

SMALL VS LARGE, ELEMENTS OF THE FOOD SAFETY
MODERNIZATION ACT

by

Cassidi Williams

FOOD REGULATION IN THE UNITED STATES

Professor Neal Fortin

12/03/12

SMALL VS LARGE, ELEMENTS OF THE FOOD SAFETY MODERNIZATION ACT

Cassidi Williams

INTRODUCTION

The Food Safety Modernization Act (FSMA), signed January 4, 2011, is the largest change in the United States Food safety laws since the enactment of the Food, Drug and Cosmetic act. The FSMA will affect the way that food safety programs are executed and designed in both large and small food manufacturing firms. This paper will examine the intrusiveness of the FSMA into large manufacturers as well as both the negative and positive effects it will have on small manufacturers/producers.

The implementation of the FSMA changes the concentration of the regulation of food production in the United States from reactive to proactive. This change in direction was prompted by years of continuous food safety outbreaks and breaches that may have been prevented if more proactive measures had been implemented by the government and/or food producers. In 2006, organic spinach that was contaminated killed 3 and sickened over 200 people.¹ In 2007, over 600 people were sickened from contaminated peanut butter. In 2008, peppers that were imported into the United States made over 1400 people sick.² And finally, in 2009, one of the most horrific food safety incidents occurred when the Peanut Corporation of America (PCA) shipped out product that initially tested positive for *Salmonella* but passed a retest. PCA also failed to clean or make any major changes to the facility after the positive *Salmonella* results were reported. The food safety failure by PCA killed eight people and sickened 500 people in 43 different states.³ The FDA is responsible for ensuring the safety of over 80% of the food produced here in the United States.⁴ With the number of Americans being killed by the food that is consumed here in the United States increasing, the government felt a need to step in.

There are five major elements that form the FSMA. These are prevention, inspection and compliance, response, imports, and enhanced partnerships. Each section is based upon the

¹ Koenig, Jonathan. "Harvard University DASH Repository." *Harvard University Dash Repository*. May 2011. <http://nrs.harvard.edu/urn-3:HUL.InstRepos:8592051> (accessed November 27, 2012).

² Fortin, Neal. "The United States FDA Food Safety Modernization Act: The Key New Requirements." *European Food and Feed Law Review*, 2011: 260-268.

³ Moss, Michael. "Peanut Case Shows Holes in Safety Net." *The New York Times*, February 8, 2009.

⁴ Strauss, Debra. "Food and Drug Law Journal." *Food and Drug Law Journal*. 66.3 (2011): 353-376.

Cassidi Williams

preventative and proactive nature of the FSMA.⁵ Due to the fact that the FSMA has been signed this year (2011), there are still details of the mandate that need to be defined in more detail, but the major and long term goals of the FSMA have been identified. In this paper, I will discuss elements in three sections of the FSMA that identify where this act has the ability to be intrusive in large-scale facilities, and also how various elements will affect small production facilities; whether negative or positive. Section one will discuss the prevention portion of the FSMA, section two will discuss elements of the inspection and compliance portion, and section three will discuss elements of the response portion of the FSMA. Overall this paper will suggest that the FSMA is beneficial to the safe production of food product in the United States but it causes very different issues for small and large manufacturers.

PREVENTION

The FSMA has been designed as an additional way for the FDA to maintain control of the safety of the food produced in the United States. Many of the policies set in the FSMA have the ability to seem intrusive to many food production facilities. According to section 102 of the FSMA, all food handling facilities, excluding farms, roadside stands, farmer's markets, and community based programs, need to register with the FDA as well as renew their registrations biennially.⁶ Along with registering with the FDA all manufacturers are required to have a HACCP plan that has been implemented and followed by the assessment of the critical areas where food safety issues could occur. This is one of the few provisions that work to the benefit of small markets and food producers. Although smaller producers have the ability to effect a smaller number of people due to the fact that in the event of some type of contamination, it would most likely be contained in a small section of the country, it is important for these producers to still follow safe manufacturing processes. This provision is also a portion of the FSMA that is lacking. Instead of designing a way for these small food producers and distributors to adhere to similar HACCP, traceability, and safety regulations as large scale facilities, simply an exemption was written for them.

