THE FOOD SAFETY MODERNIZATION ACT: ASSESSING INSPECTION AND COMPLIANCE PROVISIONS

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The Food Safety Modernization Act: Assessing Inspection and Compliance Provisions

Has the provision on inspection and compliance of the Food Safety Modernization Act improved food safety in the United States?

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"A statute without its implementing regulations is an empty vessel" [1]

[1] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human* [2018] United States District Court for the Northern District of California

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I will never forget this great opportunity of writing my master thesis with my own made-up topic. After some challenging and interesting six months, I am proud of the outcomes of this thesis.

Thea Meijer
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Abstract

This thesis investigated whether the provisions on inspection and compliance of the Food Safety Modernization Act (FSMA) improved the food safety in the U.S., using a doctrinal method and an interview. In order to enhance the food safety system, FSMA introduced provisions on inspection and compliance, including mandatory inspection frequency based on risk, access to record, testing by accredited laboratories and establishes whistleblower protection for employees. However, after several years of the adoption of FSMA, foodborne illness numbers are not decreased and hence, food safety has not been improved. Being responsible for 80 percent of the nation's food supply and the implementation of these provisions, Food and Drug Administration (FDA) received a lot of criticism, with even a lawsuit filed against them for not doing enough to prevent foodborne illnesses. Nonetheless, one may wonder if FDA should get the blame for these foodborne illness numbers, as their circumstances are not optimal for a proper implementation of the provisions. Therefore, as provisions are still in the implementation phase, it is too early to draw any final conclusions on the improvement of food safety by these specific provisions.

Key words: Food Safety Modernization Act, Inspection and Compliance, food safety

Summary

Background: The Food Safety Modernization Act (FSMA) was signed into law by President B. Obama in January 2011 to enhance the food safety system. One of the five key elements of this Act is the provisions on inspection and compliance. The research question of this thesis was: *Has the provision on inspection and compliance of the Food Safety Modernization Act improved food safety in the United States?* Methods: In this legal doctrinal methodology study, legal sources and U.S. statutes were used to comprehend what provisions on inspection and compliance FSMA include and if these provisions improved food safety in the U.S. Additionally, an interview with a staff attorney of non-profit organization Center for Food Safety (CFS) was performed. Results: After some eye-opening high-profile incidents, the dramatic saga of the adoption of FSMA succeeded. Enabling the FDA to respond effectively to food safety problems, FSMA gave the Food and Drug Administration (FDA) authority for increased mandatory inspection frequency based on risk, access to record and testing by accredited laboratories and establishes whistleblower protection for employees. Several years after the adoption of FSMA, some of these provisions have failed to meet the implementation deadlines, resulting in some criticism around the FDA. Data shows that even though the foodborne illness outbreaks have decreased after the adoption of FSMA, the total number of illnesses has increased. Recently, CFS filed a lawsuit against FDA for not doing enough to prevent those foodborne illnesses. Conclusion: One may wonder if FDA should get the blame for these foodborne illness numbers, as their circumstances are not optimal for properly implementing the provisions. Meeting all deadlines set by the FDA, and the fact that the industry knows that they are going to be inspected, is hopefully enough to force the industry to adjust how they are operating and finally reduce foodborne illnesses. However, as provisions are still in the implementation phase, it is too early to draw any final conclusions on the improvement of food safety by these specific provisions.

Contents

Abbreviation List

cGMPs	Current Good Manufacturing Practices
DHS	United States Department of Homeland Security
FDA	Food and Drug Administration
FSMA	Food Safety Modernization Act
FY	Fiscal Year
CDC	Centers for Disease Control and Prevention
CFS	Center for Food Safety
CSPI	The Center for Science in the Public Interest
HACCP	Hazard Analysis and Critical Control Points
HHS	United States Department of Health and Human Services
U.S.C.	United States Constitution
U.S.	United States
APA	Administrative Procedure Act
OAI	Official Action Indicated
OSHA	Occupational Health & Safety Administration
VAI	Voluntary Action Indicated
NAI	No Action Indicated

Part I:

Setting the Stage

Chapter 1 – Introduction

The Food Safety Modernization Act (FSMA) was signed into law in 2011 to improve the food safety system in the United States (U.S.), including provisions on inspections and compliance. Will these provisions be effective in improving the food safety in the U.S.? In this introduction, an overview of the context and motivation behind the research will be given, as well as an outline of the overall structure of the thesis.

1.1 Background

"There are certain things only a government can do. And one of those things is ensuring the foods we eat are safe and do not cause us harm".[2]

This statement of President B. Obama in March 2009 reflects the mission of the Food and Drug Administration (FDA) in the U.S., the federal agency responsible for 80 percent of the safety of nation's food supply[3] and for protecting public health in the U.S.[4]

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[2] The White House: Office of the Press Secretary, 'Weekly Address: President Barack Obama Announces Key FDA Appointments and Tougher Food Safety
Measures' (Speech Obama White House Regarding Safety of the Nation's Food, 2014) <https://obamawhitehouse.archives.gov/the-press-office/weekly-address-president-barack-obama-announces-key-fda-appointments-and-tougher-fo> accessed 14 September 2018

[3] D. M. Strauss, 'An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business' (2011) 66 Food and Drug Law Journal p. 353, p. 354
N. Hassanein, 'Matters of Scale and the Politics of the Food Safety Modernization Act' (2011) Springer p. 577, p. 578

