



The Marketing of Local Foods and FSMA: What will the Implications Be?

By Erik R. Lieberman and Christopher Hudspeth

The enactment of the Food Safety Modernization Act¹ (FSMA) in 2011 marked the most sweeping change to our nation's food laws in more than 70 years. Not since President Franklin Delano Roosevelt signed the Federal Food, Drug, and Cosmetic Act² (the FD&C Act) into law has the food industry faced such a profound change to the regulation of its business activities. FSMA applies new regulations to essentially every step of the supply chain from farm to retail:

- Fruit and vegetable growers for the first time contend with Food and Drug Administration (FDA) regulation on the farm in the form of the Produce Safety Rule.³
- FDA-registered facilities⁴ that process, pack and hold

food face the Preventive Controls Rule, an entirely new Hazard Analysis and Critical Control Points (HACCP)-like preventive controls regime with which they must comply.⁵

- Food in transportation will now be subject to new regulations under the Sanitary Food Transportation Act.
- The third-party auditors retailers and manufacturers rely on throughout the supply chain must now be accredited by FDA.
- Food importers face a spate of new legal and regulatory obligations associated with the Foreign Supplier Verification Program.



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- Retailers contend with federal requirements to notify consumers of recalls, and retailers and wholesalers face significant impacts from all of the above rules.

Many more rules are one the way, ranging from food defense to traceability. The sheer volume and complexity of regulations pose challenges to small farms and local producers.

Because of concerns over the capability of small farmers and manufacturers to comply with FSMA, an amendment offered by Sens. Tester and Hagan, was accepted by the Senate and included in the law (the “Tester Amendment”). The implementation of FSMA comes at a time when demand for local foods is high and increasing, and efforts to market local foods at retail are growing. A key question surrounding the implementation of FSMA is how it will impact the marketing and availability of local foods.

What is a Local Food?

The definition of local food varies greatly among consumers, retailers and policymakers. “State-level legislation often defines local food as anything that is grown or produced within state boundaries.”⁶ The 2008 Farm Bill contains a combined definition of local and regional foods: such foods are grown within 400 miles or the same state in which they are marketed.⁷ As we discuss later in this article, the Tester Amendment used a narrower definition in establishing an exemption for farms and registered food facilities selling food within 275 miles or the same state in which it is marketed.⁸

Consumer and Supermarket Industry Perspectives on Local

For retailers, consumer views are paramount. To the consumer, local generally

means a product produced within the state in which it is purchased or within a certain distance.⁹ The average distance that consumers perceive to be local production for a food is 81 miles from the place of purchase.¹⁰ State lines are increasingly defining what constitutes local in the minds of consumers. “In 2011, 44 percent used the state of residence to define the local designation, up from 30 percent in 2009.”¹¹ A slightly smaller proportion of consumers—41 percent—say the definition should be based within a certain mile radius of where they live or shop.¹²

The chief reasons that consumers purchase locally are freshness and support of the local economy.¹³ Other factors in descending order of prominence include taste, knowing the source of the product, price, nutritional value, environmental impact of transporting foods across great distance and appearance.¹⁴

Retailer and wholesaler views on what is a local food largely mirror those of the consumers they serve. Like shoppers, retailers and wholesalers primarily consider products produced within the state in which they are sold to be considered local.¹⁵ The latest industry poll of the Food Marketing Institute¹⁶ (FMI) found that 50 percent of retailers and wholesalers believe products produced in the same state in which they are sold are local while 42 percent believed that a specific distance should be considered local.¹⁷

The Growing Demand for Local Foods and the Supermarket Industry Response

The implementation of FSMA has coincided with an increasing demand among consumers for local foods. Sixty five percent of shoppers say they have bought local foods in the past year and one in five shoppers say they have

purchased a larger quantity of local foods than in the previous year.¹⁸

Not surprisingly, the growing demand of local foods has led consumers to seek out retailers that support local food sources. Fully 85 percent of consumers consider support of local food sources a “very important” factor in selecting a primary shopping destination.¹⁹

