal lands decisions remain intact today.”).

154. U.S. CONST. art IV, § 3, cl. 2.

155. Fischman, *supra* note 42, at 194; *see generally*, Richard H. Cowart & Sally K. Fairfax, *Public Lands Federalism: Judicial Theory and Administrative Reality*, 15 *ECOLOGY L. Q.* 375 (1988).

156. Fischman, *supra* note 42, at 196.

157. *Id.* at 196.

circumstance, dispute, or regional consideration relevant to the locus.¹⁵⁸ So-called place-based collaborations grow out of regional issues that often cross statutory boundaries, such as watersheds (for example, CALFED manages the Sacramento River Delta).¹⁵⁹

Such management can be in the form of multi-party collaboration or it can take the form of bilateral cooperation between the federal government and a single state or tribe.¹⁶⁰ While the management of, for instance, the biodiversity and habitat of a watershed may seem incongruous to an issue such as food safety, the basic facets giving rise to such place-based collaboration are indeed analogous: regional considerations, particular to a single locus, are often best addressed by a variety of stakeholders in an effort that centers around the management of the locus.

As with management and protection of a variety of endangered species, habitats, and resource areas, agriculture varies drastically from state to state and region to region. Each state and region's identity is shaped in part by the type of agricultural economy present. These variations in agricultural identity suggest an approach that adopts some of the intentions to allow a more localized approach to the issues, while also maintaining the federal objectives of food safety. Various federal-state land use plans are able to maintain the dual objectives of meeting the needs of local, state, and tribal concerns while also ensuring, for instance, protection of a federally-designated endangered species.¹⁶¹ Such collaborations, however, must be authorized by Congress,¹⁶² which would likely make the operation of the FSMA writ large, nationwide, under such a system impracticable. However, the facets of such an approach are important in understanding how considerations of place-based particularities may give rise to an implementation of the FSMA that factors local concerns into the equation.

An additional example of the broader-based concept of cooperative federalism is the type of agreement and process that exists under the Federal Land Policy Management Act, which "requires the [Bureau of Land Management] to coordinate with state and local governments in the development of land use plans to the extent consistent with the laws governing the administration of public lands and to consider input concerning land use decisions from states (and other non-federal

158. *Id.*

159. *Id.*

160. *Id.* at 196-97.

161. *Id.* at 197.

162. *Nat'l Parks & Conservation Ass'n v. Stanton*, 54 F. Supp. 2d 7, 18-19 (1999).

entities).”¹⁶³

This type of approach encourages states and other stakeholders to bring plans to the federal table, and in some cases, the federal statute may give preference to consistency with a state or local plan. Such “state favoritism in the federal process” induces states to pursue their objectives and federal objectives contemporaneously, but the federal scheme remains aimed toward respect and a degree of deference to the state’s plan.¹⁶⁴ Again, although the substantive law at issue (land use) is not entirely congruous with food safety oversight, the intentions are analogous: Congress can create a type of deference to state and regional stakeholders, so long as the state’s proposed plans remain in line with federal objectives.¹⁶⁵ While this avenue is costly for states because development and proposal of plans without a guarantee of federal approval is a sketchy approach, it does allow for states to pursue a plan tailored to their own interests.

An additional conception of cooperative federalism posits a system in which state plans, policies, or standards are adopted in accordance with federal procedures, and are then instituted by the federal government;¹⁶⁶ in such a scenario, the federal government is likely to adopt the state position. This type of cooperative federalism has been referred to by one author as federal deference to state process.¹⁶⁷ The same author utilizes, as an example of an effective institution of this process, the Coastal Zone Management Act’s consistency criterion.¹⁶⁸ Essentially, the federal government provides guidelines and offers funding for states to utilize in order to design and implement a coastal management plan; once the plan is approved by the National Oceanic and Atmospheric Administration, the federal government’s actions within the jurisdiction allotted under the management plan must be in conformity with the state’s plan.¹⁶⁹ Once a state’s management plan is approved, it has the right to insist that any federal action regarding the subject matter of the plan fall into conformity with the state’s plan.¹⁷⁰

163. Fischman, *supra* note 42, at 200 (citing 43 U.S.C. § 1712 (c) (2000) (internal quotations omitted)).

164. Fischman, *supra* note 42, at 200-01.

165. For instance, the National Forest Roadless Rule provision for state participation in planning requires that the petition contain commentary on seven separate categories of relevant information, including proposed forest management effect on animals. *See* National Forest Roadless Rule, 70 Fed. Reg. at 25,661-62. Such a burdensome approach may be an “arduous requirement for the states.” Fischman, *supra* note 42, at 203.