[4] U.S. Food & Drug Administration, 'About FDA: What We Do' (2018) <https://www.fda.gov/aboutfda/whatwedo/default.htm> accessed 3 September 2018

Food safety had been of people's concern from the beginning of civilization.[5] Nonetheless, the Centers for Disease Control and Prevention (CDC), the nation's health protection agency, estimates that each year about 48 million people (1 in 6) get ill from foodborne diseases, resulting in 128,000 people being hospitalized and 3,000 people dying in the U.S. [6]

Six major outbreaks of foodborne illnesses between 2006 and 2011 in the U.S. resulted in fourteen deaths.[7] To lower foodborne illness outbreaks, ensure safe and harmless food, reduce expensive domestic costs associated with foodborne illness outbreaks and challenge regulatory bodies, the FDA Food Safety Modernization Act (FSMA) was adopted. [8] President Obama signed this much-needed Act into law in January 2011 to improve protection of public health by strengthening the food safety system. With an expectation of having a dramatic and positive effect on the safety of the nation's food supply[9], FSMA was the first major reform in over 70 years.[10]

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[5] N.D. Fortin, '*Introduction to the Food Regulation in the United States*' (Food Regulation: Law, Science, Policy, and Practice, Michigan State 2016), p. 3

[6] U.S. Food & Drug Administration, 'Background on the FDA Food Safety Modernization Act, <https://www.fda.gov/food/guidanceregulation/fsma/ucm239907.htm> accessed 4 September 2018

[7] J. Ronald, 'The Hang-up with Hamburg: How Center for Food Safety v. Hamburg Will Alter the Food Industry' (2014) 9 Journal of Business & Technology Law, p. 357, p. 357

[8] C. Belden and D. Orden, 'Review of the FDA FSMA: What it means, where it is headed and why it matters' (2011) <http://www.gii.ncr.vt.edu/docs/gii_wp2011-3.pdf> accessed 4 November 2018

[9] M.A. Hamburg, 'Food Safety Modernization Act: Putting the Focus on Prevention' (Blog at the White House President Barack Obama, 2011) <https://obamawhitehouse.archives.gov/blog/2011/01/03/food-safety-modernization-act-putting-focus-prevention> accessed 14 September 2018

[10] S. Kennedy and K.M. Errecaborde, 'General Overview of the Food Safety Modernization Act' (Issue Brief Food Policy Research Centre October 2014) <https://conservancy.umn.edu/bitstream/handle/11299/170088/FPRC%20Issue%20Brief%20Food> accessed 18 September 2018

Although having positive expectations, foodborne illness outbreaks still occurred after the adoption of FSMA. Recently, just before Thanksgiving, there was a multistate romaine lettuce incident, whereas the CDC advised consumers, restaurants and retailers not to eat, serve or sell any romaine lettuce as it investigated an outbreak of *E. coli*. Additional to this high-profile romaine lettuce incident, 23 other multistate foodborne illness outbreaks occurred in 2018, including outbreaks in meat, poultry, various vegetables, various (dried) fruit and cereal.[11]

1.2 Relevance

With a population of over 328 million inhabitants, the U.S. is the third-most populous country in the world.[12] Although people are encouraged to consume food products close to where they live, the reality is that an enormous amount of food is shipped all over the world. Fresh products of all types are available year-round, sourcing of the ingredients used in many processed foods is a multinational effort, and foods which are shipped from farm to retailer located in different locations are commingled.[13] Meanwhile, Americans are consuming more and more of these convenience foods. It used to be that one single fresh product was prepared and consumed by one household, while nowadays products are mixed in a convenience food together with many other fresh ingredients, such as prepared salad.[14] Commingling several single ingredients can mean that contamination from one location could easily spread to many,

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[11] Centers for Disease Control and Prevention, 'List of Selected Multistate Foodborne Outbreak Investigations' <https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html> accessed 14 January 2019

[12] United States Census Bureau, 'U.S. Census Bureau Current Population' (Population Clock of U.S., 2018) <https://www.census.gov/popclock/print.php?component=counter> accessed 21 September 2018

[13] M. Olewnik, 'FSMA: Regulating Prevention, Detection and Response, and Imported Foods' (2012) 57 Cereal Foods World, p. 111, p.111

[14] R. B. Wallac and M. Oria, '*Enhancing Food Safety: The Role of the Food and Drug Administration'* (The National Academies of Science, Washington 2010) p. 518

resulting in hundreds of foodborne illnesses.[15] Furthermore, the average age of Americans is expected to increase during the years. In 1980, 15 percent of the population was 60 years or older, while it is expected that this number will increase to 25 percent by 2025. Older consumers are among those at highest risk for foodborne illnesses: small food incidents could lead to major foodborne illness outbreaks, resulting in a growth of foodborne illness numbers. [16]

In an attempt to decrease foodborne illness outbreaks and improving the food safety system, FSMA contains five key elements: preventive controls, inspection and compliance, imported food safety, response and enhanced partnerships. Each of these elements provides FDA with new powers and responsibilities to develop specific scientific standards, to provide oversight to increase conformity, to act effectively when problems emerge and to build collaboration with other local, state and foreign government agencies in order to carry out an integrated approach to food safety.[17]

Every key element establishes its own provisions, with the provisions on the element inspection and compliance including increased mandatory inspection frequency of facilities based on classifications of the level of risk by individual facilities (21 U.S.C. §350j) access to records (21 U.S.C. §350c(a)), testing by accredited laboratories (21 U.S.C. §350k) and protection of whistle-blowers (21 U.S.C. §399d). Whether these specific provisions improve food safety and prevent the public from foodborne illness outbreaks remains debatable and is worth researching in this thesis.

