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NEW POWERS UNDER FOOD SAFETY MODERNIZATION ACT: FDA PROPOSES NEW RULES TO COMBAT FOODBORNE ILLNESS

Agostino S. Filippone

I. INTRODUCTION

When families sit down at the dinner table, they assume the food that they are about to enjoy is safe and healthy. In recent years, news of foodborne illnesses – including listeria in cantaloupes, e-coli contamination in ground beef, and salmonella in peanut butter and eggs – demonstrates that these assumptions are not always true. In response to concerns over the integrity of the food supply chain, the Food and Drug Administration (“FDA”) has been prompted to act. On January 4, 2013, the FDA issued proposals for two food safety rules aimed at helping to prevent foodborne illness.¹ The proposals follow research and outreach conducted by the regulatory body since passage of the Food Safety Modernization Act (“FSMA”), signed into law by President Obama on January 4, 2011.² The law was seen as a way

¹ Press Release, U.S. Food & Drug Admin., FDA Proposes New Food Safety Standards for Foodborne Illness Prevention & Produce Safety (Jan. 4, 2013),

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm334156.htm> (“The first rule proposed today would require makers of food to be sold in the United States, whether produced at a foreign-or domestic-based facility, to develop a formal plan for preventing their food products from causing foodborne illness. The rule would also require them to have plans for correcting any problems that arise. . .The FDA also seeks public comment on the second proposed rule released today, which proposes enforceable safety standards for the production and harvesting of produce on farms. This rule proposes science-and risk-based standards for the safe production and harvesting of fruits and vegetables.”).

² *About Food Safety Modernization Act (“FSMA”)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247546.htm> (last

of allowing the FDA greater power and oversight in order to assure more proactive measures to prevent food safety issues rather than primarily acting in a reactive capacity after problems surfaced.³ Key portions of the FSMA deal with the FDA's new authorities and congressional mandates in areas concerning prevention, inspection and compliance, response, imports, and enhanced partnerships.⁴

This article will provide an overview of the two new food safety rules proposed by the FDA in January of 2013. To gain a better understanding of the proposed rules, this article will provide a brief historical background of the FDA. Part III of the article will provide a discussion of the Food Safety Modernization Act ("FSMA"), which provides the FDA with new powers and purposes with respect to food safety for the first time in 70 years. The article will conclude with a brief description of the FDA's next steps under the FSMA.

II. GROWTH OF THE FOOD AND DRUG ADMINISTRATION

The FDA came to be known under its current name in 1930.⁵ The agency's primary purpose prior to passage of the 1906

updated Jan. 4, 2013) (The FSMA "aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it").

³ *Background on the FDA Food Safety Modernization Act ("FSMA")*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm> (last updated Nov. 14, 2011) (noting a Center for Disease Control & Prevention statistics report which noted that each year approximately one in six Americans, around 48 million people total, fall ill as a result of a foodborne disease. Of that 48 million, 128,000 individuals are hospitalized and 3,000 people die).

⁴ *Id.* ("The [FSMA] . . . enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities").

⁵ *History of the FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last updated July 29, 2010) (explaining that the FDA's roots can be traced back to around 1848 when Lewis Caleb Black was appointed to the Patent Office. His position

Pure Food and Drugs Act was to complete chemical analysis studies of agricultural goods.⁶ The 1906 Act, however, tasked the FDA with its modern day regulatory function by officially prohibiting interstate commerce in food and drugs that had been found to be adulterated or misbranded.⁷ The 1906 Act provided for the first time a set of protections not previously available to American consumers.⁸ The FDA's powers and purpose were later enhanced under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA").⁹ The FDCA was more consumer-oriented and provided for strengthened regulation powers to protect the consumer's financial position as well as enacting food standards meant to conform to the "value expected" by consumers.¹⁰ In 1958, Congress enacted the Food Additives Amendment requiring FDA approval of any new food additives, under the theory that certain additives could actually adulterate food and make it unsanitary.¹¹

included completing chemical analysis of agricultural products. That work was later transferred as a function for the Department of Agriculture, formed in 1862).

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *About the 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132818.htm> (last updated Apr. 9, 2009) ("The law provided for three kinds of food standards: 1) standards (definitions) of identity, 2) standards of quality, and 3) standards regulating the fill of container. Regulators had the discretionary authority to set standards 'whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interests of consumers'" (quoting 1938 Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938)). Today, the FDA's regulatory power governs food, dietary supplements, drugs, vaccines, medical devices, electronic products, cosmetics, veterinary products, and tobacco products. *See What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm> (last updated June 21, 2012).

