

# Theme Overview: Producer Impacts of the Food Safety Modernization Act

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## Articles in this Theme:

- **The Food Safety Modernization Act and Production of Specialty Crops**

*Luis A. Ribera, Fumiko Yamazaki, Mechel Paggi and James L. Seale, Jr.*

- **The Food Safety Modernization Act and the Marketing of Fresh Produce**

*Alba J. Collart*

- **The Food Safety Modernization Act and Agricultural Imports**

*Amanda M. Countryman*

The Food Safety Modernization Act (FSMA), P.L. 111-353, is the most significant reform of the U.S. food safety laws in over 70 years. After less than two years in Congressional development, it was signed into law by President Obama on January 4, 2011. The law shifts the focus from responding to contamination to preventing it. The “Final Rule” was published on November 27, 2015, becoming effective on January 26, 2016. The lengthy period of time in rule development is, in part, explained by the complexity of our food supply system, and the implications for food safety from farm-to-table. Adding to the challenge is a decentralized division of labor for ensuring a safe food supply among governmental agencies. The modern food supply system is a complex and diverse supply chain, including significant imports, science-based knowledge, and an engaged consumer. While potential benefits have been at least partially documented, the benefits of safer food are not without cost. Some of the costs will initially be borne by the agricultural sector. This collection of articles in *Choices* focuses on likely impacts on the agricultural sector due to implementation of the FSMA rules.

## Historical Perspective on Food Safety Policy

The federal government food safety mission began in 1906 following the investigative reporting of Upton Sinclair, whose book *The Jungle* exposed the unsanitary conditions that existed in the Chicago meat packing business. The Pure Food and Drug Act (PFDA), prohibiting adulteration, and the Meat Inspection Act (MIA), placing federal inspectors in meat processing plants, became law on the same day. The U.S. Department of Agriculture (USDA) was assigned the initially responsibility for food safety, which is now shared with the Food and Drug Administration (FDA); and for seafood only, the responsibility lies with FDA and the Department of Commerce (DOC). Among Washington insiders, industry, and food safety advocates, the government home for food safety regulation, continues to be hotly debated. Historically, the USDA and the FDA have contended that they are better equipped to regulate seafood than the DOC (Merrill and Francer, 2000).

From its beginnings, there was conflict within USDA over how tightly the PFDA should be enforced (Merrill and Francer, 2000). In 1938, federal food safety law was substantially expanded with an emphasis on curbing the marketing of untested drugs, the inclusion of unsafe food additives, false labeling, and the lack of ingredient labels. However, it was not until 1940 that FDA was moved from USDA to the Federal Security Agency (FSA) with the Public Health Service. In 1953, the FSA became the Department of Health, Education and Welfare (HEW) and in 1979 it became the Department of Health and Human Services (HHS)—where FDA is housed today. Responsibility for pesticide regulation was moved from USDA to the Environmental Protection Agency (EPA) in 1970. Rounding out the list of primary agencies regulating food safety, the Center for Disease Control (CDC) was established in 1947 with a primary objective of fighting malaria (CDC, 2011).

The history of the governmental organization of food safety regulation is relevant to the focus of this theme because the historical perspective helps explain the complexity underlying the responsibilities as defined by the FMSA. Under FSMA, the responsibility for food safety in 2016 rests with five primary agencies (Rawson and Vogt, 1998).

- USDA's Food Safety and Inspection Service (FSIS), is responsible for administering the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, and the Humane Methods of Slaughter Act.
- The FDA is responsible for ensuring that domestic and imported foods—except for meats and poultry—are safe, sanitary, nutritious, wholesome, and honestly labeled. Since 1938, these responsibilities have been carried out under the statutory rubric of prohibitions of adulteration and misbranding, which itself spoke for the need for updating food safety regulation (Johnson et al., 2010).
- The DOC's National Marine Fisheries Service maintains a cooperative inspection agreement with FDA, the primary agency responsible for ensuring the safety, wholesomeness, and labeling of domestic and imported seafood products. For the approximately 20% of the fish that is consumed domestically, U.S. based fishing vessels and plants are inspected on a user-fee basis. A primary inspection activity involves conformance with FDA's HACCP guidelines for seafood. FDA maintains responsibility for inspecting seafood import facilities.
- The EPA has the responsibility for ensuring that chemicals used on crops do not endanger public health. It accomplishes this task by the statutory requirement that all new pesticides be registered.
- The CDC, like the FDA, is an agency within HHS. Its Food Safety Office (FSO) has primary responsibilities for prevention of foodborne illness diseases. Its main activities include: supporting epidemiology, laboratory, and environmental health capacity at the state and local levels; providing information and recommendations based on public health surveillance and epidemiology through programs such as FoodNet; and maintaining links with FDA and USDA (CDC, 2014).