166. Fischman, *supra* note 42, at 203.

167. *Id.*

168. *Id.* at 204 (referring to 16 U.S.C. § 1456 (c) (2000)).

169. *Id.* at 204-05.

170. *Id.* at 204.

This mode of cooperative federalism is especially attractive because the federal government is essentially bound by the state's determinations.¹⁷¹

By examining a broad swathe of federal regulations falling under an expanded conception of cooperative federalism (that is, beyond the often-analyzed pollution control realm), various facets of a cooperative approach to federal regulation seem workable. Viewing a variety of cooperative approaches through the lens of food safety, one can see how a creative combination of elements from each model could give rise to a successful implementation of federal food safety regulation—an implementation that would not be nearly as destructive to small and mid-sized owner-operated farms. The inherent local particularities of agriculture call loudly for an approach with more sensitivity, despite the criticisms of cooperative federalism schemes.

B. *Cost, Competition, and Other Criticisms: Overcoming the Obstacles*

Various criticisms of cooperative federalism have arisen, ranging from complaints about the innate high cost of utilizing federal monies as an inducement to prompt states or regions to act,¹⁷² to suppositions that states will engage in a “race to the bottom” to attract stakeholders wary of more than the minimal amount of federal regulation.¹⁷³ As with any scheme for implementation of regulation at any level, these criticisms are met—and often satisfactorily—with justifications.

One such criticism of cooperative federalism in the pollution control context is that states are unlikely to embark on research to develop their own standards in light of well-funded and established federal standards; the argument thus becomes that states are more likely to simply accept the existence of federal standards as a whole.¹⁷⁴ In the pollution control context, “[o]ne possible explanation for the states’ failure to provide effective environmental regulation is their lack of scientific expertise and their inability to provide the resources needed to implement such regulation.”¹⁷⁵ One author has commented on the rationale behind simply adopting the federal standards with regard to air pollution standards:

It makes no sense to ask every state, city, or town to measure the level, size, and type of particulates in its air, determine their

171. *Id.* at 206.

172. As noted, the primary inducement to states in adopting federal policy is nearly always the receipt of federal monies. Fischman, *supra* note 42, at 189 (“A carrot-and-stick approach to inducements is fundamental to cooperative federalism under any conception.”).

173. Glicksman, *supra* note 123, at 736.

174. *Id.* at 733-34.

175. *Id.* at 733.

connection to respiratory failure and other health problems, identify the safe level of emissions, and design cost-effective policy responses. . . . In addition, the core variables within these functions *do not vary spatially, and thus diversity claims hold little sway.*¹⁷⁶

This criticism is centered upon two factors: the innate technical intricacy of measuring and computing particulate levels and connecting those levels with incidence of health problems, and, more importantly, the minimal concern for regional particularities associated with the problem to be regulated. Arguably, agriculture varies more spatially than air pollution: more factors are at play, not just the emission of dangerous particulate into the atmosphere.

The regional differences in agriculture are more readily prevalent and tangible than the microscopic nature of most pollutants; additionally, the effects on agriculture of federal regulation are, too, more directly tangible than the often attenuated and difficult connection between air pollution and specific instances of human illness.

Agriculture is a visible manifestation resulting in the production of edibles vital to our survival. It is possible that states could conduct comparatively low-cost assessments of the risk of various sizes of agricultural entities, and tailor regulations to meet the needs and inherent risks of each sized entities. While microbial pathogens and bacteria, like the microscopic particulates associated with air pollution, require some degree of technical inquiry, constituents may feel more motivated to promote expenditures related to consumer safety. As previously noted, consumer outrage is what initially propelled the FSMA into existence.¹⁷⁷ Perhaps consumers feel more concern about the safety of the food they ingest than they do about expenditures relating to regulation of something as frequently indiscernible as pollution.