¹⁰ *Id.* (noting that the Food, Drug, and Cosmetic Act allowed for three food standards, related to identity, quality and container fill regulations).

¹¹ Federal Food, Drug, and Cosmetic Act, Food Additives, 21 U.S.C. § 348 (2010). For additional information regarding the history of food additives in the U.S., including details on procedures and a glossary of commonly used additives, see *Additives in Meat and Poultry Products*, U.S. DEPT. OF FOOD & AGRIC.,

http://www.fsis.usda.gov/FACTSheets/Additives_in_Meat_&_Poultry_Products/index.asp (last updated Nov. 2008). One exception to FDA pre-approval for

The FDA has since evolved into one of the most recognizable agencies, affecting daily consumers by protecting the greater public health through oversight areas, including the U.S. food supply, cosmetics and medical drugs and devices.¹² The agency fosters the advancement of U.S. citizens not only by educating the public and monitoring items like medicine, but also by regulating items like tobacco, which also have an adverse effect on consumer health.¹³ Interestingly enough, the FDA is also involved in national security because it prepares for counterterrorism efforts by ensuring security of the nation's food supply and aiding in the creation of medical products that might

use of a food additive is if the substance used is "Generally Recognized as Safe" ("GRAS"). See *Generally Recognized As Safe (GRAS)*, U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedAsafeGRAS/default.htm> (last updated June 25, 2012); see generally *Overview of FDA's GRAS*, NORTH DAKOTA STATE UNIV., https://www.ndsu.edu/pubweb/~saxowsky/aglawtextbk/ref_topics/GRAS.htm (providing additional discussion on the 1958 Food Additives Amendment and GRAS considerations).

¹² *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last updated June 19, 2012).

¹³ *Id.* In 2009, The Family Smoking Prevention and Tobacco Control Act, commonly referred to as the Tobacco Control Act, was passed. It provides the FDA with authority to regulate the manufacture, distribution, marketing of tobacco products. The Act was written as a response to data showing that a majority tobacco users were under the legal tobacco purchasing age of eighteen, giving the FDA enforcement authority in addition to broad sanctioning powers for violations of the law. Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (June 22, 2009), <http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>; see generally *Overview of the Family Smoking Prevention & Tobacco Control Act: Consumer Fact Sheet*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm246129.htm> (last updated Jan. 25, 2013) (providing consumers with a summary of the recent tobacco-related law). The Center for Disease Control & Prevention has found that more than 80% of adult smokers begin smoking before the age of eighteen. See *Smoking & Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (last updated Nov. 15, 2012). For a recent critique of the Tobacco Control Act, including its accomplishments and future, see Thomas J. Glynn, *The FDA & Tobacco Regulation Three Years Later*, AM. CANCER SOC'Y (Oct. 29, 2012), <http://www.cancer.org/cancer/news/expertvoices/post/2012/10/29/the-fda-and-tobacco-regulation-three-years-later.aspx>.

be used in response to public health threats.¹⁴

III. THE ROAD TO THE FOOD SAFETY MODERNIZATION ACT

As the global food environment developed, and after a series of stop-gap measures, including good manufacturing practice (“GMP”) regulations in 1969 and other regulations in 1971 forward enacted following food contamination scares, it was decided that the FDA needed updated powers to deal with modern day realities in the food supply chain.¹⁵ The FSMA sought to correct eroding public confidence in governmental protective measures and provide the FDA with greater power to set safety standards, implement Hazard Analysis and Critical Control Points (“HAACP”) programs, regulate global food imports entering the United States, and provide the agency with sufficient agility to proactively reduce the risk of a foodborne illness outbreak.¹⁶

The FSMA has been characterized by some as historic legislation that will overhaul the FDA’s statutory tools for the first time in 70 years.¹⁷ However, despite President Obama’s

¹⁴ U.S. FOOD & DRUG ADMIN., *What We Do*, *supra* note 12.