[15] M. Olewnik *supra* note 13, p.111

[16] R. B. Wallac and M. Oria *supra* note 14, p. 518

[17] D. M. Strauss *supra* note 3, p. 358

1.3 Research question

For the purpose of guiding this assessment, a research question and a set of sub-questions have been formulated.

Research question:

Has the provision on inspection and compliance of the Food Safety Modernization Act improved food safety in the United States?

Sub-questions:

- What was the goal of the Food Safety Modernization Act and how were the provisions of the Act adopted?
- What changes did the Food Safety Modernization Act introduce in the law?
- How has the provision on inspection and compliance of the Food Safety Modernization Act been implemented?
- What has been the effect of the Food Safety Modernization Act on the role/ responsibilities of the Food and Drug Administration, especially regarding the key provision inspection and compliance?
- What has been the impact of the Food Safety Modernization Act on the prevention of food borne illnesses?

1.4 Methodology

This legal doctrinal methodology study was performed involving source-based research on U.S. statutes and legal sources to comprehend what the provisions on inspection and compliance of the Food Safety Modernization Act include and if these provisions improved food safety in the U.S. Not only legal sources but also many secondary sources, such as official guidance to laws, journal articles, case law, legal textbooks, articles from newspapers and magazines, and a lot of information from the U.S. government were used during this study (see Reference List). Taking into account the dynamic nature of legislation, the ongoing amendments, and the ongoing case law, the date of access to the (legal) databases indicated in the reference list (from September 2018 to February

2019) is to be considered as the last date of access for each particular (legislative) document. Literature research during this thesis ended on 13 February 2019.

Additional to the literature study, an interview took place. When conducting the research, there has been reached out for interviews to several stakeholders, like the FDA, Center for Food Safety, Center for Science in Public Interest, Congressional Research Service and food safety experts. Unfortunately, not all stakeholders replied. Nonetheless, in December, there has been e-mail contact with the Congressional Research Service about FDA's budget, and on the 7th of December, an interview took place with a staff attorney for Center for Food Safety – Ryan Talbott – who is working on numerous cases among the law case against the FDA (see Reference List).

1.5 Thesis structure

The thesis has been structured in five parts. Part 1 sets the stage of this research, consisting of this introduction where the research is introduced and motivated. In the second part, the background of the Food Safety Modernization Act is covered, including chapter 2 and 3. Chapter 2 describes the adoption and goal of the act, and chapter 3 covers the changes regarding the provisions on inspection and compliance. Part 3 can be divided in chapter 4, describing the implementation phase of the act; chapter 5, describing FDA's role and responsibilities; and chapter 6 discussing the impact of the provisions on inspection and compliance on the foodborne illnesses. Part 4 includes proposed changes in order to enhance the food system. Finally, part 5 includes the answers on the sub questions and the final conclusion.

Part II:

Background of the Food Safety Modernization Act and its Changes Compared to Previous Amendments

Chapter 2 - The Food Safety Modernization Act: Adoption and Goal

To strengthen the food safety system, the Food Safety Modernization Act was signed into law by President Obama in 2011. However, it took some eye-opening incidents before the need of this enhanced food safety system became clear and even after that, the adoption process of the Act was not flawless. In order to get some general background information for answering the research question, the first sub question about the goal and adoption of the FSMA will be answered in this chapter.

2.1 History of food regulation in the United States

Regulation of food in the U.S. dates back to the 19th Century, whereas early food laws were nearly all state and local regulations, with federal activity limited to imported foods. Consequently, the then existing regulatory system on food safety came under pressure because of the disparity between different state laws. Nonetheless, it took Congress until 1906 to adopt the Pure Food and Drug Act and the Meat Inspection Act. Adoption of these two statutes began the modern era of the U.S. food regulation, mainly preventing adulteration and misbranding. However, the Pure Food and Drug Act was not adequate with legislative battles occurring about false claims and a lack in stringer product quality standards for the industry.

Replying to these problems, the Food, Drug and Cosmetic (FD&C) Act was enacted in 1938. While the FDA was previously only a reactive agency, acting on violations when they already had occurred, the new Act granted proactive administrative as well as (limited) regulatory powers, including: i. establishment of legally binding definitions and standards of identity of foods; ii. establishment of tolerances for unavoidable poisonous substances; iii.

prescribe standards of fill containers; iv. court injunctions; and v. factory inspections. With the implementation of the Act, the FDA was officially established as part of the U.S. Department of Health and Human Services (HHS)[18], being responsible for about 80 percent of the nation's food supply. [19]