Many other agencies could be listed as affecting food safety. For example, the USDA's Animal and Plant Health Inspection Service (APHIS) has responsibilities for protecting the health of animals and plants from domestic and international sources. In addition to protecting the food supply, APHIS protects

against the transmission of animal diseases, some of which are transmittable to humans (Knutson and Ochoa, 2007). The Organic Foods Production Act of 1990 administered by the USDA Agricultural Marketing Service (USDA-AMS), authorize the establishment of standards for the production of organic standards for organic foods. Ironically it gives little or no attention to the safety of organic products. The USDA-AMS also offers, on a user-fee basis, third-party inspection audits for compliance either public or private sector food safety standards. At the state level, the California Department of Food And Agriculture established the California Leafy Green Products Handler Marketing Agreement (LGMA) in 2007 as a cooperative public-private sector good agricultural practices (GAP) audit program to assist in cubing foodborne illness outbreaks in fresh leafy green produce (LGMA, 2016). Under the LGMA over 100 handlers, representing approximately 99% of the volume of California leafy greens, have committed themselves to sell products grown in compliance with the food safety practices through a system of mandated audits.

## Theme Articles

The articles in this theme analyze the potential impacts of FSMA largely from the producer perspective rather than the consumer or public good perspective. The articles focus on the impacts of FSMA on the production, marketing, and imports of produce rather than the benefits of reduced foodborne illness to consumers or the economy, at large.

The Ribera et al. article focuses on the potential economic impacts of the FSMA on the profitability of domestic production of specialty crops. In particular, discussion revolved around the types of farms that would be exempt from FMSA. Moreover, the article discusses the potential economic impact by farm size and how economies of scale play an important role in minimizing the impact of FSMA compliance costs.

The Collart article highlights implications of the FSMA on the marketing of fresh produce in the United States. The discussion centers on major implications in terms of costs and benefits, market structure, and public health concerns, with particular attention to the new produce safety rule.

Finally, Countryman's paper provides an overview of the provisions in the FSMA that apply to food imports. The Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, as well as the implications, costs, and exemptions relating to food imports are discussed.

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# The Food Safety Modernization Act and Production of Specialty Crops

Luis A. Ribera, Fumiko Yamazaki, Mechel Paggi and James L. Seale, Jr.

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On January 4, 2011, President Barack Obama signed into law the Food Safety Modernization Act (FSMA). This is the first comprehensive reform of the Food and Drug Administration (FDA) food safety policy since the Federal Food, Drug, and Cosmetic Act enacted in 1938, although food safety programs of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and the Environmental Protection Agency (EPA) had been modified in the interim.

The most important policy change contained in the FSMA is that it authorizes and mandates FDA to require comprehensive, science-based preventive controls across the food supply, including the growing, harvesting, packing, and holding of fresh fruits and vegetables. The final proposed rule for produce safety, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Final Rule), published on November 27, 2015, sets standards regarding agricultural water; biological soil amendment; sprouts; domesticated and wild animals; worker training and health hygiene; and equipment, tools and buildings, among other things (FDA, 2015a).

Before and during the development of the Final Rule, significant discussion involved the potential economic impacts of the FSMA on the domestic production of specialty crops, such as vegetables. Three of the major specialty crop states are California, Florida, and Texas. In particular, discussion revolved around the types of farms that would be exempt from FMSA. However, Ribera et al. (2012) concluded that the costs incurred by producers due to produce food outbreaks appear to be far greater than those involved in preventing such incidents.

## The Food Safety Modernization Act and the Final Rule

The Final Rule became effective January 26, 2016. A detailed summary of the Final Rule's provisions can be found in FDA, 2015a, and 2015b. The Final Rule applies to all fresh produce farms with annual sales over \$25,000—farms with produce sales of \$25,000 or less are exempt. Also exempt, due to a provision introduced by Senators Jon Tester and Kay Hagan, are farms with total food sales of less than \$500,000, based on a three-year average, that sell the majority of food directly to a qualified end-user located within the same state or within 275 miles from the farm.

The rule grants small farms extra time to come into compliance. Farms with annual produce sales between \$25,000 and \$250,000, classified as very small under the Final Rule, would be granted four years from the effective date (that is, January 26, 2020) of the Final Rule to come into compliance. Farms with annual produce sales between \$250,000 and \$500,000, classified as small farms under the Final Rule, would be granted three years to come into compliance (that is, January 26, 2019). Further, farms with annual produce

sales of over \$500,000 would have two years to come into compliance (that is, January 26, 2018). Furthermore, each of the categories of covered farms will have an additional two years to comply with certain agricultural water requirements.

The exception to these compliance dates is for the production of sprouts. Due to greater food safety concerns about their production, compliance dates are sooner for sprouts: three years for very small farms (that is, January 26, 2019); two years for small farms (that is, January 26, 2018); and one year for all other farms (that is, January 26, 2017).

**Table 1: FDA Accounting of Farms to be Covered by FSMA**

	Very Small	Small	Large	Total
Number of Farms	26,947	4,693	8,571	40,211
% by Size	67%	12%	21%	100%
Produce Acres	447,342	389,610	3,636,623	4,473,575
% by Size	10%	9%	81%	100%
Average Produce Acres per Farm	16.6	83.0	424.3	111.3
Average Food Sales per Farm	\$75,279	\$320,696	\$2,638,384	\$650,233

*Source: NASS, 2007 Census of Agriculture.*

The FDA (2013) reported that 40,211 farms, excluding sprouting operations in 2013, would be covered. All farm numbers were calculated from the National Agricultural Statistic Service (NASS) 2007 Census of Agriculture. Table 1 shows that 67% of these were categorized as very small farms, 12% small, and 21% large. In terms of produce acreage, there were almost 4.5 million acres covered, 10% of which were operated by very small farms, 9% by small farms, and 81% by large farms. As expected, there were many more very small and small farms than large farms, but large farms account for the lion's share of covered acreage and had higher average food sales per farm.