¹⁵ DECLAN A. CONTROY ET. AL., FOOD & DRUG LAW INST., THE FOOD SAFETY MODERNIZATION ACT: A COMPREHENSIVE, PRACTICAL GUIDE TO THE LANDMARK LEGISLATION xvii (James William Woodlee ed. 2012), *available at* <http://www.hoganlovells.com/files/Publication/85853d64-c3f2-4bc7-9fbc-f0e3878675c1/Presentation/PublicationAttachment/751c016a-fe0f-49da-9767-f62cc75b5b98/Hogan%20Lovells%20FDLI%20Article.pdf>.

¹⁶ *Id.*

¹⁷ *See, e.g., Id.*; Statement of Shelley A. Hearne, Managing Director of the Pew Health Group (Dec. 21, 2010), http://www.makeourfoodsafesafe.org/tools/assets/files/CongressFinalPassageStatement_01042011.pdf (“Congress and President Obama should be applauded for enacting historic food safety legislation that will provide the U.S. Food and Drug Administration (“FDA”) with improved authorities to oversee the safety of the nation’s food supply and prevent foodborne illness. This reform is the first major update to the law in over 70 years.”); Margaret A. Hamburg, *Food Safety Modernization Act: Putting Focus on Prevention*, WHITE HOUSE (Jan. 3, 2011), *available at* <http://www.whitehouse.gov/blog/2011/01/03/food-safety-modernization-act-putting-focus-prevention> (“The historic legislation the President will sign tomorrow directs the Food and Drug Administration, working with a wide range of public and private partners, to build a new system of food safety oversight – one focused on applying, more comprehensively than ever, the best available science and good common sense to prevent the problems that can make people sick.”); Nathan M. Trexler,

signing it into law in 2011, little was done by the FDA in actually using their new powers to protect U.S. consumers.¹⁸ While the FDA provided quarterly progress reports detailing their work in developing rules and charting work on compliance with mandates required under FSMA, work was slow.¹⁹ The public perception of inaction came to a boiling point when the Center for Food Safety and the Center for Environmental Health filed a joint suit against the FDA and Office of Management and Budget (“OMB”) for failing to implement food safety regulations required by the FSMA.²⁰ The Executive Director of the Center for Food

“Market” Regulation: Confronting Industrial Agriculture’s Food Safety Failures, 17 WIDENER L. REV. 311 (2011) (“One hundred years have passed since the enactment of the first food safety legislation—using law to punish the sins of industry—yet food safety remains as pressing a concern as ever.”). The FSMA was nearly derailed after the Senate approved the bill on November 30, 2010 but made a procedural mistake so that funding for the Act was tied to a scuttled omnibus spending bill. Funding was ultimately met through a deal brokered by Senator Harry Reid and Mitch McConnell that was passed by the Senate with unanimous consent. Patrik Jonsson, *Fewer Bad Eggs? Food Safety Bill is Revived, Heads to Obama’s Desk*, CHRISTIAN SCI. MONITOR (Dec. 20, 2010), available at <http://www.csmonitor.com/USA/Politics/2010/1220/Fewer-bad-eggs-Food-safety-bill-is-revived-heads-to-Obama-s-desk>.

¹⁸ James Andrews, *FSMA Approaches Two-Year Anniversary as Components Languish*, FOOD SAFETY NEWS (Dec. 19, 2012), <http://www.foodsafetynews.com/2012/12/fsma-approaches-2-year-anniversary-while-components-languish/#.UQ2w5RzBNpE> (noting that “many of [FSMA’s] major components are stuck in the approval process, missing deadlines along the way. Critical pillars of the act – rules on fruit and vegetables, imports and outbreak prevention – remain stalled at the White House Office of Management and Budget. Neither OMB nor the U.S. Food and Drug Administration will provide a time frame for when the rules might be released”).

¹⁹ *Id.* See also *Implementation & Progress*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm250568.htm> (last updated Jan. 18, 2013) (providing the public with an overview of the FSMA’s implementation timeline and the FDA’s quarterly progress reports to Congress on the activities and impacts of FSMA).