The small manufacturers and local farmers need to meet specific criterion for their exemption. Those seeking the exemption must have annual gross sales of less than \$500,000. The small manufacturers/farmers must also sell over half of their products directly to farmers markets, local restaurants, and groceries that sell the products directly to consumers. The term "local" was defined by end-users that are within 275 miles of the production facilities. These

⁵ Background on the FDA Food Safety Modernization Act (FSMA)." *FDA*. FDA, 12 2011. Web. 12/03/12. <<http://www.fda.gov/fsma>>.

⁶ The complete text of the Food Safety Modernization Act may be found on the FDA website at www.fda.gov/food/foodsafety/FSMA/ucm247548.htm (last visited Dec 03, 2012)

producers are still required to adhere to local and state food production laws.⁷ Although the requirements of the exemption are specific, it still leaves less than half of the products manufactured by these smaller producers the ability to be shipped around the country. Here is an example of the benefits that the small manufacturer/farmer/distributor has over a large scale processing facility.

INSPECTION AND COMPLIANCE

As a requirement of the FSMA, facilities will be inspected at varying frequencies depending on the risk levels of the items manufactured in the production facilities. As a requirement of the FSMA, all high risk facilities will be inspected within five years of the enactment of the FSMA. The inspection of foreign facilities that import product into the United States will also begin inspections at a higher rate than before. According to the FSMA, 600 foreign facilities must be inspected within the first year of enactment, and this number must double every year for at least five years.⁸ This has the ability to seem intrusive to many large scale high risk facilities. The fact that the FDA will conduct food safety audits in their facilities on a routine basis may seem daunting and unnecessary to some facilities. Although this can be viewed as a negative, it helps to ensure that the items that are at the highest risk for contamination are maintaining and following their food safety programs. It also ensures that food manufacturing facilities are “audit ready” more often, which frequently translates into cleaner facilities, and more stringent adherence to SOPs and many safety programs that have been written for the specific facilities.

The FSMA also states that the FDA has the ability to inspect and review all food safety plans as well as the records of any products that the FDA reasonably believes is adulterated.⁹ This requirement of the FSMA has the ability to seem intrusive to some large manufacturers as well as small producers/manufacturers in the fact that even if there is reasonable belief that the product is adulterated, the FDA has access to the production/traceability records. This is an excellent example of the proactive approach of the FSMA. Instead of waiting for a recall or some type of sickness due to food contamination, the FDA has the ability to review records when there is reasonable belief that product has been contaminated, prior to an actual event where contamination has been confirmed. In the event the FDA finds that food produced, held,

⁷ "Food Safety Bill Includes Important Exemptions for Local Farmers." *Sustainable Business*. Sustainable Business, 05 2011. Web. 3 Dec 2012. <<http://www.sustainablebusiness.com/index.cfm/go/news.display/id/21671>>.

⁸ Fortin, Neal. "The United States FDA Food Safety Modernization Act: The Key New Requirements." *European Food and Feed Law Review*, 2011: 260-268.

⁹ The complete text of the Food Safety Modernization Act may be found on the FDA website at www.fda.gov/food/foodsafety/FSMA/ucm247548.htm (last visited Dec 03, 2012)

processed, received, or packed by a facility that causes severely negative health effects, the FDA has the ability to suspend or revoke the registration of the food facility.¹⁰

