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# The Food Safety Modernization Act and the Marketing of Fresh Produce

Alba J. Collart

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## Establishing the Need

The number of foodborne illness outbreaks linked to the consumption of fresh produce has been on the rise. From 1973 to 1997, the Centers for Disease Control and Prevention (CDC) received reports of 190 produce-associated outbreaks, which translated to 16,058 illnesses, 598 hospitalizations, and 8 deaths. In 1997, President Clinton charged the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) with identifying aspects to improve the safety of the food supply. In their report entitled “Food Safety from Farm to Table: A National Food Safety Initiative” they identified produce as an area of food safety concern as fruits and vegetables can harbor contaminants without apparent loss of quality. As a result, voluntary guidance on Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) for the produce industry were issued. GAPs are practices used to reduce food safety hazards during growing, harvesting, sorting, packing, and storage of fresh produce at the farm-level, whereas GMPs are used during processing, sorting, packing, storage, and transportation of fresh produce in manufacturing/processing plants. The U.S. Food and Drug Administration (FDA) offered these guidelines but, since they were voluntary, they were not charged with enforcing them. Instead, the safety of the U.S. food supply relied on the food industry’s responsibility under the Food, Drug, and Cosmetic Act (FD&C Act) to supply safe food and on public-private partnerships (Paggi et al., 2013).

Despite a myriad of food safety standards that have emerged over time from public, private and non-governmental groups, deadly outbreaks due to consumption of raw produce have continued and in many cases spread rapidly across states. From 1996 to 2010, CDC received reports of about 131 outbreaks associated with 20 contaminated produce commodities, which resulted in at least 14,132 illnesses, 1,360 hospitalizations, and 27 deaths (FDA, 2013). The most recent reports by CDC indicate that at least 130 produce-associated outbreaks and 4,088 illnesses occurred in the lapse of three years from 2011 to 2013 (CDC, 2014a, 2014b, 2015).

## The Food Safety Modernization Act

Responding to a need for action, the federal government made it a priority to revamp the nation’s food safety system. On January 4, 2011, the Food Safety Modernization Act (FSMA), signed into law by President Obama, authorized the creation of a more comprehensive and restrictive food safety system in the United States. Under FSMA, the FDA, an operating division within HHS, is charged with crafting, implementing, and enforcing most of the rules that constitute FSMA. In essence, FDA is introducing more frequent food safety inspections and, for the first time, science-based prevention-oriented mandatory standards for different stakeholders in the U.S. food supply chain. These standards pertain to five key areas: food preventive controls; produce safety; import safety; intentional adulteration; and sanitary transportation of food.

Apart from modifications to other agency-level food safety programs, a sweeping food safety reform has not happened since the FD&C Act was enacted in 1938, and, given FSMA’s magnitude, is undoubtedly coming at a cost for the public and private sectors in terms of both time and resources. Since FSMA was enacted in 2011, several

rules have slowly yet successfully evolved from the proposal stage to the final stage, with five of the FDA's seven proposed foundational rules being finalized and published last year.

## The Move from a Reactive to a Preventive Approach

The cornerstone of FSMA is to switch from a reactive approach to a preventive approach when dealing with foodborne illness outbreaks. The two final rules dealing with food preventive controls were the first to be issued on September 10, 2015. The first, *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, regulates mostly facilities manufacturing/processing food for human consumption, while the second, *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*, applies to animal food manufacturing/processing facilities, with the exception of vertically integrated operations. Operations defined as “farms” by FDA—including off-farm packing facilities—may still have to comply with other FSMA's rules, but are not subject to food preventive controls. Food preventive controls require that food facilities have written food safety plans in place that describe how they will identify and prevent biological, chemical, and physical hazards, which is a management system similar to a Hazard Analysis Critical Control Point (HACCP). They also establish Current Good Manufacturing Practices (CGMP) and, if preventive actions are not in place, require a program to control hazards along the supply chain. FDA built in some flexibility into the supply-chain program requirement by allowing food manufacturers and processors to rely on other parties in the supply chain to control for hazards, granted that written assurances are made during the hazard analysis stage. Should an outbreak occur, these efforts will help, in theory, identify and document who along the supply chain is responsible for controlling each hazard, thereby increasing liability.

