FOOD SAFETY: THE COSTS OF REGULATING FOOD PRODUCTION IN THE UNITED STATES

NOTE

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ABSTRACT

This Note will focus on the recent wave of legislation in food safety regulation—specifically the Food Safety Modernization Act. By identifying concerns about the costs of such regulation and weighing the actual and potential benefits of food production regulation, this Note demonstrates the value and necessity of regulation, and impact public safety concern has on changing the way food safety enforcement has developed in the market.

INTRODUCTION

The United States has faced a revolution in food production over the past century. A tension exists between 1) the need to regulate food production to keep consumers safe, and 2) the desire to keep food natural and local. In recent years, after an influx of foodborne illness cases, the need for safety and regulation proved stronger. Thus, the last decade has brought a drastic transformation in the way the United States regulates food production to ensure consumer safety.

The major force of the change was the Food Safety Modernization Act (FSMA), signed into law in January 2011. It is known as the most complex food safety legislation since the Food, Drug, and Cosmetic Act of 1938. Through expansion of the FDA's responsibility and authority, the FSMA seeks to modernize food regulations and change the focus to preventing food borne illness—not just reacting to outbreaks. The Act was amended in Fall 2015, to add stricter rules for produce hazard prevention plans, testing, and surveillance.

In this Note, I will analyze whether the costs to small businesses are worth the gains in food safety brought by the newly amended FSMA. In Part I, I will discuss the history of food safety regulation and the FSMA, including the need for its enactment, and the impact it has had thus far. Next, in Part II will follow an analysis of potential gains in food safety and health in the American population brought by the FSMA and other food safety regulation. In Part III, I will

discuss concerns of potential costs to small businesses. Finally, I will explain why the potential benefits of food safety regulation will outweigh the costs.

I. HISTORY OF FOOD SAFETY REGULATION BY THE FDA & THE FMSA

This Note begins by explaining: (A) past efforts in food safety regulation by the federal government; (B) the rise in foodborne illness that created demand for food safety regulation; (C) the proposal for and enactment of the FSMA, its purpose, and what it regulates; and (D) the case that forced the FDA to hammer out final FSMA regulations: *Center for Food Safety v. Hamburg*.

A. FDA Regulation of Food Products Prior to FSMA: 1900-2000

Many people today cannot imagine the conditions of food production that existed in the 1800s. Journalistic reporting of horror stories of poor working conditions and unsanitary food production, like in the book *The Jungle*, by Upton Sinclair, created a public awareness of a need for food safety regulation. For example, here is a passage from *The Jungle* on meat production:

> There was meat that was taken out of pickle and would often be found sour, and they would rub it up with soda to take away the smell, and sell it to be eaten on free-lunch counters; also of all the miracles of chemistry which they performed, giving to any sort of meat, fresh or salted, whole or chopped, any color and any flavor and any odor they chose.[1]

To bring a measure of safety and purity to food production in the United States, Congress enacted the Pure Food and Drugs Act in 1906. This legislation was the first of its kind, and later developed into the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301-399.

B. Rise of Foodborne Illness & Pressures on the FDA to Regulate

The FFDCA did not prevent all errors in food production. The rise of foodborne illness cases in recent years made food safety a hot topic again. The Center for Disease Control and Prevention's (CDC's) 2011 estimates reported that roughly 48 million people are sickened by

[1] Sinclair, Upton. *The Jungle.* New York: Grosset & Dunlap, 1906. Print.

foodborne disease each year.[2] In the 2000s a series of major outbreaks and recalls put food safety back in the spotlight. For example, there were two large salmonella outbreaks—one in 2010, when Wright County Egg recalled over 500 million eggs associated with over 1,500 illnesses, and in 2009, when the Peanut Corporation of America's peanut products were found to be contaminated and associated with 704 illnesses spread throughout 46 different states.[3] These outbreaks increased pressure for better regulation enforcement in tracing systems[4] to identify the source of illness earlier and take preventative measures.

C. Proposal & Enactment of FSMA

The resulting pressure led to the promulgation of the FSMA.[5] Like all legislation, it was not produced overnight, and there was pushback. Congress did agree there was a need for the FSMA, summarizing their findings in the Congressional Report:

> BACKGROUND AND NEED FOR LEGISLATION
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> There is substantial evidence that the nation's food safety system could be improved to better address potential food safety threats. There has been a string of food-borne illness outbreaks in recent years in foods consumed by millions of Americans each day . . .. As numerous reports and congressional hearings have shown, the ability of the [] FDA to oversee the safety of our food supply is compromised by inadequate authorities and insufficient resources.[6]
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> ***Purpose of FSMA***