²⁰ Press Release, Ctr. for Food Safety, Center for Food Safety Lawsuit Targets FDA, OMB on Stalled Food Safety Act (Aug. 30, 2012), <http://www.centerforfoodsafety.org/2012/08/30/center-for-food-safety-lawsuit-targets-fda-omb-on-stalled-food-safety-act/>. Upon filing the lawsuit, Charles Margulis, the Food Program Director at Center for Environmental Health, stated, “This unreasonable and dangerous political foot-dragging on FSMA has to stop now. While illness outbreaks continue and Americans question the health and safety of their food supply, FDA issues excuses instead of new regulations. The time is now for modernizing our federal food safety laws.” *Id.* See also *Complaint, Center for Food Safety v. Hamburg* (2012) (CV 12-4529),

Safety, Andrew Kimbrell, expressed the frustration felt, saying “It’s a disgrace that a crucial, lifesaving law sits idle while the bureaucracies of FDA and OMB grind along with a hint of results. The American people shouldn’t have to wait another second for safer food policies that are already law.”²¹

IV. THE FSMA – WHAT IS IT ALL ABOUT?

The FSMA is comprised of three main sections detailing the Act’s purpose and tools available to achieve those aims, which are 1) improving the capacity to prevent food safety problems, 2) improving the capacity to detect and respond to food safety problems, and 3) improving the safety of imported food.²² The FDA has further noted that they will focus efforts on drafting proposals that specifically deal with the five major elements of the law: 1) preventative controls, 2) inspection and compliance, 3) imported food safety, 4) response, and 5) enhanced partnerships.²³

available at <http://www.centerforfoodsafety.org/wp-content/uploads/2012/08/2012-08-29-FSMA-Complaint-FILED.pdf>.

²¹ Ctr. for Food Safety, *supra* note 20.

²² Food Safety Modernization Act, Pub. L. 111-353, 124 Stat. 3885 (2011), *available at* <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.

²³ *FAQ: What are the Major Elements of the Law?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm> (last updated Feb. 1, 2013). The elements are:

“Preventive controls - For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.

Inspection and Compliance- The legislation recognizes that inspection is an important means of holding industry accountable for its responsibility to produce safe food; thus, the law specifies how often FDA should inspect food producers. FDA is committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.

Imported Food Safety- FDA has new tools to ensure that those imported foods meet US standards and are safe for our consumers. For example, for the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.

Response- For the first time, FDA will have mandatory recall authority for all food products. FDA expects that it will only need to invoke this authority infrequently since the food industry largely honors our requests for voluntary recalls.

Enhanced Partnerships- The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies—U.S.

The two rules proposed by the FDA are concerned with the safety standards on produce and preventative controls for human food.²⁴ First, the produce proposal seeks to “establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms,” while the preventative controls proposal would “require a food facility to have and implement preventative controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. . . [while] intend[ing] to prevent or, at a minimum, quickly identify foodborne pathogens before they get into the food supply.”²⁵ The produce proposal seeks to tackle bacterial contamination during the picking and production of fruits and vegetables by legally requiring sanitary procedures and

federal, state, local, territorial, tribal and foreign—to achieve our public health goals. For example, it directs FDA to improve training of state, local, territorial and tribal food safety officials.” *Id.*

²⁴ *Overview of the FSMA Proposed Rules on Produce Safety Standards and Preventative Controls for Human Food*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm334120.htm> (last updated Jan. 8, 2013). Both proposed rules are currently open for comment until May 16, 2013 and docket information is available for public review. See *Fact Sheet on the FSMA Proposed Rule for Produce: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm334114.htm> (last updated Jan. 16, 2013) (stating the text of the proposed produce rule); *Docket for Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921> (providing the full docket for the produce rule); *Fact Sheet on the FSMA Proposed Rule for Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm334115.htm> (last updated Jan. 14, 2013) (stating the text of the proposed preventative controls rule); *Docket for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920> (providing the full docket for the preventative controls rule).

²⁵ *What You Need to Know: Proposed Rule on Standards for Produce Safety Under the FDA Food Safety Modernization Act*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm334554.htm> (last updated Jan. 9, 2013); see also *Docket for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920>.

maintenance.²⁶ The guidelines created include considerations as to how farms should deal with water, worker hygiene, things put into the soil, and worker sanitation during product packaging.²⁷ The preventative controls proposal would additionally require manufacturers of processed food sold in the U.S. to identify and implement measures aimed at reducing food contamination risk, including maintaining plans for correcting any potential outbreak issues that might arise and keeping records for FDA auditing.²⁸

Given the globalization of today's modern day food supply, the FSMA calls for global responsibility and a shifting of responsibility to producers of food to implement proactive measures to prevent food related illness.²⁹ The FSMA holds importers responsible for making certain that their foreign suppliers have taken equivalent preventative care steps as those required of U.S. based producers and processors.³⁰ To ease

²⁶ Stephanie Storm, *FDA Offers Broad New Rules to Fight Food Contamination*, N.Y. TIMES (Jan. 4, 2013), available at <http://www.nytimes.com/2013/01/05/business/fda-offers-rules-to-stop-food-contamination.html?ref=foodanddrugadministration&r=0>.

