The Impacts of Food Safety Modernization Act on Food Suppliers:

An Implication on the U.S and Foreign Tomato Producers with Different Sized Farms

Lisha Zhang
Clemson University
Email: lishaz@clemson.edu

James Seale
University of Florida
Email: jseale@ufl.edu

PRELIMINARY RESULTS: PLEASE DO NOT QUOTE

Selected Paper prepared for presentation at the Southern Agricultural Economics Association, 2016
SAEA Annual Meeting, San Antonio, Texas on February 6-9, 2016

Introduction

Food safety issues resulting from foodborne illness are a common, costly − and yet preventable − public health problem. An outbreak of foodborne disease is defined as the occurrence of two or more cases of a similar illness resulting from ingestion of a common food. According to the Center for Disease Control and Prevention (CDC), on average, each year about 48 million people (one in six Americans) get sick from contaminated foods or beverages, of whom 128,000 are hospitalized, and 3,000 die, as a result of foodborne diseases (Center for Disease Control and Prevention 2011). Although some critics have contested the calculation of these estimates, it is undisputed that recent incidents involving food contamination(Scallan et al. 2011).

Rising consumption of imported foods poses a challenge for U.S. food safety concerns (Becker 2008; Buzby 2003; Buzby, Unnevehr, and Roberts, 2008). According to USDA, today approximately 80 percent of seafood and 60 percent of fresh fruits and vegetables are imported, one-third of fruits and nuts come from abroad, as do numerous ingredients that are components of U.S. products. Canada and Mexico, among all countries, have been the largest suppliers of food, agricultural and seafood imports (Food and Drug Administration 2011). Imported foods that appear to be adulterated, misbranded, or which fail to comply with U.S. labeling requirements or other laws can by refused by the Food and Drug Administration (FDA). In figure 2-1, in 2010, the top imported food categories to be refused due to food safety and other violations under FDA law were: fishery and seafood products (16%); vegetables and

vegetable products (15 %); and fruits and fruit products (9%) (USDA Economic Research Service - EIB39 2015).

Over the past few years, outbreaks related to various foods have underscored the need to make continuous improvements in food safety regulations. Reducing foodborne illness by 10% would keep five million Americans from getting sick each year (CDC and Food Safety 2015). The basic provisions of the previous law on food safety, which dates back 1938, have become ill-equipped to deal effectively and efficiently with contemporary food safety issues (DeWaal and Plunkett 2007). As a result, Congress and the FDA needed to update the policies regarding food safety in order to account for a number of these contemporary issues, including: (1) the global nature of the food system; (2) the increased importance of fresh, raw, and highly processed products in diets; (3) the increased importance of away-from-home consumption; and (4) the tremendous technological changes that have taken place in food production, handling, transporting, processing, and retailing (Knutson and Ribera 2010).

Overview of the Food Safety Modernization Act

After many years of deliberation, Congress passed a new food safety law, mandating a paradigm shift to prevention — that is, to ensure the safety of the U.S. food supply, Congress shifted the focus to *preventing* food safety problems, rather than merely reacting to them after they occur. On January 4, 2011, the U.S. Food and Drug Administration Food Safety Modernization Act, was signed into law by President Obama.

Based on new scientific evidence, the FSMA has given the FDA new authority to regulate the way foods are grown, harvested, and processed, and addresses the hazards of food production from farm to table. For the first time, the FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply chain in order to prevent food-borne illness from both domestic and imported foods. To do this, the FSMA authorizes new regulations for farmers who grow certain kinds of fresh produce (fruits and vegetables), and for certain facilities that process food for people to eat.

Specifically, the FSMA requires: 1) comprehensive prevention-oriented food safety standards across the food system; 2) mandates for the frequency of domestic inspection, based on risk, to ensure high rates of compliance; 3) a national integrated food safety system based on full partnership with states; and 4) a new import safety system, based on food safety accountability for importers, increased foreign presence, and more collaboration with foreign governments (Nutrition 2015).

The FSMA puts a major emphasis on imported foods. For instance, under the FSMA, importers will be held accountable for the safety of their products. The law requires that importers verify that the food they bring into the U.S. was produced in a manner consistent with U.S. laws and regulations. More precisely, foreign food growers and producers wishing to export foods to the U.S. will have to prove that they have produced the food in compliance with U.S. laws and regulations regarding soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water. Failure to meet these

regulations will inhibit access to the U.S. market and erode consumer confidence in the brand.