## Produce Safety

### *What's In It?*

A rule of particular importance to the fresh produce industry is the produce safety rule, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, which was issued on November 13, 2015. This rule establishes on-farm safety standards for growing, harvesting, packing, and holding fruits and vegetables on domestic as well as foreign farms. Given that the sources of several previous outbreaks had been traced back to early stages in the production chain, this rule establishes, for the first time, mandatory science-based preventive regulation at the farm level. Of particular concern are standards to prevent biological hazards that may spread via five routes: worker training and health and hygiene; agricultural water; biological soil amendments; domesticated and wild animals; and equipment, tools, and buildings.

To account for the diversity in fruit and vegetable production, FSMA focuses on practices rather than on specific commodities, however, in light of the routine role that sprouts have played in foodborne illness outbreaks, sprouts is the only set of commodities for which FDA developed a separate set of strict standards. To reflect a science- and risk-based approach to policy making, standards for all produce focus on reducing the risk of microorganisms that have been found to be of public health significance, such as *E. coli*, *Salmonella*, and *Listeria*. For example, water and biological soil amendments used directly in the production process must now follow established numerical microbial criteria. It should also be noted that physical or chemical hazards, which are non-biological hazards, are beyond the scope of the produce safety rule.

### *Who Must Comply?*

These standards apply to producers and packers of specific raw agricultural commodities (RACs), both domestically-produced and imported, for which FDA has determined that such standards will minimize the risk of serious adverse health consequences. These raw fruits and vegetables are listed in section 112.1 of the final rule (FDA, 2015a). Exclusions apply to certain produce that is rarely consumed raw, or produce grown for personal or on-farm consumption. Farms growing produce that ultimately receives commercial processing that reduces contamination may be eligible for exemption from the rule if certain disclosures, recordkeeping, and written assurances are made.

### *Farm Size, and Direct-to-Consumer and Selected Local Sales*

Farm size as determined by its monetary value of sales will also help determine whether a farm is covered, and if so, eligible for a qualified exemption, extended compliance period, or both. Farms that have an average annual

value of produce sales—and not all food sales—during the previous 3-year period of \$25,000 or less are not covered by the rule (Table 1). Moreover, farms with less than \$500,000 in annual food sales—and not just produce sales—and selling mostly directly to consumers or to local restaurants or retail food establishments can apply for a qualified exemption through which they need only comply with modified requirements such as, for example, identifying the name and address of the farm where the produce was grown in a label, at the point of purchase, or in an electronic notice in the case of online sales. For the purpose of FSMA, local sales are defined as those sales made to a restaurant or retail food establishment within the same state or Indian reservation as the farm, or fewer than 275 miles away from the farm. Farms over the \$25,000 threshold are subject to the rule and must follow different compliance dates depending on their size, what they produce, and whether they are eligible for a qualified exemption. The stricter compliance date is for businesses that do not fall under the very small or small categories and that grow sprouts, who, unless an extension is granted, will need to comply with all requirements by January 26, 2017 (FDA, 2015a).

**Table 1: Farm Size in the Produce Rule of the Food Safety Modernization Act (FSMA)**

<b>Average annual value of produce sales during previous 3-year period</b>	<b>Farm size under FSMA's Produce Rule</b>
≤ \$25,000	Not covered
> \$25,000 to < \$250,000	Very small business
\$250,000 to < \$500,000	Small business
≥ \$500,000	All other businesses

### Organic Agriculture

Major provisions of the produce safety rule affecting organic operations involve their use of water and biological soil amendments. The National List of Allowed and Prohibited Substances, developed by the National Organic Standards Board (NOSB), identifies substances that may or may not be used in organic production and handling operations. To be in compliance with both the National Organic Program (NOP) and FDA's new water quality criteria established under the produce safety rule, organic farmers may treat their water sources as long as the treatment mechanism does not involve a prohibited substance from NOSB's National List. Moreover, USDA organic regulations regarding the use of treated and untreated biological soil amendments of animal origin may be revised to reflect FDA's food safety standards, since—somewhat strikingly—FSMA's environmental impact statement states that a comprehensive risk assessment was not performed when discussing USDA organic regulations and the potential food safety concern of using raw manure to grow human food crops. Instead, current USDA organic requirements, such as specified application intervals for untreated manure and composting criteria, are a reflection of organic practices at the time and recommendations by NOSB (FDA, 2015b).