RESPONSE

An example of the FDA exercising its right to suspend a food manufacturer's registration is the case of Sunland Inc. The suspension of the registration eliminates Sunland Inc.'s ability to introduce any food product into intrastate or interstate commerce. Peanut butter produced by Sunland Inc. was linked to an outbreak of *Salmonella* Bredeney. There were 42 people infected by Sunland Inc's product and it spanned over 20 states. It was not simply the most recent 2012 outbreak of *Salmonella* Bredeney but also the review of records by the FDA that proved that Sunland Inc. released over 11 product lots of nut butter between 2009 and 2012 that tested positive for the presence of *Salmonella*.¹¹ Along the same lines of the suspension of a food manufacturer's registration, with the enactment of the FSMA the FDA has the ability to call for a mandatory recall of product. Previously the FDA was able to recommend a recall, in which most producers adhered to, but in this new requirement ensures that if there is a manufacturer that is reluctant to complete a recall the FDA can ensure the safety of the consumer by making it mandatory.¹² The mandatory recall seems to be somewhat intrusive due to the fact that the majority of manufacturers that are given the recommendation to have a recall on product do so. This new mandate can be viewed in two ways. One, is that the FDA is protecting the consumer by maintaining the ability to force a company to have a recall in the event that they are reluctant or taking their time to recall the product. The other view is that if a company genuinely feels that a recall is not necessary, is it really the government's responsibility to intervene? If the product is not contaminated, or the manufacturer does not believe that the product implicated should be recalled isn't it their responsibility as the manufacturer to do so? The FSMA also changes how and when the FDA can make the decision to order administrative detention of product if there is a reason that the product could be adulterated or misbranded. The change to this in comparison to the previous regulation is that before the FDA inspector or representative needed to express that the food that is going under administrative detention has the ability to cause serious harm or death. With the present regulations, the need of serious harm or death has been taken out, and even misbranding is reasonable for the FDA representative to place product in a manufacturing facility on hold. This is an interesting change to the law. The fact that an inspector can come into a facility and believe that there could be misbranding and place product on hold at that facility is interesting, and in many cases some manufacturers may believe that this is intrusive. This is also

¹⁰ The complete text of the Food Safety Modernization Act may be found on the FDA website at www.fda.gov/food/foodsafety/FSMA/ucm247548.htm (last visited Dec 03, 2012)

¹¹ . "FDA Investigates Multistate Outbreak of Salmonella Bredeney Infections Linked to Peanut Butter made by Sunland Inc.." *FDA U.S. Food and Drug Administration*. FDA, 30 Dec 2012. Web. 3 Dec 2012. <<http://www.fda.gov/food/foodsafety/CORENetwork/ucm320413.htm>>.

¹² Strauss, Debra. "Food and Drug Law Journal." *Food and Drug Law Journal*. 66.3 (2011): 353-376.

an example of the proactive nature of the FSMA. The FSMA is working to decrease the number of non life-threatening but still serious food safety breaches.¹³

The FSMA is an all encompassing overhaul of the food safety regulation that occurs in the United States. Although many of the new regulations may seem intrusive, or overreaching, the main goal of the FSMA is to prevent sickness and deaths due to food safety breaches instead of simply reacting to them. The FSMA has the ability to be beneficial to the safety of the food produced in the United States as long as the funds are available, and in my opinion, the smaller food processing plant and facilities are required to work under the same regulations as large scale facilities. The fact that a producer is small and is in close contact with their customers does not eliminate the need for hazard analysis as well as the inspection of its facilities by outside sources. Many times these exclusions are put in place to protect the smaller producers by not causing them to forego large amounts of capital, but the entire manufacturing operation will be lost if serious sickness or deaths are caused by the inadequate food safety practices of these producers. On the other end of the spectrum, many large scale manufacturers are currently producing with documented food safety programs and HACCP plans. It is the intrusion of the FDA and many of the new regulatory abilities that are given to the FDA by the FSMA that may cause issues for large scale producers. Whether a small, medium, or large producer the constant use of solid food safety practices, excellent traceability, and analysis of the processing procedures will many times help eliminate any food safety issues before they leave the facilities.

¹³ Endres, Bryan, and Nicholas Johnson. "Food Law and Policy." *Food Law and Policy*. 7. (2011): 383-413.