²⁷ Joe Satran, *FSMA Regulations On Produce, Manufactured Food Finally Released for Public Comment*, HUFFINGTON POST (Jan. 4, 2013), http://www.huffingtonpost.com/2013/01/04/fsma-regulations_n_2410456.html. It is important to note that while the new guidelines can apply to farms of varying sizes, not all farms have to comply with the new guidelines. "[T]he rules only apply to farms that sell produce that is often eaten raw, such as berries or melons. Farms that grow produce that is typically cooked before it's eaten—potatoes, for example, or green beans for canning—are exempt, as are farms that are extremely small." *Id.*

²⁸ Storm, *supra* note 26.

²⁹ See JOSEPH A. LEVITT & STUART M. PAPE, FOOD & DRUG LAW INST., *FDA FOOD SAFETY MODERNIZATION ACT: THE ROAD TO PASSAGE 25* (James William Woodlee ed. 2012), available at <http://www.hoganlovells.com/files/Publication/85853d64-c3f2-4bc7-9fbc-f0e3878675c1/Presentation/PublicationAttachment/751c016a-fe0f-49da-9767-f62cc75b5b98/Hogan%20Lovells%20FDLI%20Article.pdf>.

³⁰ Food Safety Modernization Act, Pub. L. 111-353, §§ 302-303, 124 Stat. 3885, 3955-56 (2011), <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm#SEC303>. For a more in-depth review of the effects of third-party audits on food safety under the FSMA, see David W. K. Acheson, *Third-Party Audits—Their Crucial Role in Moving Forward with FSMA and Food Safety*, FOOD SAFETY NEWS (Nov. 27, 2012), <http://www.foodsafetynews.com/2012/11/third-party-audits-their-crucial-role-in-moving-forward-with-fsma-and-food-safety/#.UQ2D7xzBNpE> (noting that potential third-party auditors could include foreign governments, an agency of a foreign government, any third-party that the Secretary of Health and Human Services deems appropriate, single individuals, and audit agents).

implementation, the FSMA includes the creation of a third-party certification program, independent from the government, that allows producers to secure a stamp of approval from qualified auditors.³¹ Under the law, the FDA, for the first time, will have the authority to mandate companies to withdraw foods that the agency suspects are contaminated, whereas before the FDA could only request companies to withdraw said food.³² This change will allow the FDA to more swiftly contain the effects of a foodborne illness that has manifested itself in the U.S.

V. THE FDA'S NEXT STEPS UNDER THE FSMA

The release of the two proposals has led to a sigh of relief by food safety and consumer advocates that have harshly criticized the FDA along with the Office of Management and Budget for their slow response in issuing the proposals for comment despite specific timelines that were written into the bill.³³ Implementation of any passed regulation, however, may be delayed due to ongoing issues concerning limited government resources.³⁴ The Congressional Budget Office released a report estimating the gross cost for the FDA to administer the new activities as authorized under FSMA at about \$1.4 billion for the years 2011 through 2015.³⁵ That cost would be defrayed by fees the FDA will be able to assess on companies as well as exporters and importers, but the fees would be limited to amounts determined in appropriation acts (meaning any fee collection

³¹ Food Safety Modernization Act, Pub. L. 111-353, §§ 302-303, 124 Stat. 3885, 3955-56 (2011), <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm#SEC303>. The European Union has voiced concern over the third party auditing and verification procedures, believing that the use of independent third party entities, instead of government-only inspections would duplicate controls and not be a fair or pragmatic approach. Dan Flynn, *EU Might Block Parts of Food Safety Modernization Act*, FOOD SAFETY NEWS (July 24, 2012), <http://www.foodsafetynews.com/2012/07/eu-doesnt-like-much-of-food-safety-modernization-act/#.UQ2GLRzBNpE>.

³² Gardiner Harris, *Recalls of Imported Foods Are Flawed, a Government Audit Reports*, N.Y. TIMES (June 21, 2011), available at <http://www.nytimes.com/2011/06/21/business/21recall.html>.