### Import Safety

Two final rules dealing with import safety were issued along with the produce safety rule on November 13, 2015. These provisions seek to ensure that food imported from abroad is as safe as food produced within U.S. borders. Given the position of the United States as a net importer of fruits and vegetables since the mid-90s, the success of the programs authorized under this rule and of foreign government programs to help foreign farms, if any, will play a major role on produce importers' ability to continue meeting an increased U.S. domestic demand. In 2010, about 49% and 25% of U.S. consumption of all fresh fruits and of all fresh vegetables, respectively, originated from imports (Johnson, 2014). Furthermore, the import value of fruits and vegetables has consistently grown between 2010 and 2014 at average annual growth rates of 9% for fruits and 7.8% for vegetables (USDA-ERS, 2015).

The first rule, *Foreign Supplier Verification Program (FSVP) for Importers of Food for Humans and Animals*, creates the FSVP program, which requires importers to verify that each food product brought into the United States from every foreign supplier is produced in a manner that provides the same level of food safety assurance as that required of U.S. food producers, and, if that were not the case, to take corrective actions. Thus, FSVP shifts food safety assurance responsibilities to importers. The second rule, *Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications*, establishes authority for the FDA to provide, most likely under a user-fee program, FDA-recognition to accreditation bodies. These accreditation bodies may be public and private agencies and organizations, including foreign governments that, in turn, accredit third-party certification bodies also known as auditors. Auditors are charged with conducting food safety audits and issuing

certifications of foreign food facilities. These certifications may be used by U.S. importers to participate in programs to expedite the review and entry of food, like the Voluntary Qualified Importer Program (VQIP).

## Economic and Marketing Implications

### *Costs and Benefits*

The Food Safety Modernization Act (FSMA) represents a massive undertaking that demands time and resources, as evidenced by the deadline extensions needed to finalize some of its rules and the ongoing rulemaking process. Costs of compliance for both the private and public sectors go beyond one-time investments on new hires, procedures, or equipment. To name a few, they include the time and resources invested in the rulemaking process, searching and learning costs, and future recurring costs. FDA estimates that the annualized average cost per farm of implementing the produce safety rule will be \$2,885 for very small farms, \$15,265 for small farms, and \$28,452 for large farms, which may differ widely within farm size categories depending upon the farm's current level of compliance (FDA, 2015c). As suggested by previous studies (Paggi et al., 2013; Ribera and Knutson, 2011), the most likely scenario is that FDA will pass on many of the implementation costs to state and local governments, who will pass them on to the private sector. Larger enterprises may have a greater capacity to absorb costs, but these costs may be passed on down the supply chain to final consumers in the form of higher food prices.

The obvious benefit of FSMA is that once these standards are put into action, the incidence of foodborne illness outbreaks is expected to decrease. Consequently, the associated costs to individuals and families, the health care system and the costs to the industry of a foodborne outbreak, such as product recalls, may also decrease. Moreover, consumers may gain more confidence in the commodities being provided by the food supply, including fresh fruits and vegetables, and in the existing private-public partnership.

In order for the public-private partnership to be successful, however, it needs to be stronger than it has been in the past. Producer education will be key. For the produce industry, programs such as the Produce Safety Alliance, based in Cornell University, and the Sprout Safety Alliance are already primary tools to reach produce farmers. Extension programs at land-grant universities focusing on fruit and vegetable production or horticultural marketing will also need to target their education and technical assistance efforts, both through in-person meetings and online tools, to help farms and food businesses across the nation comply with these standards.