Although its new authority powers, the FDA struggled in the 1990's not having the resources to assess and monitor the safety of all different dietary supplements. During the 1990's Republicans acquired a majority of seats in the 104th Congress allowing for a new wave of deregulation (1995-1997).[20] They used their legislative power to limit the rulemaking by federal administration for the benefit of business, hindering the FDA in its oversight. The outbreak of *E. coli* in a fast food chain named 'Jack in the Box' in 1993[21] triggered new regulatory initiatives, where the inspections by Food Safety and Inspection Service (FSIS), the public health agency in the USDA[22], proved insufficient to prevent the outbreak of foodborne illnesses. To reduce pathogens risks, a new science based strategy was developed and implemented by the USDA in 1995: Hazard Analysis and Critical Control Points (HACCP) principles. In 1997, FDA followed by effectively mandating the implementation of HACCP principles for processing fish and seafood. In 1998, FDA proposed to apply the HACCP for the production and imports of fruit and vegetables juices, which took until 2001 to adopt. Nonetheless, major food borne illness outbreaks continued to occur:

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[18] N. Meijer, N. Tilkin-Franssens and B. van der Meulen, 'Eleven Decades of US American Federal Food Law' (2015) 6 European Food and Feed Law Review, p. 433, p. 433-437

[19] D. M. Strauss *supra* note 3, p. 353, 354

[20] N. Meijer, N. Tilkin-Franssens and B. van der Meulen, *supra* note 18

History, Art & Archives United States House of Representatives, 'Party Divisions of the House of Representatives, 1789 to Present' (n.d.) <https://history.house.gov/Institution/Party-Divisions/Party-Divisions/> accessed 10 February 2019

[21] "', 'Company News: Jack in the Box' Worst Nightmare' The New York Times (6 February 1993) <https://www.nytimes.com/1993/02/06/business/company-news-jack-in-the-box-s-worst-nightmare.html> accessed 26 January 2019

[22] United States Department of Agriculture, 'Food Safety and Inspection Service' (PowerPoint presentation, 2014) <https://www.fsis.usda.gov/wps/wcm/connect/7a35776b-4717-43b5-b0ce-aeec64489fbd/mission-book.pdf?MOD=AJPERES> accessed 3 January 2019

the FD&C Act was no longer effective. A major overhaul in the regulatory system on food safety was needed, since the old system needed reform.[23]

2.2 Adoption of the inspection and compliance provisions of the Food Safety Modernization Act

After more than 20 years of pushing for a reform for food safety legislation by consumer advocates, including members of Congress, the FSMA was enacted. After some eye-opening high-profile incidents, including the outbreak of *E. coli* in spinach and the recalls of peanut butter and eggs and many others, the perception of a food safety problem was awakened. Consumer groups, industry, and the FDA worked together to develop policy white papers on what legislative reform was needed.[24]

In 2007, a series of Congressional hearings took place raising several issues suggesting a new legislation on food safety. It became clear that the FDA had been working over capacity, under-resourced and had an inadequate authority to response to an increasingly complex and globalized food system. [25] Hence, it appeared that the House of Representatives would pass a legislation to provide FDA authority for mandatory recalls and broader powers to investigate food contamination situations more thoroughly by expanding the authority to obtain information from food facilities.[26]

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[23] N. Meijer, N. Tilkin-Franssens and B. van der Meulen *supra* note 18, p. 437-439

R. Talbott, 'the Food Safety Modernization Act', (Interview, 2018)

N.D. Fortin *supra* note 5, p. 5-6

[24] M.T. Oldfield, 'Enactment of the Food Safety Modernization Act' (2015) 6 European Journal of Risk Regulation, p. 488, p. 495

[25] M.T. Oldfield *supra* note 24, p. 495-496

[26] M.D. Flanagan, ' Congressional Hearing on FDA's Ability to Safeguard the Nation's Food Supply' (2007) <https://www.foley.com/congressional-hearing-on-fdas-ability-to-safeguard-the-nations-food-supply-05-09-2007/> accessed 10 October

U.S. Government Printing Office, 'Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?' (2007) <https://www.gpo.gov/fdsys/pkg/CHRG-110hhrg45731/html/CHRG-110hhrg45731-ptb.htm> accessed 9 October 2018

Shortly after, the administration of President George W. Bush issued several reports and studies calling for major changes such as in the FDA's *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply,* and the Interagency Working Group on Import Safety's *Action Plan for Import Safety: A Roadmap for Continual Improvement*[27]*,* part of which dealt extensively with food product reports generally called for a more preventive risk-based approach to food safety oversight, including more attention to imported foods, among numerous other recommendations.[28] Both plans gave recommendations for improving the food safety system in the U.S. based on three elements of protection: i. prevent foodborne contamination; ii. intervene at critical points in the food supply chain; and iii. respond rapidly to minimize harm.

One of the key intervention steps of FDA's *Food Protection Plan* was to focus on inspections and sampling based on risk. According to FDA's plan, additional legislative authority was needed to authorize FDA to accredit highly qualified third parties for food inspections and require new reinspection fee from facilities that fail to meet current Good Manufacturing Practices (cGMPs) or other FDA requirements. It highlighted the need to know the science on how and where the food might be contaminated in the process and the associated risks with it. Additionally, it emphasized the use of science to determine optimal interventions to reduce the likelihood of contamination. If contamination does occur, the priority is to minimize the likelihood that it will cause significant harm.[29]

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[27] Interagency Working Group on Import Food Safety, 'Action Plan for Import Safety: A Roadmap for Continual Improvement' (Report to the President, 2007) <http://www.itagc.org/docs/ITAGC-2010-11-10-FDA-4.pdf> accessed 10 October 2018