**Table 2: Baseline of Representative Farms Developed, 2012-2014**

	California			Florida			Texas		
	Small	Med	Large	Small	Med	Large	Small	Med	Large
	Production Cost/acre	Production Cost/acre	Production Cost/acre	Production Cost/acre	Production Cost/acre	Production Cost/acre	Production Cost/acre	Production Cost/acre	Production Cost/acre
Cantaloupe	\$6,337	\$5,069	\$4,999.67	X	X	X	\$3,782	\$3,025	\$2,984
Citrus	\$7,237	\$5,971	\$5,901	X	X	X	\$1,488	\$1,267	\$1,254
Onion	\$11,160	\$9,278	\$9,003	X	X	X	X	\$5,625	\$6,863
Spinach	\$3,455	\$2,872	\$2,787	X	X	X	\$3,638	\$3,024	\$2,935
Tomato	\$6,688	\$5,560	\$5,396	\$4,166	\$3,464	\$3,361	X	X	X
Watermelon	\$8,933	\$7,145	\$7,048	\$4,563	\$3,650	\$3,600	\$3,381	\$2,705	\$2,668
Cabbage	\$8,398	\$6,982	\$6,775	\$3,271	\$2,719	\$2,639	\$4,733	\$3,935	\$3,819

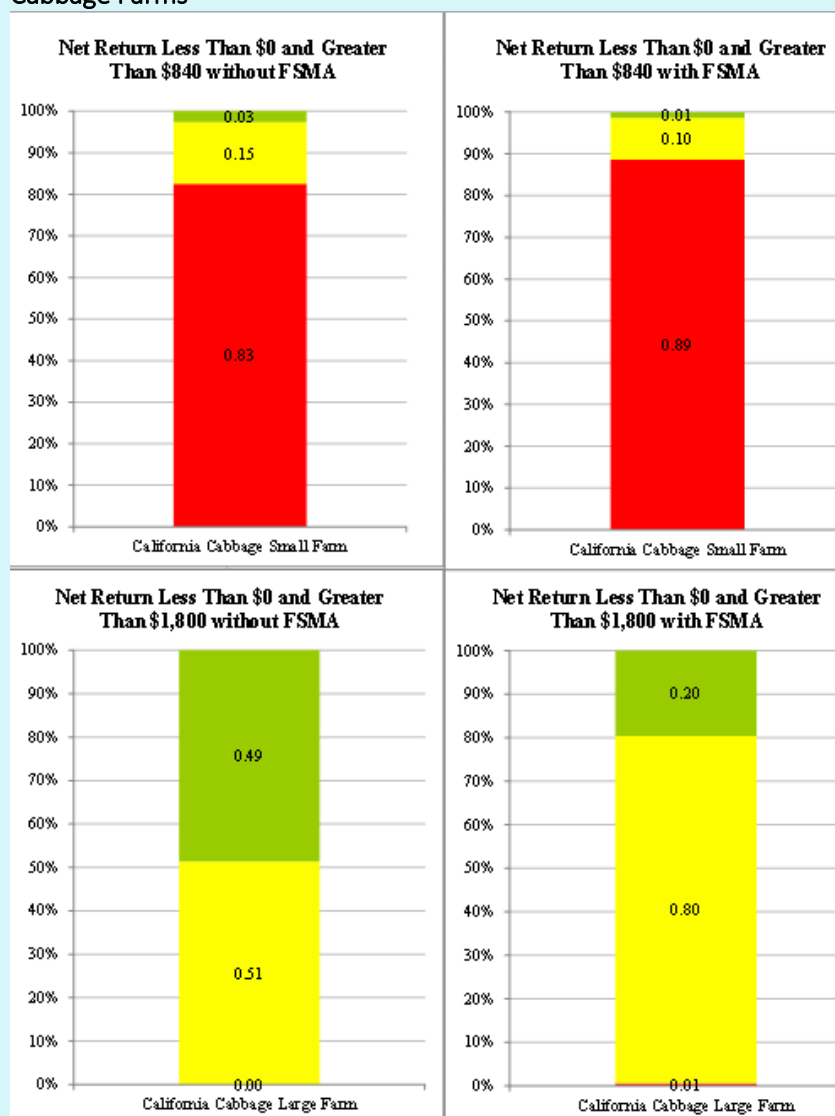
*Source: Ribera et al., 2014*

## What Do We Know about FSMA Impacts on Cost and Profitability?

One way economists use to evaluate the impacts of policies on farms is through the development and analysis of so-called “representative farms.” Representative farms are virtual farms developed by a panel of producers for a specific crop or crop mix at a specific location. In some cases, existing regional-specific cost and return budgets were updated to include the most recent data for prices, yields and related production expenses and subject to review by farm advisors. The constructed farm represents the typical cost of production, revenues and common production practices for a specific crop in a specific area. In order to consider impacts from FMSA, representative farms were developed for cabbage, cantaloupe, citrus, onion, spinach, tomato, and watermelon production, where applicable, in California, Florida, and Texas (Ribera et al. 2014). Table 2 shows three different sizes of farms used to analyze the impacts of FSMA requirements by farm size. The three representative sizes were for a small farm with annual sales less than \$250,000; a medium farm with annual sales between \$250,000 and \$500,000; and a large farm with annual sales over \$500,000, measured as annual sales of a specific crop.