An additional criticism of cooperative federalism is the theory that, in the absence of strict federal standards, states will engage in a “race to the bottom” to “attract new business by adopting increasingly lenient controls on activities.”¹⁷⁸

Given the mobility of industry and commerce, any individual state or community may rationally decline unilaterally to adopt high environmental standards that entail substantial costs for industry and obstacles to economic development for fear that the resulting environmental gains will be more than offset by movement of capital

176. *Id.* at 733-34 (citing Daniel C. Esty, *Revitalizing Environmental Federalism*, 95 MICH. L. REV. 570, 614 (1996) (emphasis added)).

177. *See supra* note 10.

178. Glicksman, *supra* note 123, at 736.

to other areas with lower standards.¹⁷⁹

The “race to the bottom” theory has been roundly criticized; noted in Part I.C, *infra*, consumers, especially in New England, are striving to become more connected with the sources of their food. As such, consumer awareness of food safety mandates is growing.¹⁸⁰ This author does not suggest an absence of food safety regulation; instead, workability and scalability is key. In the “race to the bottom” theory, the industry actors are posited as malevolent, and looking to decrease costs.¹⁸¹ Simply put, small and mid-sized farmers are not looking to evade food safety, but rather to make food safety workable for all sizes of entities. Because of the more direct accountability associated with small and mid-sized, owner-operated farms,¹⁸² evading food safety is not a goal as it would tend to dissuade consumers.¹⁸³ Quite simply, such a criticism can be easily rebutted: although this “race to the bottom” theory may (or may not) be an apt criticism of pollution regulation,¹⁸⁴ direct consumer demand for food safety would drive good faith efforts to produce safe foods in the realm of small and mid-sized, owner-operated farms.

C. *Where Can the FSMA Go from Here?*

The FSMA, as written, makes only superficial efforts in promoting state and local interests. This involvement is limited to training and instruction in accordance with what will likely eventually be blanket FDA regulations.¹⁸⁵ In any event, the Tester-Hagan Amendment to the

179. *Id.* (citing Richard B. Stewart, *Pyramids of Sacrifice?: Problems of Federalism in Mandating State Implementation of National Environmental Policy*, 86 YALE L.J. 1196, 1212 (1977)).

180. Nathan M. Trexler, Comment, “Market” Regulation: Confronting Industrial Agriculture’s Food Safety Failures, 17 WIDENER L. REV. 311, 319 (2011).

181. Richard L. Revesz, *Rehabilitating Interstate Competition: Rethinking the “Race-to-the-Bottom” Rationale for Federal Environmental Regulation*, 67 N.Y.U. L. REV. 1210, 1243 (1992).

182. O’REILLY, *supra* note 27, at 113 (“food is produced more carefully by actual farmers—persons who either sell at a farmer’s market or whose identities are known to repeat customers in the local community”).

183. Nathan M. Trexler, Comment, “Market” Regulation: Confronting Industrial Agriculture’s Food Safety Failures, 17 WIDENER L. REV. 311, 337 (2011) (noting that consumers have looked to local food as a means of protecting themselves).

184. *See, e.g.*, Richard L. Revesz, *Rehabilitating Interstate Competition: Rethinking the “Race-to-the-Bottom” Rationale for Federal Environmental Regulation*, 67 N.Y.U. L. REV. 1210 (1992).

185. “Examples of current ongoing activities include efforts to standardize training and expertise levels of inspectors. Another example of integration is the effort to develop national standards for federal, state, and local laboratories.” U.S. FOOD AND DRUG ADMINISTRATION, *Food Safety Modernization Act, Frequently Asked Questions*, (last updated Sept. 19, 2014),

FSMA reflects a federal urge to understand and regulate the agricultural industry based on gross revenue—a facet of agriculture that, as illustrated, varies remarkably from state to state and region to region. The element of the Tester-Hagan amendment capping the exemption at \$500,000 betrays this federal failure to consider regional diversity.