[28] R. Johnson, 'The FDA Food Safety Modernization Act' (CRS report for Congress, 2011) <http://nationalaglawcenter.org/wp-content/uploads/assets/crs/R40443.pdf> accessed 7 October 2018

[29] Secretary of Health and Human Service, 'Food Protection Plan: An integrated strategy for protecting the nation's food supply', report, (2007),

In the build-up to the election of a new Congress and President in 2008, Obama's overarching campaign theme was the need for change.[30] Some of his promises during this campaign were improving health care, ending the practice of writing legislation behind closed doors, and double the U.S. experts of the next five years (2013-2017). However, none of the promises at first included a change in food safety system as recommended by the administration of President George W. Bush.[31]

On June 9 2009, the first version of the law, the Food Safety Enhancement Act (H.R.2749), passed the House of Representatives.[32] Nonetheless, it did not gain approval in the Senate largely due the raising concerns of small farmers and producers that the new regulations would be too costly and to unmanageable for their businesses. Responding to their concerns, the Senate adjusted the bill (S.510) by an amendment of Senator Jon Tester (Tester-Hagan amendment)[33] and other changes that were satisfying most food safety advocates, resulting in bringing to life the Food Safety Modernization Act. Although many consumer and industry groups preferred the original version of the House of

<https://www.fda.gov/downloads/aboutfda/centeroffices/oc/officeofoperations/ucm121761.pdf> accessed 8 October 2018

[30] Institute for Social Research University of Michigan, 'The 2008 Election: Campaign Themes, Strategies, and Developments' (n.d.), <https://www.icpsr.umich.edu/icpsrweb/instructors/setups2008/campaign-strategies.jsp> accessed 3 October 2018.

[31] K. Soffen, 'After 8 Years, Here Are the Promises Obama Kept – and the Ones He Didn't' The Washington Post (January 23 2017) <https://www.washingtonpost.com/graphics/politics/obama-promises/> accessed 5 October 2018

[32] 111th Congress, 'H.R.2749 – Food Safety Enhancement Act of 2009' (2009-2010) < https://www.congress.gov/bill/111th-congress/house-bill/2749/text?q=%7B%22search%22%3A%5B%22HR2749%22%5D%7D&r=5&s=2> accessed 11 February 2019

[33] 111th Congress, 'S.510 – FDA Food Safety Modernization Act' (2009-2010) < https://www.congress.gov/bill/111th-congress/senate-bill/510?q=%7B%22search%22%3A%5B%22S510%22%5D%7D&s=1&r=5> accessed 11 February 2019

Representatives (H.R.2749), because it included more money for inspections and fewer expectations, most still supported the Senate bill (S.510) as it was better than no new food safety law: they all agreed that an overhaul of the food safety system was needed. [34]

On 30 November 2010, the bill (S.510) was passed by Senate by a vote of 73 yeas against 25 nays, with strong bipartisan support.[35] However, this effort was voided and the Senate votes did not count. It was revealed that the bill S.510 included several revenue-raising measures that had to originate from the House of Representatives, as it is a constitutional requirement stated in the Constitution of the U.S., article I, section 7. [36] After amending the bill again, Senator Reid brought the bill (H.R.2751) for unanimous voice voting meaning the bill was adopted with no objection from the senators.[37] The House of Representatives election in the end of November 2010 could switch control of the House of Representatives to the republicans arising the possibility that if

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[34] D. M. Strauss *supra* note 3, p. 355-358

[35] United States Senate, 'Roll Call Votes 111th Congress – 2nd Session', (n.d.) https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=111 0&session=2&vote=00257 accessed 8 October 2010

GovTrack, 'S510 (111th): FDA Food Safety Modernization Act', (n.d.) https://www.govtrack.us/congress/bills/111/s510/text/es accessed 9 October 2018

[36] D. M. Strauss *supra* note 3, p. 356

H. Bottemiller 'Constitutional Slip Up Adds Uncertainty to S.510' Food Safety News (2 December 2010) https://www.foodsafetynews.com/2010/12/future-of-s510-uncertain-due-to-constitutional-slip-up/ accessed 10 February 2019

J.V. Saturno 'The origination Clause of the U.S. Consititution: Interpretation and Enforcement' (CRS Report for Congress, p. 2, 2011) < https://fas.org/sgp/crs/misc/RL31399.pdf> accessed 10 February 2019

111th Congress, 'H.R. 2751 – FDA Food Safety Modernization Act 111th Congress (2009-2010)' (2009-2010) <https://www.congress.gov/bill/111th-congress/house-bill/2751> accessed 9 October 2018.

United States Constitution 1787

[37] U.S. House of Representatives Committee on Rules Majority Office, 'Voting in the House of Representatives' (n.d.) < https://archives-democrats-rules.house.gov/archives/voting_house.htm> accessed 11 February 2019

the legislation was not passed under the 111th Congress, it would never pass. With time running out, and concerns of the survival of the bill, the Senate passed the amended bill by unanimous consent by a voice vote in December.[38] Shortly after, the House of Representatives followed by passing the food safety bill by a vote of 215 yeas and 144 nays.[39] On 4 January 2011, President Barack Obama signed the bill into public law,[40] hoping to enhance the food safety system.