Table 2 shows the average cost of production per acre for the representative farms, excluding any food safety compliance costs. It is important to note that most producers in the panels reported that most of the compliance costs associated with FSMA were already covered by their own Good Agricultural Practices (GAPs) and Good Handling Practices (GHPs) programs. For example, in the case of leafy green producers in California, these producers already abide by the California Leafy Green Handler Marketing Agreement. In almost all the farms in table 2, regardless of location and crop produced, larger farms have lower cost of production per acre, displaying economies of scale. The only exceptions are the medium and large onion farms in Texas where the large farms reported higher cost of production than the medium sized farms. Also, there seems to be diminishing economies of scale between medium and large farms compared to small and medium.

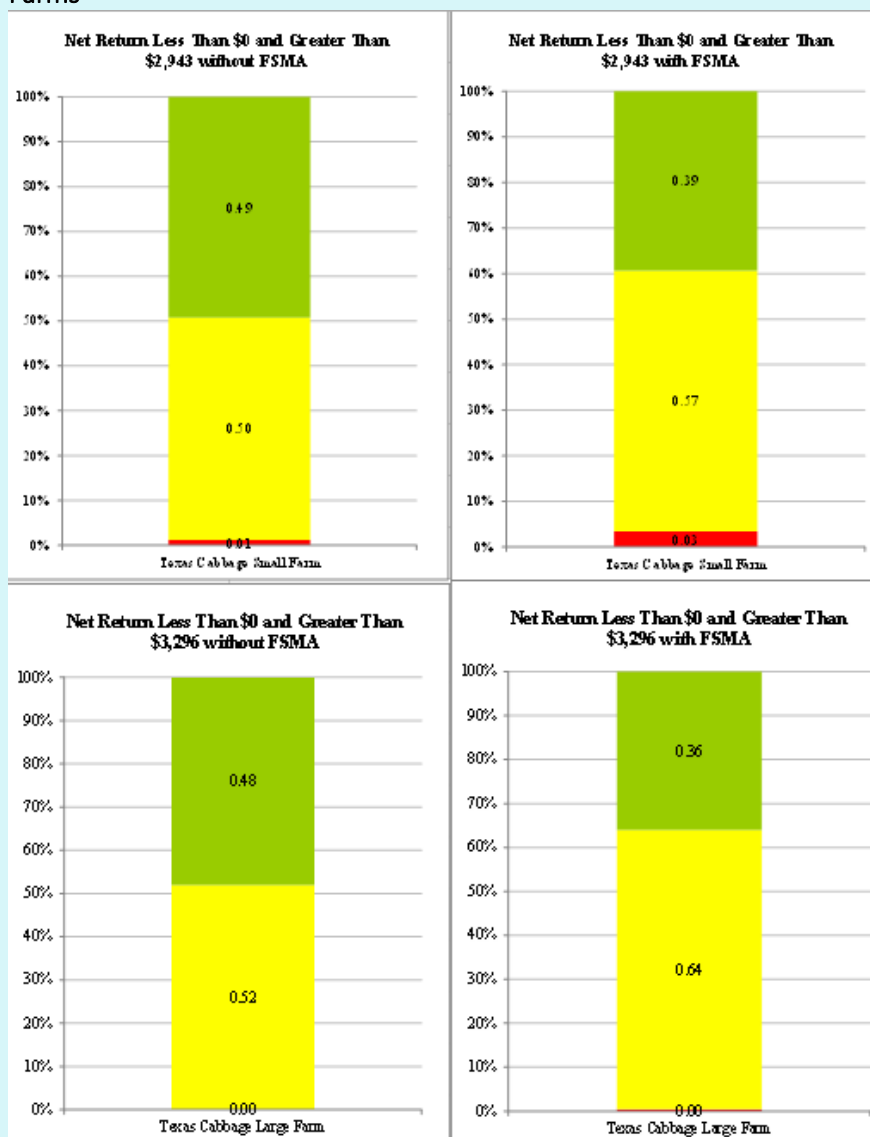
Figure 1: FSMA Impact on Net Returns for California Small and Large Cabbage Farms



Source: Ribera et al., 2014



Figure 2: FSMA Impact on Net Returns for Texas Small and Large Cabbage Farms



Source: Ribera et al., 2014

Figures 1, 2, and 3 show the results of the analysis of the impacts on the profitability of selected representative farms by comparing results without and with FSMA compliance costs in the cost of production. Profitability is measured as the 2013-14 net present value of after-tax income, per acre. Only results of cabbage farms in California, Texas, and Florida are included in this article in the interest of space; however, the results from the other crops listed above follow the same pattern. All representative farms were developed with historical prices and yields used to simulate production and marketing risks, so the results on costs and returns with FSMA compliance are statistically derived estimates. Therefore, the bars indicate the probability that profitability will fall between the average return, without and with FSMA compliance costs. In other words, red represents the probability of losing money, yellow represents the probability of falling short of average net returns, and green the probability of exceeding the average net returns.