Specifically, the new authorities granted to the FDA in order to ensure that imported products meet U.S. standards, and so are safe for U.S. consumers, include the following: 1) Importer accountability: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe; 2) Third-Party Certification: The FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards; 3) Certification for high-risk foods: the FDA has the authority to require that high-risk imported foods be accompanied by a credible third-party certification, or other assurance of compliance, as a condition of entry into the U.S.; 4) Voluntary qualified importer program: the FDA must establish a voluntary program for importers that provides for the expedited review and approval of foods from participating importers (eligibility is limited to those importers offering food from certified facilities, among other things); and 5) Authority to deny entry: the FDA can refuse food from a foreign facility entry into the U.S. if the FDA is denied access to that facility, whether by the facility itself or by the country in which the facility is located (Food and Drug Administration 2011). As an outgrowth of this new safety law, FDA has announced that it plans to work more closely with other countries and share findings, potentially reducing the number of plant inspections necessary per year (Larkin and Edney 2015).

Impacts of Food Safety Modernization Act on Food Producers with Different Farm Sizes

FSMA exempts some producers and processors based on the size of their business. This is because small farmers originally opposed FSMA fearing the increased costs and paperwork of regulation. However, some Industry trade organizations have argued this inclusion of exemptions based on non-scientific qualifications will limit the ability of FDA to assure consumers that all foods they purchase have met the same food safety standards (Strauss 2011).

There are approximately 189,636 farms in the U.S., the District of Columbia, and the Commonwealth of Puerto Rico that grow produce for sale, excluding sprouting operations (United States National Agricultural Statistics Service, 2004). This number includes farms with on-farm packing, farms with greenhouses, farms eligible for qualified exemptions, and farms that are not covered by the FSMA. Farms are eligible for qualified exemptions if 1) the farm produces only for personal or on-farm consumption, 2) the farm's products are rarely consumed raw (e.g., squash), 3) the production process includes commercial processing to kill microorganisms, or 4) the farm has an average annual value of food sold during the previous three-year period of $25,000 or less, regardless of the type of produce sold. In other words, to qualify for a complete exemption from FSMA requirements, a farmer needs to either not sell produce at all, sell only low-risk or processed produce, or meet the $25,000 revenue cap.

Besides defining the farms eligible for qualified exemptions, the FDA also defines different sizes of farms. More precisely, the FDA defines three sizes of

farm for use in its economic impact analysis: 1) Very Small Farms: farms with production of $250,000 or less in total monetary value of food per year; 2) Small Farms: farms with production of more than $250,000 but no more than $500,000 in total monetary value of food per year; and 3) Large Farms: farms with production of more than $500,000 in total monetary value of food per year (Food and Administration 2011).

In the FDA's report (Food and Drug Administration 2007), they estimated the numbers of farms covered by FSMA based on the National Agricultural Static Service (NASS) 2007 Census of Agriculture. Table1 lists, on the one hand, the total number of domestic farms that are eligible for a qualified exemption and so are not covered by the proposed rule, and on the other hand, the number of farms covered by the proposed rule, including the number of farms of each size. Table 2-2 describes the number of covered farms in more detail, including the total number of produce acres operated, the average produce acres operated per farm, and the average food sales per farm, all broken down by farm size. There are 40,211 farms (other than covered farms that are sprouting operations) covered under FSMA (from Table1: 189,636 total farms – 149,425 farms not covered or exempt). Among these, 285 covered farms are sprouting operations. There are approximately 26,947 very small farms, 4,693 small farms, and 8,571 large farms covered in the proposed rule, not including sprouting operations. Very small farms account for 67 percent of these covered farms, and operate 10 percent of covered acreage. Large farms account for 21 percent of these covered farms, and operate 81 percent of covered acreage. The average produce

acreage operated per farm is 111 acres, and the average value of food sales per farm is approximately $650K.

Fresh produce sections are characterized by limited markets controlled by a few vertically integrated firms. Therefore, vegetable and fruit producers are mostly price takers. As a result, those producers will be required to comply with whatever food safety standards their buyers require if they wish to be active market participants, even if the compliance costs are especially high for some farms (Paggi et al. 2013).