2.3 The Food Safety Modernization Act's Goal

The adoption of the FSMA marked a historic revolution in U.S. food safety laws[41], amending the Federal Food, Drug and Cosmetic Act with respect to the safety of the food supply[42] and enabling FDA to better protect public health by strengthening the food safety system. It shifts the food safety system from preventing food safety problems rather than relying on reacting to problems after they occur with the objective to protect consumers from unsafe food.[43] FSMA expands FDA powers to reach the final goal of the act: strengthening the food safety system. [44]

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[38] M. Shiner, 'Senate Oks food safety measure' Politico (19 December 2010) https://www.politico.com/story/2010/12/senate-oks-food-safety-measure-046598 accessed 6 October 2019

[39] 111th Congress, *supra* note 36

[40] 111th Congress *supra* note 36

[41] S. Gunawardhana and J.N. Czaban, 'What FSMA Really Tells Us about the Focus of Food Safety' FoodSafety Magazine (June/July 2013) <https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2013/what-fsma-really-tells-us-about-the-focus-of-food-safety/> accessed 10 November 2018

[42] Food Safety Modernization Act 2011, section 1

[43] *In Re Breast Cancer Prevention Partners et al.* v *United States Food and Drug Administration and Scott Gottlieb* [2018] United States Court of Appeals for the Ninth Circuit

[44] US Food and Drug Administration, *supra* note 6

A. Kheradia and K. Warriner, 'Understanding the Food Safety Modernization Act and the role of quality practitioners in the management of food safety and quality systems' (2013) 25 The TQM Journal p. 347, p. 347

D. M. Strauss *supra* note 3, p. 358

Chapter 3 - Changes on the Provision Inspection and Compliance of The Food Safety Modernization Act

The FSMA can be divided into five key elements with one of these key elements being inspection and compliance. Several provisions on inspection and compliance were established including i. increased mandatory inspection frequency of facilities based on classifications of the level of risk by individual facilities (21 U.S.C. §350j); ii. access to records (21 U.S.C. §350c(a)); iii. testing by accredited laboratories (21 U.S.C. §350k); and iv. protection of whistle-blowers (21 U.S.C. §399d).[45] More detailed information about the adoption of inspection and compliance provisions are described in this chapter, answering the second sub questions regarding the key changes on inspection and compliance.

3.1 The five key provisions established by the Food Safety Modernization Act

FSMA requires the FDA to implement many rules and regulations on various effective dates and implementation schedules. FSMA consists of five key elements: i. preventive controls; ii. inspection and compliance; iii. response; iv. imported food safety; and v. enhanced partnership. All key elements include changes in FDA's role and authorities (see Background – the five key elements established by the Food Safety Modernization Act). [46]

One of the major changes of FSMA is the given authority to the FDA to mandate recalls during an FDA inspection, given more power in case of a violation. This change is included in the provisions of the key element response (iii) and in consonance with the provisions on inspection and compliance (ii) (see Background: Five Key Elements Established by the Food Safety Modernization

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[45] N. Obolensky, 'The Food Safety Modernization Act of 2011: too little, too broad, too bad' (2012). 17 Roger Williams University Law Review p. 887, p. 891

[46] S. Gunawardhana and J.N. Czaban, 'What FSMA Really Tells Us about the Focus of Food Safety' FoodSafety Magazine (June/July 2013) <https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2013/what-fsma-really-tells-us-about-the-focus-of-food-safety/> accessed 10 November 2018

Act). Before the adoption of FSMA, the FDA could only request a recall of a facility or had to pursue a court order to mandate one. Hence, violations during FDA inspections had to be focused on building a court case and could not always be performed immediately. Under the FSMA, the FDA can threaten facilities to withdraw batches of products in order to secure compliance with the law.[47] This new authority to the FDA to mandate recalls is an important provision for during an FDA inspection, giving more power in case of a violation. Specific provisions on the key element inspection and compliance are described below (section 3.2).

BACKGROUND: FIVE KEY ELEMENTS ESTABLISHED BY THE FOOD SAFETY MODERNIZATION ACT

1. Preventive controls - FSMA convey the FDA role from reactive to more preventative by requiring the FDA to mandate comprehensive, prevention-based controls across the food supply and providing new authority to prevent intentional contamination.
2. Inspection and compliance - FSMA grants the FDA more authority for inspection and compliance through mandated inspections with its frequencies based on the level of risk.
3. Response - FSMA grants the FDA the possibility for mandatory recall, enabling to react promptly on problems when they emerge.
4. Imported food safety - FSMA provides the FDA with 'unprecedented authority' to regulated imported food, and imposes preventative duties on the industry since a significant part of the US food supply is imported. FDA has provided the ability to help ensure that food imports meet US food safety standards.
5. Enhanced partnerships - FDA will enhance partnerships with other food agencies and private entities and improve the rule making process.[2] FSMA provides the FDA with the authority to improve training of state, local, territorial, and tribal food safety officials.