Thus, increased enforcement authority and resources were key elements of improving food safety regulation through the FMSA. The new legislation's primary focus was "preventing

[2] CDC 2011 Estimates: Findings, Center for Disease Control & Prevention, http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html (last updated Jan. 8, 2014).
[3] Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008-2009 (FINAL UPDATE), CDC Website, http://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html (last updated May 11, 2009).
[4] *See* Colin Mieling, Are You Really Going to Eat That? Product Tracing, the Food Safety Modernization Act, and the Promise of Rfid, U. Ill. J.L. Tech. & Pol'y, Spring 2014, at 251, 252.
[5] 21 U.S.C. § 2201 *et. seq.* (2015).
[6] H.R. REP. No. 111-234 (2009), at 36.

food safety problems before they occur."[7] The idea was to force food facilities to implement preventive safety plans in order to identify potential hazards and take preventative measures.[8]

How is any of this implemented? The legislation provided the Secretary with authority to create standards and requirements of food producers, to do inspections, to create a better tracking system of outbreaks, to create a surveillance and education system, and to enforce penalties for violations.[9] For example, mandatory performance standards for reducing hazards, as set by the Secretary, must be followed by food producers, and are monitored by the FDA.[10]

What FSMA Regulates - Main Components

The FDA's overarching objective of the FSMA is to protect the U.S. food system from farm to production to table. There are seven major areas of the FSMA.[11] In response to the FSMA, the FDA has been developing the seven final rules that serve as the foundation of FSMA regulation and enforcement.[12] Each rule impacts a fundamental area of the U.S. food system. In September and November 2015, the FDA issued the first five final rules: (1) Preventive Controls for Human Food; (2) Preventive Controls for Animal Food; (3) Foreign Supplier Verification Program; (4) Standards for Produce Safety; and (5) Accredited Third-Party Certification.[13]

On April 6, 2016, the FDA officially published the sixth of seven total final rules implementing the FSMA.[14] The sixth final rule on Sanitary Transportation of Human and Animal Food seeks to limit the risk of food contamination during transportation by establishing criteria

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[7] *Id.* at 35–36.
[8] *Id.*
[9] H.R. REP. No. 111-234 (2009).
[10] *Id.*
[11] *See* 21 U.S.C. § 2201 *et. seq.* (2015).
[12] *See* The Food Safety Law and the Rulemaking Process: Putting FSMA to Work, U.S. Food and Drug Administration, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm277706.htm (last updated July 13, 2015) (describing the ongoing process of comprehensive rulemaking, and the comment period opportunity).
[13] *See* Constituent Update: FDA Releases Groundbreaking Rules on Produce and Imported Foods to Modernize and Strengthen Food Safety System, U.S. Food and Drug Administration, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm472505.htm (last updated November 13, 2015).
[14] Federal Register, 21 CFR Parts 1 and 11, Sanitary Transportation of Human and Animal Food; Final Rule, Vol. 81, No. 66, https://www.gpo.gov/fdsys/pkg/FR-2016-04-06/pdf/2016-07330.pdf.

for sanitary transportation.[15] The last area, Focused Mitigation Strategies to Protect Against Intentional Adulteration of Food, is pending and expected to be published later in 2016.[16]

D. *Ctr. for Food Safety v. Hamburg*

There is always pressure for federal agencies to roll out new rules according to new legislation, but rarely are deadlines met because of administrative process burdens in rulemaking. This was so with the FDA's rollout of the new regulations it was supposed to create under the FSMA. A food safety organization became frustrated with the FDA's slow progress, and brought an action against Commissioner pursuant to the Administrative Procedure Act (APA), seeking declaratory and injunctive relief for the FDA's failure to promulgate final regulations by the mandatory deadlines.[17] The parties reached settlement and the court-ordered deadlines by which FDA was originally required to issue final rules were pushed back pursuant to a consent decree.[18]

II. POSITIVES OF FMSA REGULATION

The benefits and necessity of food safety regulation are great in terms of human health and health costs, as can be projected by its motivating events—the recent horrors in foodborne illness cases. The major positive of the FSMA regulations will come if they are effective in their purpose and effective in combating incidents of food borne illness from a preventative approach.