For example, Figure 1 illustrates the results for a small and large cabbage farm in California without and with FSMA compliance costs. When excluding FSMA compliance costs, the probability of a small farm having negative after-tax net returns per acre is 82%, the probability of having a net return between \$0 and the average expected net return, \$839, for this farm at this location is 15% while the probability of a net return above the average expected net return per acre is 3%. When including FSMA compliance costs, the probability of the same farm having negative net returns increases to 88% and reduces to 10% of having net income between \$0 and the average expected net return, and only 2% of having a net return above the expected net return. These results indicate that FSMA compliance costs have a negative effect on large cabbage farms in California, but the negative effect on small farm profitability is greater.



Figures 2 and 3 display the results for Texas and Florida, respectively. Although the size and cost structure vary by state, similar qualitative impacts were found in Texas and Florida, as described for California cabbage production. The profitability of representative small farms is more negatively affected than the profitability of representative large farms under FSMA. Also, the level of the impact of FSMA compliance costs varies significantly among different states as well. For example, the source of irrigation water, either surface or underground, has to be treated differently, as surface water has higher chances of having a higher microbial count; therefore surface water needs to be tested more often, which increases FSMA compliance costs.

Other studies using different research approaches for different commodities and regions report similar findings. An FDA (2013) study found that the average FSMA compliance cost is considerably higher for small farms than for large farms. They reported that the average compliance cost as a percentage of average production values for very small farms was 6.3%, 4% for small farms, and 1.2% for large farms.

Similarly, Lichtenberg and Tselepidakis (2014) considered the impacts of FSMA compliance costs on different farm sizes in the Mid-Atlantic region that produce leafy greens and tomatoes. Their report indicates that all the practices under the Produce Rule, except possibly field inspection for flooding and wildlife encroachment, exhibit increasing returns of scale, meaning that costs rise less than proportionally with product acreage. As a consequence, the burden of complying with the provisions of the Produce Rule—measured by food safety cost as a share of production cost—is much lower for large operations than for small ones. These findings provide some justification for the small farm exemptions and extended phase-in times proposed by FDA. However, they do not account for the risk of food safety outbreaks that could come from farms that are exempt from FSMA compliance due to size, marketing channels and distance from farm to consumers, as is the case with the Tester-Hagan exemption.

**Figure 3: FSMA Impact on Net returns for Florida Small and Large Cabbage Farms**



Source: Ribera et al., 2014

## Not the Final Step

The FSMA is an important step toward a modern science and risk-based approach to food safety, but it most certainly is not the final step. The cost of compliance with the new FSMA rules does not appear to be size neutral and can have negative impacts on the profitability of small farms, exacerbating difficulties for those producing relatively risky commodities. For large enterprises, the additional cost is small relative to revenue and appears to have small effects on the probability of overall profitability. Moreover, innovations and new technology could help reduce the impacts of FSMA compliance costs for all farm sizes. Regardless, the cost of produce outbreaks outweighs the additional cost incurred to comply with FSMA regulations. Substantial care will need to be taken in designing implementation strategies that minimize adverse structural impacts, such as considerably reducing the number of small farms and/or diversity of farms, while reducing the risks of foodborne illness.

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

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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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# The Food Safety Modernization Act and Agricultural Imports

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*JEL Classifications: Q1, Q17, Q18*

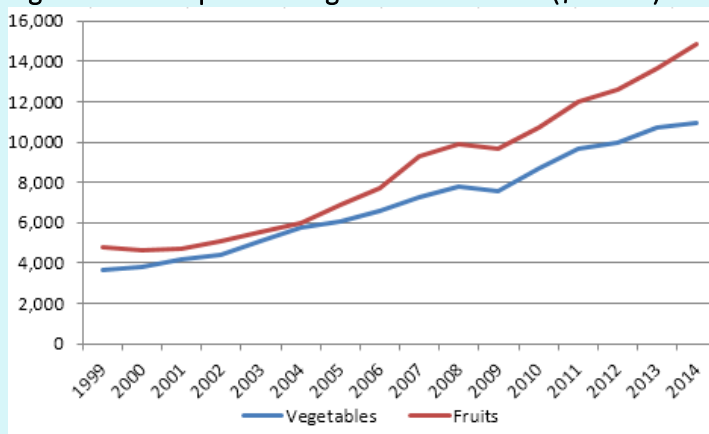
*Keywords: Food Policy, Food Safety, Agricultural Imports*

The Food Safety and Modernization Act (FSMA) was passed in 2011 after more than 70 years without major reform of food safety guidelines administered by the Food and Drug Administration (FDA). The FSMA overhauls the FDA's ability to regulate food suppliers in an effort to ensure the safety of the U.S. food supply and prevent food contamination that may cause foodborne illnesses. The FSMA aims to move from a response-based system to a supply chain system with risk-based preventative strategies to avoid contamination of food in the U.S. supply chain. The FSMA is also comprehensive in that it governs all U.S. food handling facilities, including certain farming operations. FSMA has exemptions for food products under U.S. Department of Agriculture (USDA) monitoring, including meat and poultry products. However, the FDA will now directly oversee 80% of the U.S. food supply giving the FDA a greater role in monitoring U.S food safety (Strauss, 2011).