Agriculture is a vast and diverse industry. In New England, perhaps moreso than elsewhere, small, sustainable, owner-operated farms are on the rise.¹⁸⁶ The FSMA was initially explicitly aimed at regulation of corporate bad actors.¹⁸⁷ The Tester-Hagan Amendment attempts to, but does not adequately, protect smaller entities.

Because states are more likely to have the best connection and understanding of their own agricultural economies, each state should receive some amount of discretion in its implementation of food safety laws. While food safety is a national issue, protecting small entities cannot easily be achieved by unilateral effort on the federal level. Each state should, at the very least, be able to create its own exemption criteria for small and mid-sized farmers and producers. Risk assessment of entities, performed by state agencies, could analyze and respond to varying levels of risk inherent in different types of facilities and farms. By creatively drawing on facets from various models of cooperative federalism, Congress and state legislatures could create more protection for the smaller players.

For instance, a federal baseline requiring some form of preventive controls could be set, giving states the opportunity to expand and creatively implement programs centered on the federal policy. Looking into broader conceptions of cooperative federalism, portions of place-based collaboration (namely, attention paid to locus-centered considerations and local management plans) could be easily translatable to addressing the regional diversity of agriculture.

Additionally, states could pursue and propose their own plans under federal policy objectives, to be approved and adopted by the FDA. As long as the essence of the food safety plans centers on the policy objectives, it should square with the federal policy of preventive

available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>. These efforts show partnership in the form of uniform implementation—not eliciting statutory considerations in shaping the new regulations to be responsive to regional concerns.

186. See *Number of Farms on Rise in New England*, <http://www.newenglandfarmersunion.org/number-of-farms-on-the-rise-in-new-england/> (last visited May 22, 2015); see also Steve Grant, *Let it Grow: Connecticut Leads Farm Growth in New England*, HARTFORD COURANT, Mar. 23, 2014, http://articles.courant.com/2014-03-23/news/hc-farm-survey-results-ct-20140322_1_new-farmers-agriculture-census-andy-billipp.

187. Endres & Johnson, *supra* note 46, at 40.

approach. At very least, states should have the ability to assess their own criteria for exemption (in part or in whole) or variances from compliance with costly measures.

In essence, each state would become a laboratory of democracy,¹⁸⁸ *creatively* implementing important policy objectives while still retaining a basic goal of preventive food safety strategy. Retaining small, sustainable agricultural entities is and should be treated as equally important as pursuing heightened food safety regulations.

CONCLUSION

The FSMA is an important piece of legislation, and its goals have become important to consumers, especially in light of unacceptable outbreaks of foodborne illness.¹⁸⁹ The Tester-Hagan Amendment to the FSMA is laudable in its concern for protection of small agricultural entities; however, because of regional considerations, and the inherent diversity of agriculture, the exemption provided by the amendment is simply unworkable on a national scale.

In particular, New England will likely suffer a disparate impact. Arguably, New England's agricultural economy is rich, distinct, and beneficial—and it is growing.¹⁹⁰ The exemption framework will, in all likelihood, cause a net loss of small agricultural entities and will hinder growth and new entry of farmers into the industry. A creative solution must be embraced; exploring various permutations of cooperative federalism illustrates the possibility of tailoring food safety policy to create a better fit for each state and region.

While federal delegation of the ability to create exemption and variance frameworks will not solve all of the problems of our federal agricultural regulations, it would be an important first step in increased sensitivity to regional concerns, and indeed a first step in approaching regulation of agriculture holistically.

*Laura Fisher**

188. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

189. *See* NAT'L SUSTAINABLE AGRIC. COALITION, *supra* note 12.

190. *See supra* note 92.

* J.D., Western New England University School of Law, 2015. I dedicate this Note to my late grandfather, Ted Sparko, with whom I spent my childhood on our family farm. He taught me life's most important lessons, including "everything that grows is beautiful." My sincerest gratitude to my family and friends for their ongoing support. And a special thanks to Jeff, whose patience never wavered.