The vast majority of shoppers purchase locally-sourced items at supermarkets. Nearly 10 percent of shoppers buy local items whenever possible and over 80 percent buy them occasionally.²⁰

Retailers and wholesalers are responding to consumer demands for local foods. Nearly 70 percent of retailers have increased the number of locally-sourced items from the prior year according to the latest industry survey and not one reduced it.²¹ Fully 85 percent of retailers and wholesalers expect to increase the number of locally-sourced products they offer in the next five years.²² Produce, specifically apples, corn, tomatoes and strawberries leads the list of local products offered, followed by dairy, beef and bread.²³ This is not surprising considering that produce and nut farms account for only 5 percent of all farms in the country, but represent 40 percent of farms serving local markets.²⁴ Although produce dominates local offerings in supermarkets, increasingly, retailers and wholesalers are providing consumers with local options for meat, salsas, sauces, jams and cheeses.²⁵

In 2010, Walmart, the nations’ largest food buyer, pledged to double its percentage of local produce offered in its stores from 4.5 to 9 percent.²⁶ Just two years after making this pledge, Walmart’s local food sourcing expert Ron McCormick testified in front of the Senate Agricultural Committee that Walmart had already met and exceeded its goal and that 11 percent of its produce was being sourced

from local farms.²⁷ SUPERVALU, a large retailer and wholesaler, estimates that it buys between 25 and 40 percent of its produce locally.²⁸ Safeway, one of the largest retail supermarkets in the U.S., sources more than 30 percent of produce from regional growing partners.²⁹

Shoppers have taken notice of retailers' efforts. Nearly 90 percent of shoppers rated their primary store's performance on locally-grown products as good or excellent.³⁰ Nearly half of shoppers said that their primary store offers locally-grown products and more than 90 percent of consumers use or purchase them on occasion.³¹ Against the backdrop of increasing prominence of local foods in the marketplace, small farmers and manufacturers won a victory in securing relief from the largest regulatory burdens of FSMA. This victory was embodied in the Tester Amendment included in the law.

The Tester Amendment

The Tester Amendment was introduced to provide relief from what was perceived as FSMA's "brush approach" to regulating farms, and sought to reduce the burdens on certain smaller, more locally-focused farms.³² Sen. Tester feared that the regulatory burdens imposed by FSMA would force smaller producers out of business, ceding more market share and influence to fewer, larger farms and businesses.³³ The Amendment was initially met with mixed responses. Some praised the Amendment as protecting the "renaissance" of local food,³⁴ while others noted that foodborne pathogens do not differentiate between farms of different sizes.³⁵ Due to concerns raised over the breadth of how "local" was defined, the Amendment's language limiting the mile radius was lowered from the 2008 Farm Bill standard of 400 miles to 275. The Tester Amendment exempts certain small businesses from the Preventive

Controls regulations and certain small farms from the Produce Safety Rule.

Preventive Controls Rule Exemption

The proposed Preventive Controls Rule applies HACCP-like requirements to domestic and foreign food facilities that are required to register with FDA pursuant to section 415 of the FD&C Act,³⁶ with limited exceptions. Each covered facility is required to prepare and implement a written food safety plan which includes:

- Hazard analysis
- Preventive controls
- Monitoring
- Corrective actions
- Verification activities
- Recordkeeping

Pursuant to the Tester Amendment "qualified facilities" are exempt from these requirements. A qualified facility is a (1) a "very small business" or (2) a small firm that sells locally as explained below.