Importantly, FSMA also includes provisions to hold imported food products to the same standards as those governed by domestic FSMA monitoring to minimize potential public health risks. The provisions of the FSMA authorize U.S. agricultural producers, food processors, and importers to follow specific strategies and procedures that are considered science- and risk-based guidelines for food safety (Ribera and Knutson, 2011). Various studies have assessed the economic implications of food safety measures under the FSMA on U.S. farmers, food processors, and food importers (Knutson and Ribera, 2011; Paggi et al., 2013).

The regulation of food imports under the FSMA is of particular importance given that the United States is a net importer of fresh fruits and vegetables, and imports have been growing faster than domestic production leading to a greater share of consumption coming from foreign-sourced suppliers. As illustrated in Figure 1, imports of fruits and vegetables have grown consistently since 1999. The average growth rate of total U.S. food imports was 7.7% from 2005-2014, with 9.7% growth of fruit imports and 6.8% growth in vegetable imports over the same time period. As indicated in Table 1, the key suppliers of imported fruits and vegetables include many developing countries where domestic food safety standards are not equivalent to those in the United States (USDA-ERS, 2016). This is a key driver for the inclusion of rules for imports under FSMA. Fresh produce imports with the greatest food safety concerns—as

**Figure 1: U.S. Imports of Vegetables and Fruits (\$million)**



Source: USDA-ERS, 2015.

**Table 1: Top 10 Sources of U.S. Imports of Fruits and Vegetables, by value (\$ million)**

Fruits					
	2014	2015		2014	2015
Fresh or Frozen			Prepared or Preserved		
Mexico	4,067	4,692	China	513	550
Chile	1,680	1,790	Mexico	354	403
Guatemala	1,005	1,066	Thailand	335	377
			European		
Costa Rica	1,001	890	Union-28	191	227
Peru	442	538	Canada	205	220
Ecuador	441	481	Philippines	163	169
Canada	370	423	Chile	111	120
Honduras	282	304	Turkey	101	84
Colombia	225	212	Indonesia	55	72
			Korea,		
Argentina	144	158	South	67	67
World	10,325	11,301	World	2,473	2,738
Vegetables					
	2014	2015		2014	2015
Fresh or Frozen			Prepared or Preserved		
			European		
Mexico	5,111	5,296	Union-28	918	919
Canada	2,081	2,058	Mexico	409	423
Peru	352	375	China	364	413
China	212	234	Canada	293	306
European					
Union-28	159	215	Peru	200	213
Guatemala	164	175	Thailand	108	119
Costa Rica	94	96	India	71	83
Ecuador	44	54	Turkey	73	78
Honduras	39	44	Japan	35	35
Dominican					
Republic	56	36	Chile	29	32
World	8,478	8,772	World	2,856	2,986

Source: Compiled by USDA-ERS (2016) from U.S. Department of Commerce

evidenced by rejection frequency—include fruit vegetables and root/tuber vegetables which are primarily imported from Mexico and other Latin American countries (Paggi et al., 2013). The implications of the FSMA for foreign suppliers are important, particularly for suppliers and producers in countries with limited domestic food safety regulation.

The key focus areas of FSMA include preventative controls, inspection and compliance, food safety regulation of food imports, FDA authority for mandatory food recalls, and enhanced partnerships with existing food agencies domestically and abroad (HHS and FDA, 2015). The FSMA includes regulatory provisions for food imports primarily through the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals, as well as the Voluntary Qualified Importer Program (VQIP) made possible through the Accredited Third-Party Certification Final Rule (FDA, 2015b). Understanding the provisions under the Final Rule of the FSVP, and the provisions for the VQIP that specifically focuses on food imports, is imperative as the legislation will affect how U.S. importers trade with partners around the globe.

## Foreign Supplier Verification Programs

On November 13, 2015, the FDA announced the Foreign Supplier Verification Programs (FSVP) for

Importers of Food for Humans and Animals Final Rule, with mandatory compliance for some import firms occurring as soon as 18 months from the issuance of its Final Rule. The intent of the FSVP is to assure the safety of imports by holding foreign-sourced food to the safety standards inherent in the FSMA. Accordingly, importers that are subject to FSVP must verify that imports from foreign suppliers that are also subject to FSVP are using production, handling, labeling, transportation practices, and other actions along the distribution channel that meet the same level of public health standards as domestically produced food. To accomplish this, importers must implement food safety programs to assess both commodity-related risk and supplier performance. The FSMA defines an importer as, “the U.S. owner or consignee of a food offered for import into the U.S.” (FDA, 2014). If there is no domestic owner, the foreign supplier must designate a U.S. agency or representative at the time of entry that is

held liable for FSVP compliance. There are a variety of exemptions that may exclude importers and suppliers from compliance with the FSVP.

For importers subject to the FSVP Final Rule, there are three steps that must be part of a food safety program. First, importers must complete an analysis of currently known or potential hazards for each commodity imported. Second, the potential food risk of each commodity must be evaluated, given the hazards identified, as well as the performance of the supplier in question. Third, dependent upon the evaluation of potential risk and supplier performance, a supplier of a given commodity may be approved as an acceptable potential foreign supplier; the importer must then determine appropriate supplier verification activities to be carried out.