A. Gains in Public Health

The CDC classifies foodborne illness as a public health issue that is "common, costly—yet preventable."[19] The agency states that every single year, 1 in 6 Americans gets sick by consuming contaminated foods or beverages.[20] Why is foodborne illness so common yet labeled

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[15] *Id.*
[16] FDA News Release, FDA releases final rule to ensure food safety during transport, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494125.htm (last updated April 6, 2016).
[17] Center for Food Safety v. Hamburg, 954 F. Supp. 2d 965 (N.D. Cal. Apr. 22, 2013).
[18] Consent Decree, Case No. 12-cv-04529-PJH, http://www.centerforfoodsafety.org/files/2014-2-20-dkt-82-1--joint--consent-decree_26503.pdf.
[19] FOODBORNE GERMS AND ILLNESSES, http://www.cdc.gov/foodsafety/foodborne-germs.html (last visited Mar. 20, 2016).
[20] *Id.*

as preventable? Many different disease-causing microbes, or pathogens, can contaminate foods, so there are many different foodborne infections.[21] There are also many opportunities for food to become contaminated as it is produced and prepared.[22] Additionally, food processing today is more complicated, involves technology, and is centered on efficiency. If the FSMA successfully creates a better tracing system for illnesses, and the preventative procedure standards are followed, the United States will have a healthier population and less cases of foodborne illness.

B. Lowered Heath Care Costs

In a study published in 2011, it was estimated that each year, major known pathogens acquired in the United States caused 9.4 million episodes of foodborne illness, resulting in 55,961 hospitalizations and 1,351 deaths.[23] Beyond what this does to public health, this has a severe impact on health care costs in the United States. If foodborne illness is preventable, so should be the resulting healthcare costs. A 2012 report from members of the U.S. Department of Agriculture's Economic Research Service found foodborne illness among the most common pathogens results in a $77.7 million economic burden in the United States each year.[24] If the FSMA's food safety measures such as tracing are effective, the source of illness or bacteria can be identified earlier, and less people will get sick. The less sick people, and the more who do get sick that receive effective treatment, the less health care costs.

C. More Fruitful Investigations and Preventions in Food Contamination

These gains will not come unless the FSMA does prevent foodborne illnesses earlier on. The FSMA requires the Secretary of Health and Human Services to establish "a product tracing system to receive information that improves the capacity of the Secretary to effectively and

[21] *Id.*
[22] *See* Foodborne Germs and Illnesses, Center for Disease Control, http://www.cdc.gov/foodsafety/foodborne-germs.html (last updated December 21, 2015).
[23] Scallan, Elaine et al. "Foodborne Illness Acquired in the United States—Major Pathogens." *Emerging Infectious Diseases* 17.1 (2011): 7–15. *PMC*. Web. 20 Mar. 2016.
[24] Sandra Hoffmann et al., Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States Due to Foodborne Pathogens, 75 J. of Food Protection 1292 (2012).

rapidly track and trace food . . . ."[25] The FDA designed and conducted product-tracing pilots, with help from the Institute of Food Technologists (IFT), to find the most effective technologies for tracing available.[26] It remains to be seen how effective the implemented systems will be.

III. COSTS OF REGULATION

There has been much commentator criticism of increased regulation of food production from small businesses and farms.[27] Common concerns are: 1) that it will increase their costs; and 2) that it will inhibit investment and marketing success of small food production firms.

A. Costs to Small Businesses and Farms

Overall, the cost of preventing foodborne illness is not small. The FDA estimated that "the baseline estimate for preventing all illnesses associated with microbial contamination of FDA-regulated produce is $1.88 billion."[28] An obvious and major expense of each new FSMA regulation for food industry members is compliance. Part of complying is paying the registration fee,[29] and then other compliance costs follow: sanitation, due diligence of suppliers, staffing compliance functions, etc. High compliance costs make it difficult for small businesses to maintain a profit margin, and make entry more difficult for small start-ups into the industry.

The FSMA requires the FDA to take into consideration the limited resources of smaller-scale farms and food producers, including reduced paperwork and compliance mandates.[30] The FDA has faced these concerns in a couple different ways. For example, compliance dates for the

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[25] FDA Food Safety Modernization Act, § 204(c), 124 Stat. at 3931.
[26] Product Tracing, U.S. Food & Drug Admin., http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm270851.htm (last updated October 6, 2014).
[27] *See, eg.*, Joella Roland, The Hang-Up with Hamburg: How Center for Food Safety v. Hamburg Will Alter the Food Industry, 9 J. Bus. & Tech. L. 357, 370 (2014).
[28] Analysis of Economic Impacts - Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, Food and Drug Administration, 51, http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf.
[29] 21 U.S.C.A. § 379j (2012).
[30] Food Safety Modernization Act, PL 111-353, January 4, 2011, 124 Stat 3885.

final rule on transportation are different for small businesses, include some exemptions and waivers, and adhere to the following scheme:

> Small Businesses: businesses other than motor carriers that are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than $27.5 million in annual receipts will have to comply two years after the publication of the final rule.