### *Market Structure*

FSMA may have an impact on the industry in terms of market structure. A characteristic of fruit and vegetable production, both nationally and internationally, is its diversity among farms and farming practices, not only vis-à-vis the number of crops grown and its use as a complement to other operations, but regarding farm size as well. Under FSMA, farms below the \$25,000 threshold in annual produce sales are exempt from complying with the produce safety rule. On the one hand, this may be beneficial for such farms, since complying with these food safety-related standards will increase their costs and may even put them out of business. However, lack of FSMA compliance may also constrain their access to sell at mainstream retail outlets. Unless a consistent supply and an attainable alternative safety certification are available to fulfill the requirements of mainstream outlets, these farms will be limited to selling their products in direct-to-consumer outlets such as farmers' markets, Community Supported Agriculture (CSAs), roadside stands, U-pick farms, and online direct-to-consumer markets, or to sell locally subject to businesses' own food safety requirements. Farms subject to FSMA modified requirements will also be limited to selling mostly in direct marketing outlets and local restaurants and food retailers, while FSMA-covered farms may commit their production to mass retailers. The change in market structure is likely to pose a great challenge for produce farms in the southern region, which is characterized by small acreage holders (Paggi, et al., 2013). Moreover, it is possible that despite FDA's best efforts to provide extended compliance periods, smaller farms, diversified farms, and food businesses subject to FSMA may still exit the industry during the implementation period and smaller producers abroad may search for alternative export markets.

### *Public Health*

Farm size exclusions and qualified exemptions granted in the produce safety rule also raise health concerns among the industry. During the public comment of the rulemaking process, it was suggested that produce farms not covered by FSMA based on their size, or farms eligible for a qualified exemption should be regulated under scale-appropriate state-run food safety programs. According to FDA, all farms below the \$25,000 limit account for only

1.5% of covered produce acres, and imposing FSMA on them would thus have little measurable public health impact (FDA, 2015a). Even though FDA's final produce safety rule maintains limited oversight over such farms, this remains a legitimate concern for the industry. In the past, the negative impacts of foodborne illness outbreaks on individual commodities have spread industry-wide despite the source of the outbreak (Rosson et al., 2007).

Farm exclusions and qualified exemptions may also represent a concern for consumers. By taking farm size into consideration, FSMA decreases the potential impact that the exit of smaller firms may have on market concentration, which, as described by Ribera and Knutson (2011) affects consumer choice in terms of product diversity and prices. However, it shifts the problem of consumer choice from one of product diversity to one of food safety oversight. Because, by law, FSMA does not impose third-party food safety verification for unregulated farms, food safety assurance for products from these farms will depend on whether buyers demand it. For the case of direct-to-consumer sales it will depend on verification by end-consumers. Hence, unregulated farms may find it in their best interest to inform consumers about their food safety practices, or to market their adherence to one of the many private or public food safety standards available. Many farmers' markets, for example, have established food safety rules that vendors must comply with.

## Going Forward

Eating fruits and vegetables is an important part of a healthy diet, but equally important is to adhere to food safety standards when consuming fresh produce. FSMA reflects the substantial interest of the federal government in reducing the risks for foodborne illness outbreaks.

Perhaps at a considerable cost, FSMA does mark a shift towards a common, harmonized set of much-needed science-based standards to better protect fresh produce safety. To navigate this reform, the private-public partnership needs to be stronger than it has ever been. Farms that are not covered by or exempt from FSMA will need information on alternative standards in order to remain active market participants while contributing to a safe food supply. Covered producers need access to practical information that will enable them to comply with FSMA, and any other industry food safety requirements, in a timely manner at the lowest cost possible. To the extent possible, they need to be active participants in the rulemaking process by expressing their views through FDA's public engagement sessions.

If, as expected, costs are passed down to end-consumers and FSMA's implementation costs translate into higher food prices, access to a safe supply of fresh fruits and vegetables, particularly for vulnerable populations, should remain a pressing food policy priority. The Agricultural Act of 2014 made some advances to support the specialty crop industry by re-establishing or funding new programs, many of them in the nutrition title, to increase access to fruits and vegetables (Collart and Coble, 2014). However, nutrition policy should go hand in hand with food safety policy, and both coupled with consumer education. Particularly for residents of food deserts, consumer education has been shown to be a better predictor of healthy food choices than increasing access to healthy food options alone (Elbel et al., 2015; Handbury, Rahkovsky, and Schnell, 2015). In the end, education has the potential to not only help consumers access a safe food supply, but also help them reconnect with where their food comes from.

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**Author Information**

*Alba J. Collart ([Collart@agecon.msstate.edu](mailto:Collart@agecon.msstate.edu)) is Assistant Professor and Extension Economist, Department of Agricultural Economics, Mississippi State University.*

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