These compliance costs will have substantial structural impacts, however. For instance, they will raise food prices (Hardesty and Kusunose 2009; Paggi et al. 2013), and more importantly, they will also impose different cost burdens on different sized farms. Specifically, complying with the mandatory regulations would be expected to impose substantial variable and fixed costs associated with specified changes in the input mix, as well as with the implementation of procedures required for production, harvesting, handling, and processing, along with possible third-party audit verification procedures. The rise in fixed costs would be expected to increase at a decreasing rate as the size of the farm increases. Therefore, the operational systems required for compliance with these standards appear to favor large acreage operations that can absorb the fixed and seasonal food-safety-related costs. Small acreage producers, by contrast, may be placed at a disadvantage. Paggi et al. (2013) comments that farm size is very important to understanding the impacts of the FSMA on fresh produce sectors.

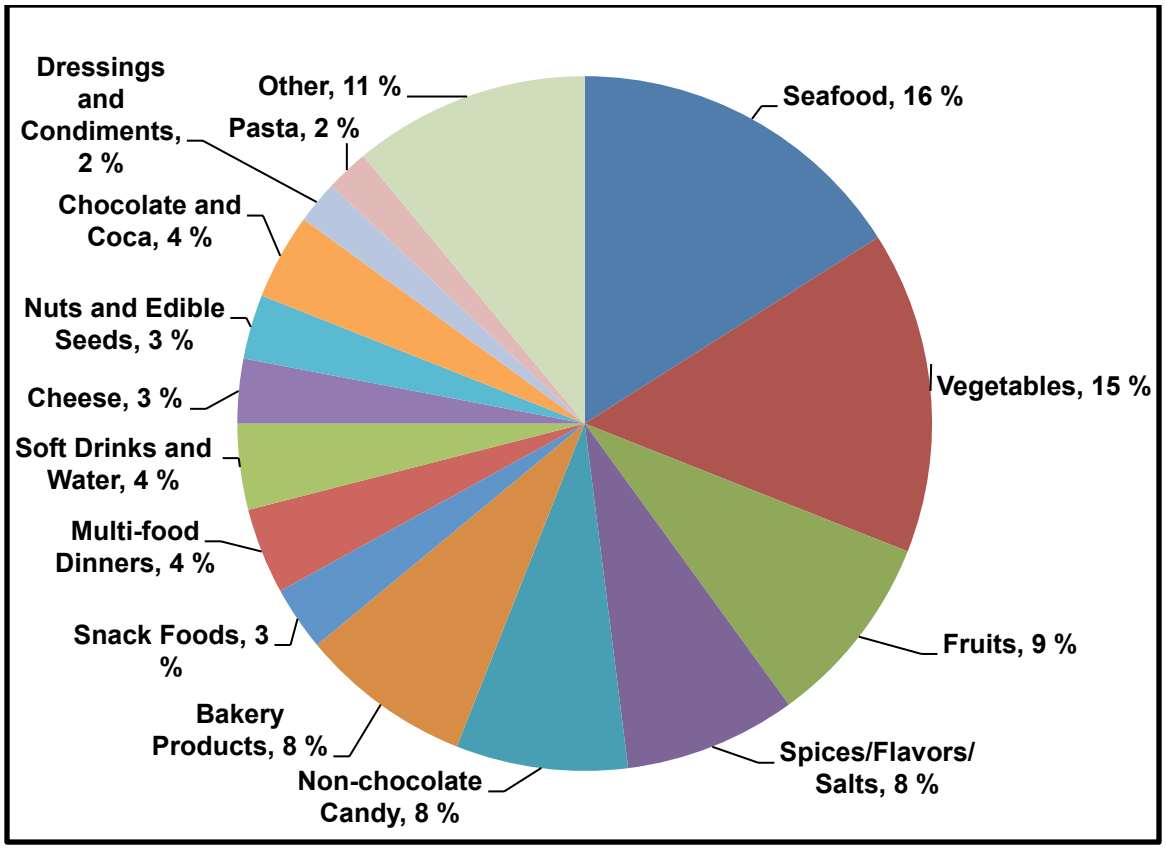

Figure 1. FDA Import Violations by Food Product, 2010

Table1. FDA Accounting of Farms Eligible for Qualified Exemptions and Covered and Not Covered by FSMA, in 2007

	$25K or less monetary value of food produced	Very Small	Small	Large	Total
Total Number of Farms	113,870	53,429	9,147	13,191	189,637
Total Covered Farms	-	26,947	4,693	8,571	40,211
Total Farms Exempt/Not Covered	113,870	26,482	4,454	4,620	149,426

Table2. FDA Accounting of Farms to be Covered by FSMA, Other Than Sprouting Operation, in 2007

	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	424.3	111.3
Average Food Sales per Farm	$75,279	$320,696	$2,638,384	$650,2