The FDA is also empowered to waive the requirements of the final rules on transportation, in certain circumstances, such as if it determines that the waiver will not result in conditions that would be unsafe for human or animal health.[31] The FDA has already announced that it intends to publish waivers for food establishments such as restaurants, supermarkets, and home grocer delivery operations holding valid permits issued by a regulatory authority.[32]

The regulations on Preventive Controls for Human Food also have embedded exceptions for small businesses. The first is the Tester-Hagan Amendment, which gives a variance from the minimum standards for the safe production and harvesting requirements to farms that fall within the FDA definition of a small business that harvest low risk produce, and those that are engaged in direct-farm marketing.[33] Small to very small businesses get more time for compliance, and farms that engage in direct-farm marketing get a complete exemption from the standard.[34] Small businesses have flexibility in having to perform hazard analysis and risk-based preventative controls as well, and again, very small businesses get a complete exemption.[35]

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[31] Sanitary Transportation of Human and Animal Food, 81 FR 20092-01.
[32] Sanitary Transportation of Human and Animal Food, 81 Fed. Reg. 20106 (April 6, 2016) (to be codified at 21 C.F.R. pt. 1 and 11).
[33] 21 U.S.C. § 350h (2011).
[34] *Id.*
[35] 21 U.S.C. § 350g (2012); Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3998.

However, once the rules do apply to small business, the costs of implementing and complying, especially with tracking systems, could still be high and burdensome. The IFT final report analyzing the pilot tracing programs included stakeholder comments and concerns in moving forward. Many stakeholders expressed concern for small businesses. IFT was "urged to evaluate appropriate low-cost product tracing solutions for those participating in local and regional sectors of the food production supply chain, and to assess the compliance costs of all product tracing platforms based on the size of the producer."[36] A major concern was that small-scale farmers and food businesses are not financially able to bear the costs of oversight functions like large businesses. It was argued that large businesses already have staff dedicated to handling regulatory functions, and the budget to invest in electronic monitoring equipment.[37] A small business may have a hard tome staffing someone simply in a "compliance" role.

Stakeholders argued that any "unreasonable mandates" could quickly put small business or farmers out of business.[38] Input was offered that the product tracing solutions that would be effective for large-scale, highly-capitalized supply chains would also be inefficient to apply to the smaller producers due to limited cost/benefit effectiveness in terms of protecting public health.[39] One example of this was explained: small groups who do not subscribe to electronic systems could be completely shut out of business, like the Amish.[40] Is it fair to require that they use new tracing systems? The FDA has responded to many concerns already.[41] It remains to be seen the actual effects of the regulations practice, but it is likely more adjustments will come.

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[36] Jennifer McEntire & Tejas Bhatt, Inst. Food Technologists, Pilot Projects for Improving Product Tracing Along the Food Supply System - Final Report 48 (2012), available at http:// www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf.
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *See* FSMA Final Rule for Preventive Controls for Human Food, Food and Drug Administration, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm (last updated Jan. 22, 2016*)* (explaining that

IV. THE TRADE-OFF: IS WORTH IT?

The question is this: are the benefits in public heath and health care costs of FSMA regulations worth the costs of compliance and burden on small businesses? It is my opinion that the answer must be yes. If FSMA regulation enforcement is carried out correctly, costs should be minimized. The FDA considered all stakeholder concerns and costs when implementing the program, as evidenced in the many regulatory hearings and comments over the past ten years.[42]

Recent outbreaks like the 2015 Chipotle *Salmonella*, *E-coli* and *Norovirus* illnesses bring the question into perspective.[43] Restaurants and food producers need incentives to prevent contamination. If left without incentives, it is natural for businesses to just be reactive. In addition to public health benefits, the economic benefits are projected to exceed the costs. The FDA projected, "we estimate a potential annual cost savings of approximately $5.34 billion dollars if all illnesses attributable to FDA-regulated foods were eliminated."[44]

V. CONCLUSION

Food safety regulation has made great bounds in the last decade and will evolve significantly over the next. There will always be a tension between freedom to produce food in a manner chosen by the producer, and the need for food safety regulation. However, food safety is coming to the forefront, and will likely be increasingly important.

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revisions were made to the rule proposals in response to input received during the comment period, designed to make the originally proposed rule more practical, flexible, and effective for industry.)

[42] *See* The Food Safety Law and the Rulemaking Process, *supra* note 12.

[43] Zuraw, Lynda. *A Timeline of Chipotle's Five Outbreaks*. Food Safety News. December 15, 2015, http://www.foodsafetynews.com/2015/12/a-timeline-of-chipotles-five-outbreaks/#.VwxnOmM0yLs.

[44] Analysis of Economic Impacts, *supra* note 28 at 387.