The law delegated authority to FDA to define what constitutes a very small business. As of the date of this article, FDA had yet to make a decision on this definition but was currently considering three possible thresholds: total annual food sales of \$250,000, \$500,000 or \$1,000,000 adjusted for inflation.³⁷

The threshold for small firms that sell locally was spelled out in the Tester Amendment, codified in section 103 of FSMA. Businesses qualify if:

1. During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to "qualified end-users" exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

2. The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000 adjusted for inflation.

Qualified end-users are consumers of the food (where they are not businesses), or restaurants and retail food establishments that are located in the same state as the small firm seller of the food or not more than 275 miles from such firm and that are purchasing food for sale directly to consumers at such restaurant or retail food establishment.³⁸

To enjoy the exemption, qualified facilities are required to submit to FDA:

1. Documentation showing that the facility meets the applicable requirements to be a qualified facility; and
2. Documentation that demonstrates that the owner, operator or agent in charge has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards and is monitoring such controls to ensure they are effective; or
3. Documentation (licenses, inspection reports, certificates, permits, credentials, certification by an appropriate state agency (state dept. of agriculture) or other evidence of oversight) that the facility is in compliance with state, local, county or other applicable non-federal food safety law.³⁹

If documentation that a facility has identified hazards and implemented preventive controls is not submitted to FDA then the facility must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed on either a label on the food package or at the

point of purchase. The law contains no requirement that such label explicitly state that a facility is exempt from the Preventive Controls requirements.

FDA may withdraw the exemption:

1. In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or
2. If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed or held at such facility.

An additional exemption outside of the qualified facility exemption is for specific “low risk” on-farm packing/holding and manufacturing/processing activities of small businesses (defined as a business employing fewer than 500 persons) and very small businesses. An exhaustive list of such activities is written in the Preventive Controls Rule and includes activities such as packing or storing candy, honey, jam or peanuts and chopping nuts, making maple syrup and candy, making sugar and extracting oil from grains among other things.

Produce Safety Rule Exemption

The proposed Produce Safety Rule marks the first time FDA has regulated fruit and vegetable production on the farm. The rule establishes new federal standards in the following areas:

- Worker training and health and hygiene
- Agricultural water
- Biological soil amendments
- Domesticated and wild animals
- Equipment, tools and buildings
- Sprouts

The regulation applies to farm activities involving raw agricultural commodities, but not activities subject to section 415 of the FD&C Act.⁴⁰

Businesses with \$25,000 or less revenue from food are excluded from coverage of the Produce Safety Rule. A qualified exemption from the Produce Safety Rule pursuant to the Tester Amendment largely parallels the exemption in the Preventive Controls Rule. Namely, if during the previous 3-year period, more food was sold to qualified end-users than all other buyers and the average annual value of all food sold was less than \$500,000.

Similar to the Preventive Controls Rule, a farm enjoying the exemption must provide notification to consumers as to the name and complete business address on either the food package label or at the point of purchase. FDA can withdraw a farm’s exemption in the Preventive Controls Rule. Unlike the Preventive Controls Rule, a farm does not have to file documentation with FDA demonstrating its eligibility for an exemption; however, the agency is considering requiring farms to maintain such information.

What Will the Impact of FSMA be on the Marketing of Local Foods at Retail?

The impact of FSMA on the availability and marketing of local foods at retail is unlikely to have broad reaching impacts on consumers. Contrary to popular belief, most local foods are produced by farms too large to meet the Tester Amendment thresholds. While small farms account for over 80 percent of the number of farms in the local food market, they only account for 11 percent of total local food sales.⁴¹ On the other hand, large farms represent less than 5 percent of the number of local farms but account for almost 70 percent

of the total sales volume, averaging \$1.3M per farm.⁴² Furthermore, small farms are much more likely to market exclusively through direct-to-consumer channels because they are unable to meet the volume required by larger retail outlets such as grocery stores.⁴³ The Tester Amendment is unlikely to provide relief to most growers and manufacturers of foods sold in supermarkets.

The requirement of the Tester Amendment that farms and facilities enjoying the FSMA exemption must disclose to consumers on a label, or otherwise at the point of purchase, their name and complete business address, is unlikely to have an impact absent a separate consumer education effort. Existing FDA regulation, 21 C.F.R. 101.5 requires that the name and place of business of the manufacturer, packer or distributor be conspicuously displayed on packaged foods.⁴⁴ The regulation requires that the statement of the place of business shall include the street address, city, state and zip code; however, the street address may be omitted if it is shown in a current city directory or telephone directory.