References: M.T. Oldfield *supra* note 23, p. 495
S. Kennedy and K.M. Errecaborde s*upra* note 9

[47] N. Obolensky *supra* note 45, p. 887, p. 891-895

3.2 Provisions on inspection and compliance

Inspections

FDA gained its power to inspect facilities producing FDA-regulated foods with section 704 of the FD&C Act. Through inspections, FDA can determine compliance with the law and gather evidence for enforcement if there is noncompliance, assuring food safety standards are met in a facility. Inspections are the primary source of information for the FDA's enforcement actions.[48]

In a 2010 report evaluation FDA's inspections of domestic facilities, OIG found out that more than half of all food facilities have gone without an FDA inspections for five or even more years.[49] Before the adoption of FSMA, inspections were infrequent and based on facilities with the most risk or if adulteration occurred, yearly inspections were not required by the law. [50] Congress addressed this in the FSMA by establishing mandated inspections based on risk for food facilities and requiring an increase of the frequency of inspections. FSMA created section 421 of the FD&C Act – also included in FSMA section 201 - which mandates FDA inspection frequencies (see part of the Act on page 22).[51] Congress required FDA to designate foods in two risk groups – high-risk and non-high-risk - by January 2012. All high-risk domestic facilities have to be inspected within five years and no less than every three years thereafter; all non-high-risk facilities within seven years and every five years thereafter. Within one year of adoption, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years. [52] The purpose of these "high-risk" food provisions is facilitating effective and rapid tracking and tracing of high-risk food in the event that it is

[48] N.D. Fortin, '*Inspections*' (Food Regulation: Law, Science, Policy and Practice, Michigan State 2016) c17

[49] N.D. Fortin *supra* note 48, c17

[50] C. Belden and D. Orden *supra* note 8, p. 17

[51] N.D. Fortin *supra* note 48, c17

[52] D. Acheson, 'FSMA's Evolution: Education & Build to Regulation & Maintenance' (2018) <https://www.achesongroup.com/single-post/2018/05/30/FSMA-Evolution-Education-Build-to-Regulation-Maintenance> accessed 5 October 2018

implicated in a foodborne illness outbreak and speeding up the recall process.[53] However, the FDA did not receive the needed funding to carry out this congressional mandate and still has not designated high-risk foods (see chapter 4 and chapter 5).[54]

[53] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human supra* note 1

[54] N.D. Fortin *supra* note 48, c17

Federal Food, Drug and Cosmetic Act 1938, section 421

Food Safety Modernization Act 2011, section 201

FOOD SAFETY MODERNIZATION ACT – SECTION 201

““(2) INSPECTIONS. –

“(A) IN GENERAL. – Beginning on the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall increase the frequency of inspections of all facilities.

“(B) DOMESTIC HIGH-RISK FACILITIES. – The Secretary shall increase the frequency of inspection of domestic facilities identified under paragraph (1) as high-risk facilities such that each such facility is inspected-

“(i) not less often than once in the 5-year period following the date of enactment of the FDA Food Safety Modernization Act; and

“(ii) not less often than once every 3 years thereafter.

“(C) DOMESTIC NON-HIGH-RISK FACILITIES. - The Secretary shall ensure that each domestic facility that is not identified under paragraph (1) as a high-risk facility is inspected

“(i) not less often than once in the 7-year period following the date of enactment of the FDA Food Safety Modernization Act; and

“(ii) not less often than once every 5 years thereafter.

“(D) FOREIGN FACILITES. –

(i) YEAR 1. In the 1-year period following the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall inspect not fewer than 600 foreign facilities.

(ii)SUBSEQUENT YEAERS. – In each of the 5 years following the 1-year period described in clause (i), the Secretary shall inspect not fewer than twice the number of foreign facilities inspected by the Secretary during the previous year.

“E) RELIANCE ON FEDERAL, STATE, OR LOCAL INSPECTIONS. – In meeting the inspection requirements under this subsection for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation.”

Access to records

Section 704 of the FD&C Act (U.S.C. §374) applies a general standard to all FDA regulated products, where it is written that in case of a factory inspection the agency's "duly designated" officers or employees - upon presenting appropriate credentials and written notice to the "owner, operator or agent in charge" - are

"authorized (A) to enter, at reasonable times, any factory, warehouse or establishment in which, food, drugs, devices or cosmetics are manufactured, processed, packed or held .. or to enter any vehicle being used to transport or hold such food .. and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labelling therein".

Section 704 of the FD&C Act (U.S.C. §374) is permitting physical inspection of the facility, equipment, labelling and products but it does not mention anything about records, reports and files.[55] Before the adoption of the FSMA, the FDA could only access records for a specific food if it had reason to believe the food was adulterated.[56] Nonetheless, the law did not prohibit an FDA investigator from asking a regulated firm to provide access to more records than the investigator has statutory grounds to demand for. Many firms voluntarily cooperate to this request.[57] In section 101 of FSMA (U.S.C. §350c), the law enables the FDA to have access to all records relating to an article of food 'the Secretary reasonably believes' will cause 'serious adverse health consequences or death to humans or animals,' or that might be 'likely to affect in a similar manner' (see part of the Act on page 25).[58] Compared with FD&C Act, the key

[55] N.D. Fortin *supra* note 44, c17

[56] M. Olewnik *supra* note 13, p.112
Federal Food, Drug and Cosmetic Act 1938
Food Safety Modernization Act, 2011

[57] N.D. Fortin *supra* note 44, c17
Federal Food, Drug and Cosmetic Act, 1938
Food Safety Modernization Act, 2011

[58] N.D. Fortin *supra* note 44, c17
Federal Food, Drug and Cosmetic Act 1938
Food Safety Modernization Act 2011

change of FSMA is that previously FDA could only access records for a specific food if it had reason to believe the food was adulterated.[59] By implementing this provision, a threat of serious adverse health consequences or death to humans or animals might be prevented by the FDA.

