CHOICES
A publication of the Agricultural & Applied Economics Association
AAEA Agricultural & Applied Economics Association
1st Quarter 2016 • 31(1)

The Food Safety Modernization Act and Agricultural Imports

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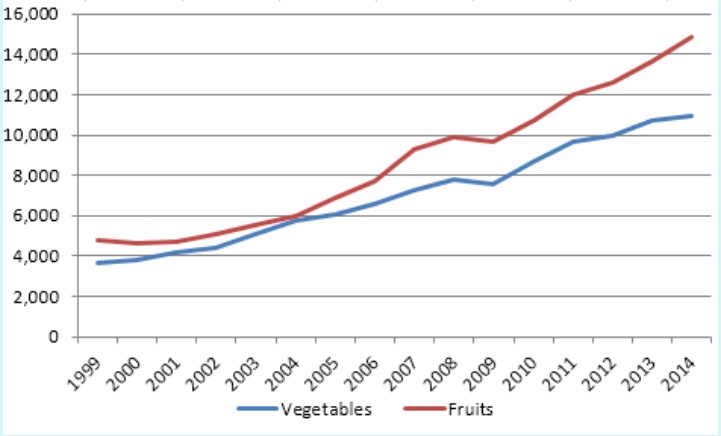
JEL Classifications: Q1, Q17, Q18
Keywords: Food Policy, Food Safety, Agricultural Imports

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 FMSA 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
Costa Rica	1,001	890	European 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
Argentina	144	158	Korea, South	67	67
World	10,325	11,301	World	2,473	2,738
Vegetables					
	2014	2015		2014	2015
Fresh or Frozen			Prepared or Preserved		
Mexico	5,111	5,296	European 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.

For More Information

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