Finally, importers must account for corrective actions to be taken if problems arise during verification activities or during the trade partnership. The aforementioned steps must be carried out for each commodity considered for import as well as for every supplier of a given commodity imported. Importers must provide documentation to only import from the suppliers who have been approved through the FSVP. However, unapproved suppliers may be used on a temporary basis if necessary, subject to adequate verification activities to ensure food safety before importation. Also, the FSVP includes the provision that importers may rely on a third party to complete the aforementioned steps of the food safety program to comply with the FSVP, but the importer is liable for ensuring compliance with the legislation.

### Step 1: Hazard Analysis

Hazard analysis involves investigating the potential for any biological, chemical, or physical hazards that may currently be of concern or could be a reasonable future concern for any given food product that is considered for import. This involves the importer using a variety of acceptable research tools to evaluate the potential presence of any hazards. The importer must also determine the probability that any hazards identified could occur without control measures, as well as information relating to any foodborne illness that could arise as a result of any hazard identified. Hazard evaluation must include a suite of factors including the makeup of the food product, equipment and processing facilities, food ingredients, transportation, supply-chain activities from production to packaging, labeling, storage and distribution, and sanitation including facilities and employees (FDA, 2016).

### Step 2: Evaluation of Food Risk and Supplier Performance

Upon completion of the hazard analysis, the importer must then evaluate the risk posed by the particular food as well as the performance of the supplier. The process of evaluating supplier performance is to determine whether or not the foreign entity will implement efforts to minimize the potential for an occurrence of any identified current or potential hazards. Foreign suppliers' food safety practices, compliance with relevant FDA regulations, as well as the history of supplier performance on matters of food safety also must be considered. This includes factors concerning production, handling, packaging, labeling, storage, transportation, and any other factors that may affect food safety. This stage is challenging in that supplier performance depends not only on the supplier but also the entities that provide materials and ingredients to the foreign supplier (FDA, 2016).

### Step 3: Supplier Verification and Corrective Activities

For foreign suppliers who qualify after hazard, risk, and supplier performance evaluations, importers must determine appropriate supplier verification activities that will be carried out to approve a foreign supplier. The appropriateness of the verification activities are dependent upon the risks related to each food product and the characteristics of the supplier. The specific verification activities may be customized based on the food and supplier. There are a variety of options including annual on-site inspections of supplier facilities, sampling and testing, and continual review of the trade partner's records relating to food safety—depending on the potential risk related to the imported good and supplier in question. Verification activities must be employed to ensure that the foreign supplier is producing, handling, processing, labeling, storing, and transporting food in a manner that complies with U.S. safety standards. Importers are to trade only with suppliers who have been vetted and approved through the FSVP; however, unapproved suppliers may be used on a temporary basis if necessary, as long as food imports undergo adequate food safety inspection and verification (FDA, 2016).

If there is a problem that is identified during verification activities or arises during the trade relationship, corrective actions identified by the importer must be implemented by the foreign supplier to correct any issues that arise.

The corrective actions will depend on the circumstances of the noncompliance issue, and range from measures to fix the problem or halting the purchase of food from the supplier (FDA, 2016).

## Voluntary Qualified Importer Program

FSVP requires significant research and investigation regarding risks associated with every imported food as well as the characteristics of every foreign supplier. Given the cumbersome nature of such analysis that must be performed for each food product and every supplier, there are provisions that allow for the voluntary streamlining of approval for importers who have demonstrated control and management of their foreign supply chains.

The Voluntary Qualified Importer Program (VQIP) is a fee-based program to expedite imports for firms who have demonstrated exemplary control of the safety and security of their supply chains. The VQIP is made possible through certification by a third-party entity that is approved based on the Accredited Third-Party Certification Final Rule of the FSMA. Key criteria that an importer must meet to be approved for the VQIP include:

- Importers must have a Quality Assurance Program (QAP) to assure the safety and security of their supply chains. This includes assurance of compliance with FDA regulations on imports under the FSVP, or Hazard Analysis and Critical Control Points (HACCP) if juice or seafood is the imported product.
- The importers must have certification through FDA for the facilities of each foreign supplier intended for import.
- A minimum three-year history of importing into the United States.
- No history of noncompliance with food safety regulations by the importer or any suppliers included in the supply chain.

There is an approximate annual fee of \$16,400 for importers to participate in VQIP, which grants expedited access into the United States. This expedited access includes the immediate release of shipments, along with limiting sampling and testing of shipments to only occur in the event of a known public health concern. When there is a known public health concern, a laboratory analysis will be expedited for VQIP participants (FDA, 2015b). In essence, VQIP importers must maintain the standards of the FSVP, and may pay a fee for expedited treatment if the firm has a strong history of maintaining food safety standards and control of the supply-chain and implements a QAP to ensure that these food safety actions are continued (FDA, 2015c; FDA, 2015d).