The Tester Amendment mandates only a couple of subtle differences to 21 CFR 101.5. Namely, (1) it requires that a street address or PO Box be listed regardless of whether or not the business address is in a city directory or phonebook; and (2) the address of the actual farm where the produce was grown or registered facility where the food was processed, packed or held must be listed rather than just a corporate address. Consumers are unlikely to notice such a distinction and thus it will not likely affect their purchasing decisions.

In addition, more and more retailers are requiring their suppliers to be certified pursuant to a Global Food Safety Initiative benchmarked scheme, such as FMI’s

Safe Quality Food Initiative, which apply stringent HACCP-based requirements and should prepare suppliers well for compliance with the Preventive Controls and Produce Safety rules. Retailers are also increasingly providing assistance to small producers on food safety matters.

Retailers Help Small Producers to Meet Food Safety Standards

In assessing the impact of FSMA on producers it is important to consider that more and more retailers are providing a variety of means to help their suppliers in meeting food safety requirements. For example, Walmart notes that they “have worked with GFSI to create a scalable approach to food safety for our small and developing suppliers providing locally grown and produced food which is aligned with GFSI principles. . . . These suppliers are then in a position as their business grows to follow a stair-step path towards full GFSI certification and continue to enhance their food safety programs.” Walmart has created a training template for both processors and primary producers which will help them understand the requirements they need to meet for the basic or foundational and intermediate level assessments.⁴⁵

Wegmans is another retailer focusing on local foods who assists their suppliers in developing strong food safety practices. All Wegmans suppliers are required to perform an annual Good Agricultural Practices (GAP) audit.⁴⁶ GAP is voluntary guidance by FDA which includes among other things, developing and implementing a food safety plan.⁴⁷ To help its small growers meet the GAP standards, Wegmans holds training sessions for suppliers in collaboration with regulators and universities during and offers to pay up to \$400 in expenses growers incur related to the training.⁴⁸

Numerous other retailers provide similar forms of assistance to small producers.

Conclusion

The impact of FSMA on the marketing and availability of local foods is unlikely to be severe if FDA fully considers the comments of small businesses in its rulemakings. Most local foods are produced by farms and manufacturers who are too large to qualify for the Tester Amendment exemption. Consumers are not likely to notice the labeling distinction at retail between products originating from farms and manufacturers that enjoy the Tester Amendment exemption and those that comply with FSMA. What remains to be seen is the ultimate cost of compliance. Small businesses bear a disproportionate share of the regulatory burden. If compliance costs are high, FSMA rules could make it more difficult for small businesses to compete with their larger counterparts. Regulatory costs are simply harder to absorb for small firms. If costs are too high, small producers may find it difficult to compete with larger firms and could exit the marketplace, which would impact consumer choice at retail. As retailers have worked with suppliers both small and large to meet their own stringent food safety standards, it is probable that most suppliers of local foods in supermarkets are well equipped to handle the requirements FSMA will impose. Δ

1. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) [hereinafter FSMA] (codified as amended in scattered sections of 21 U.S.C.).
2. Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) [hereinafter FD&C Act] (codified as amended in 21 U.S.C. §§ 301-399d (2011)).
3. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Proposed Rule, 78 Fed. Reg. 3504 (Jan. 16, 2013) (corrected Mar. 20, 2013, 78 Fed. Reg. 17155).
4. Section 415 of FD&C Act
5. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646 (Jan. 16, 2013).
6. Nicholas R. Johnson & A. Bryan Endres, Small Producers, Big Hurdles: Barriers Facing Producers of “Local Foods,” 33 Hamline J. Pub. L. & Pol’y 49, 65 (2012).
7. Food, Conservation, and Energy Act, Pub. L. No. 110-246, 122 Stat. 1651 (2008).
8. FSMA § 103(l)(4)(B)(ii)(I)(bb).
9. Food Marketing Institute, U.S. Grocery Shopper Trends 2011 44 (2011).
10. *Id.*
11. *Id.*
12. *Id.*
13. *Id.* at 45.
14. *Id.*
15. Food Marketing Institute, The Food Retailing Industry Speaks 2011 25 (2011).
16. The Food Marketing Institute proudly advocates on behalf of the food retail industry. FMI’s U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost \$770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores.
17. *Id.*
18. Food Marketing Institute, 2012 Shopping for Health Survey 24 (2012).
19. National Grocers Association, 2013 NGA-SupermarketGuru Consumer Panel Survey (2013).
20. Industry Speaks 2011, *supra* note 15, at 24.
21. 2012 Food Retail Industry Speaks Data Tables 9 (2012).
22. *Id.*
23. Industry Speaks 2011, *supra* note 15, at 24.
24. Sarah A. Low & Stephen Vogel, United States Dept. of Agriculture, Economic Research Service, Direct and Intermediated Marketing of Local Foods in the