³³ Satran, *supra* note 27.

³⁴ *Id.*

³⁵ U.S. CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE OF FOOD SAFETY MODERNIZATION ACT 4 (Aug. 12, 2010), <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/117xx/doc11794/s510.pdf>.

would be an offset to discretionary spending).³⁶

In the interim, the FDA will be expected to continue researching and drafting proposals that tackle the three remaining major points dealing with imported food safety, response, and enhanced partnerships.³⁷

VI. CONCLUSION

With the passage of the FSMA, the FDA was given new tools in its continued aim toward maintaining consumer safety. Through the use of new powers designed to help deal with the evolution of our current global food chain supply, the United States will be better able to monitor, proactively care for, and manage any foodborne illness issues. Had the FSMA been in effect when half a billion eggs were recalled in 2007 due to a nationwide salmonella scare, the FDA, under its registration suspension authority, would have been able to force egg producers to take their products out of interstate commerce.³⁸ Before the FSMA, the FDA could only request that a producer recall contaminated foods.³⁹ Today, the FSMA gives the FDA the

³⁶ *Id.*

³⁷ Brian Wolfman, *FDA Proposes Food Safety Rules to Implement 2011 Food Safety Modernization Act, With More Rules to Come*, PUB. CITIZEN CONSUMER L. & POL'Y BLOG (Jan. 7, 2013), <http://pubcit.typepad.com/clpblog/2013/01/fda-proposes-new-food-safety-rules-to-implement-2011-food-safety-modernization-act-with-more-rules-t.html> (“Three more rules to implement the 2011 Act are yet to come. . . [1] Foreign Supplier Verification for Importers: This program will require importers to verify that foreign suppliers are following procedures that provide the same level of health protection as that required of domestic food producers. About 15 percent of the food consumed in the U.S. is imported, including about 49 percent of fresh fruit and 21 percent of vegetables. [2] Accredited Third Party Certification: The accreditation of third-party auditors would help ensure that food producers in other countries comply with U.S. food safety laws. [3] Preventive Controls for Animal Food: This is the implementation of preventive controls at animal food facilities that are similar to those proposed for human food”).

³⁸ CNN Wire Staff, *Half a Billion Eggs Have Been Recalled*, CNN HEALTH (Aug. 20, 2010), *available at* <http://www.cnn.com/2010/HEALTH/08/20/eggs.recall.salmonella/index.html>; Alicia Mundy, *Egg Recall Gives Boost to Food Safety Bill*, WALL ST. J (Aug. 23, 2010) (“At the moment—even with salmonella eggs—the FDA can’t force a company to take its products off the market. (If an egg producer violates safety standards, the FDA does have authority to divert shell eggs to a pasteurization process, which egg producers would rather avoid.)”).

³⁹ *New Inspection and Compliance Mandates Under FDA Food Safety*

power to actually order a recall of foods it considers having “a reasonable probability of causing serious adverse consequences or death to humans or animals.”⁴⁰ A company’s refusal to comply with a recall order is subject to an injunction or prosecution.⁴¹ The release of the first two proposals, while delayed, are still a welcome step in providing detailed considerations of what will ultimately be the five overall protection areas that spawned the impetus for congressional action. However, applause will need to be withheld until the FDA is able to show successful implementation of protections afforded under the law.

Modernization Act, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/FSMA/ucm257978.htm> (last updated Feb. 4, 2013).

⁴⁰ *FDA Investigation Summary: Multistate Outbreak of Salmonella Bredeney Infections Linked to Peanut Butter Made By Sunland Inc.*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2013), available at <http://www.fda.gov/food/foodsafety/corenetwork/ucm320413.htm> (illustrating the FDA’s investigation of the salmonella contamination in peanut butter last year and its first use of its registration suspension authority to remedy the outbreak. As a result, the company that produced the contaminated peanut butter “cannot process or distribute food from its peanut butter plant or peanut mill plant. . .until it has complied with the. . .requirements to the agency’s satisfaction. Sunland must receive written authorization from the FDA prior to resuming operations at both its peanut butter and peanut mill plant”).

⁴¹ U.S. FOOD & DRUG ADMIN., *FDA FACTS: FOOD SAFETY ENFORCEMENT* (May 2012), <http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM304672.pdf>.