## FSVP Exemptions and Modified Standards

There are exemptions that allow importers to abstain from FSVP activities as well as modified FSVP standards, both determined by characteristics of the food for import, the importer, and the foreign supplier. There are a suit of exemptions related to dietary supplements that are already governed by the FDA, as well the meat, poultry, and egg products already inspected by the USDA. Low-acidic or canned foods, juice, fish and fisheries products that are covered under other FDA food safety policies are also not covered by the FSVP. Furthermore, foreign suppliers from countries whose food safety standards are deemed to be equivalent to U.S. standards may be exempt from FSVP (FDA, 2016).

## Cost of Compliance

The FSVP holds importers accountable for the safety of food imports, and creates additional costs associated with imported food. To expedite the import process that will prevail under the FSVP, importers may pay to participate in the VQIP, yet are still held accountable for maintaining compliance with FSVP. The requirements of the FSVP, with or without VQIP will undoubtedly increase the cost of imports, and may be too costly for small-sized importers. It seems unreasonable and costly for importers to be held responsible for verifying their foreign trade partners' suppliers. In fact, it may be impossible in some cases for an importer to verify the production practices of all the entities that supply to the foreign supplier that will export the food item to the United States, and this is independent of the size of the importer.

The complexities and costs of the foreign supplier performance evaluation are nontrivial, especially since importers are ultimately held liable for practices of all the suppliers to the foreign supplier. Furthermore, while importers are responsible, the costs of compliance will likely be placed on producers, with costs being highest for foreign suppliers that are the farthest out of compliance (Paggi et al., 2013). Despite the expected cost increase for FSVP compliance, Ribera et al. (2012) estimate that, in general, the added costs to producers for food safety procedures



that prevent produce food outbreaks are less than the potential losses to suppliers if an outbreak were to occur. However, further research to determine compliance costs of the FSVP is needed.

## Third-Party Certification

To comply with the FSVP, importers must either rely on their own resources or employ a third-party to conduct the hazard analysis, evaluate risk and supplier performance, and conduct the verification activities, which likely include annual audits of supplier facilities. The FSMA includes guidelines for third-party auditors to be accredited by the FDA through the Final Rule on Accredited Third-Party Certification. However, the potential prevalence of relying on third-party auditors to complete the steps for compliance with FSVP is of concern (Fagotto, 2010). This is particularly relevant, given that noncompliance with FSVP that results in a foodborne illness from foreign-sourced food could lead to criminal investigation of the importer by the FDA. Ultimately, the FSVP holds the importer liable for ensuring the safety and security of all food imports.

## Firm Size Exemptions

One of the more controversial exemptions and modified standards are granted for small importers and for importers of food from small foreign suppliers. This exemption stems from provisions for exceptions and modified standards in the FSMA for small U.S. firms. While this exemption alleviates the costliness of FSVP compliance, it creates a different problem by not requiring all imports to adhere to the same standards. Concerns regarding the safety of imported foods from small suppliers are valid, given evidence of past foodborne illnesses being traced back to very small foreign operations, and that smaller operations may be more vulnerable to food safety compliance issues (DHHS and FDA, 2008). Furthermore, firms that do not want to comply with FSVP have an incentive to manipulate the size of the operation to seek exemption (Gombas, 2014). The potential for the small firm-size exemptions is a valid concern as this erodes the coverage of the FSVP.

## WTO Compliance

Another concern of the FSVP is the potential for a future challenge in the World Trade Organization (WTO). The WTO is the international organization that governs trade between member nations, and covers the majority of world trade. Imported food must be treated the same as domestically produced food to remain in compliance with the WTO. If implementation of FSVP results in a foreign supplier being at a disadvantage relative to domestic producers, there could be cause for a WTO complaint. For example, through FSVP, hazard analysis for foreign-sourced products must investigate microbial, chemical, and physical hazards, while only microbial hazard investigation is required for domestically produced products under the Produce Safety Final Rule. This is an example where hazard analysis under the FSVP is more extensive and imposes additional costs on imported foods that are not incurred by domestic firms, thereby allowing for a potential WTO complaint. However, given the science-based nature of the FSVP to ensure the safety of U.S. food imports, FSVP guidelines may be permissible under the WTO (McNeill, 2012). Furthermore, the requirements for foreign supplier verification activities may be particularly challenging in developing countries while imports from suppliers from countries with equivalent food safety regulations may be exempt from FSVP (Humphrey, 2012). Again, this may potentially put developing country producers at a disadvantage relative to foreign suppliers from developed countries.

## Questions Remain

The goal of the FSMA is to ensure the safety of the U.S. food supply, including food produced both domestically and abroad by moving to food safety regulations that are preventative measures to avert food contamination before outbreaks occur. Accordingly, the FSVP has been created to govern the standards that imported food must adhere to. While an important step in verifying the safety of imported food, the provisions are complex and many questions remain after announcement of the Foreign Supplier Verification Programs Final Rule. While the provisions of the FSMA may reduce the risk of foodborne illness from imported food, the effectiveness of the food safety provisions are certainly weakened by the various exemptions and modified standards that are currently allowed under the regulation. Furthermore, the new food safety standards will cause an increase in the cost of imported food, particularly for imports from developing countries without domestic food safety policies that are similar to those in the United States. The extent to which the FSMA will affect import supply chains remains to be seen and merits continued attention as the regulations are implemented in the coming year.

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