- United States 7 (2011).
25. Shopper Trends 2011, *supra* note 7, at 43.
 26. Wal-Mart Stores, Inc., Walmart Unveils Global Sustainable Agricultural Goals (Oct. 14, 2010) <http://news.walmart.com/news-archive/2010/10/14/walmart-unveils-global-sustainable-agriculture-goals>
 27. Healthy Food Initiatives, Local Production and Nutrition: Hearing before the S. Comm. on Agriculture, Nutrition and Forestry, 112th Cong. 69 (2012) (statements of Ron McCormick, Senior Director of Local Sourcing and Sustainable Agriculture, Wal-Mart Stores, Inc.).
 28. James Rushing & Jens Ruehle, A.T. Kearney, Buying into the Local Food Movement 2 (Jan. 2013) <http://www.atkearney.com/documents/10192/709903/Buying+into+the+Local+Food+Movement.pdf/68091049-b5c2-4d2a-a770-ee5b703da8fd>.
 29. Stephen Martinez et al., United States Dept. of Agriculture, Economic Research Service, Local Food Systems: Concepts, Impacts, and Issues 13 (2010).
 30. Shopper Trends 2011, *supra* note 7, at 105.
 31. *Id.*
 32. Chelsea Krotzer, Sen. Tester Promotes Amendment to Food Safety Bill, *Billings Gaz.* (Nov. 17, 2010) <http://www.testersenate.gov/?p=news&id=637>.
 33. *Id.*
 34. Ezra Klein, Michael Pollan on the Food Safety Bill, *Wash. Post* (Nov. 18, 2010) (Michael Pollan is a well-known food writer and journalist and the author of *The Omnivore's Dilemma* (2006)) http://voices.washingtonpost.com/ezra-klein/2010/11/michael_pollan_on_the_food_saf.html.
 35. See generally, Letter to Senators Harkin and Enzi (Nov. 15, 2010) <http://www.meatami.com/ht/a/GetDocumentAction/i/64238> (30 food associations signed onto a letter to voice their disapproval over the Tester Amendment).
 36. Section 415 was enacted as part of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and requires all U.S. and foreign establishments (which export to the US.) that process/manufacture, pack or hold/store food to register with FDA.
- Note that FSMA amended section 415 to require that facilities renew registrations every other year and provided FDA with authority to suspend such registrations under certain circumstances among other things.
37. 78 Fed. Reg. 3800 (Jan. 16, 2013).
 38. FSMA § 103.
 39. 78 Fed. Reg. 3808 (Jan. 16, 2013).
 40. See *supra*, note 33.
 41. Sarah A. Low & Stephen Vogel, U.S. Dept. of Agric., Econ. Research Serv., Direct and Intermediated Marketing of Local Foods in the United States 4 (2011).
 42. *Id.* at 6.
 43. *Id.* at 4.
 44. 21 C.F.R. 101.5.
 45. *Id.*
 46. Wegmans Food Markets, Inc., Food Safety and Small Growers, Food Marketing Institute (May 29, 2013) <http://www.fmi.org/docs/default-source/webinars/food-safety-and-smallgrowers.pdf?sfvrsn=6>.
 47. *Id.*
 48. *Id.*

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