[59] M. Olewnik *supra* note 13, p.112
Federal Food, Drug and Cosmetic Act, 1938
Food Safety Modernization Act, 2011

FOOD SAFETY MODERNIZATION ACT – SECTION 101
"SEC. 101. INSPECTIONS OF RECORDS.

(a) IN GENERAL. – Section 414(a) (21 U.S.C. 350c(a) is amended-

(1) by striking the heading and all that follows through "of food is" and inserting the following: "RECORDS INSPECTIONS. –

"(1) ADULTERATED FOOD. - If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is";

(2) by inserting ", and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner," after "relating to such article";

(3) by striking the last sentence; and

(4) by inserting at the end to the following:

"(2) USE OF OR EXPOSURE TO FOOD OF CONCERN. - If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each per- son (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

(1) "(3) APPLICATION. - The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location"."

Laboratory Accreditation for analyses of foods

In section 422 of FSMA, FSMA requires FDA to establish a program for testing of food by accredited laboratories and establish a system for laboratory accreditation. [60] Laboratories that are used for food emergencies or conduct testing (foreign and domestic) must be accredited by the FDA according to the new law (see part of the Act below). The objective of laboratory accreditation is to align commercial laboratories with governmental labs which would facilitate the acceptance of analytical data, improve the efficiency of governmental labs and support testing of food imports.[61] Before the adoption of the FSMA, laboratories used for responding to foodborne illness were not FDA-accredited.[62]

FOOD SAFETY MODERNIZATION ACT – SECTION 422
"SEC. 422. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS.

"(a) RECOGNITION OF LABORATORY ACCREDITATION. –

"(1) IN GENERAL. – Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall –

"(A) establish a program for the testing of food by accredited laboratories;

"(B) establish a publicity available registry of accreditation bodies recognized by the Secretary and laboratories accredited by a recognized accreditation body, including the name of, contact information for, and other information deemed appropriate by the Secretary about such bodies and laboratories; and

"(C) require, as a condition of recognition or accreditation, as appropriate, that recognized accreditation bodies and accredited laboratories report to the Secretary any changes that would affect the recognition of such accreditation body or the accreditation of such laboratory."

[60] N. Obolensky *supra* note 45, p. 894

[61] P. Kennedy 'Questions Surround FSMA Mandate for Lab Accreditation' (Merieux NutriSciences, May 2015) <http://foodsafety.merieuxnutrisciences.com/2015/05/22/questions-surround-fsma-mandate-for-lab-accreditation/> accessed 8 January 2019

[62] C. Belden and D. Orden *supra* note 8, p. 17

Whistleblower protection

Additionally, in section 402 (21 U.S.C. §399(d)), FSMA establishes protection from retaliation for employees of entities involved in the manufacturing, processing, packing, transportation, distribution, reception, holding or importation of food, who provide information relating to a violation of food safety laws. Employees who believe they have been retaliated after providing information may file a complaint within 180 days. This provided information may relate to any violation or when the employee has reasonable belief for any violation, testifying, assisting or participating in proceeding a violation or objecting to or refusing to participate in any activity reasonably believed as violation. Retaliation includes firing or laying off the employee in question, reducing the pay or hours, blacklisting, demoting, denying overtime or promotion, disciplining, denying benefits, failing to hire or rehire, intimidating, making threats and reassigning (see part of the Act on the next page).[63] By giving protection to employees who provide information about possible violations, it is hoped that the food system will become more effective, and the food safety will be enhanced. In the FD&C Act of 1938, no employee protection was included.[64]

[63] OSHA, 'Filing Whistleblower Complaints under the FDA Food Safety Modernization Act' (Factsheet, n.d.) <https://www.osha.gov/Publications/OSHA3714.pdf> accessed 8 January 2019

[64] C. Belden and D. Orden *supra* note 8, p. 17

FOOD SAFETY MODERNIZATION ACT – SECTION 402
"SEC. 402. EMPLOYEE PROTECTIONS

"(a) IN GENERAL. – No entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee)—

"(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reason- ably believes to be a violation of any provision of this Act or any order, rule, regulation, standard, or ban under this Act, or any order, rule, regulation, standard, or ban under this Act;

"(2) testified or is about to testify in a proceeding concerning such violation;

"(3) assisted or participated or is about to assist or participate in such proceeding, or;

"(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this Act, or any order, rule, regulation, standard, or ban under this Act."

Part III: Implementation and Impact of the Food Safety Modernization Act

Chapter 4 - Implementation of The Food Safety Modernization Act

In order to assess the impact of food safety by the provisions on inspection and compliance, the implementation phase should be discussed first. With the implementation of the FSMA, the food safety system in the U.S. should have been strengthened, and the protection of public health enhanced.[65] Unfortunately, after several years, some provisions on inspection and compliance are still not completely implemented, resulting in criticism against the FDA.

FSMA shifted the food safety system from reactive to more preventive, meaning more inspections and increased access to record for the inspector during inspections of facilities. Not only the government has to put in place changes incurred by the FSMA, the industry will also have to adapt.

4.1 Implementation of inspection and compliance provisions

Inspections

Food inspections play an essential role in oversight so the FDA can determine whether food processors, producers, and importers are complying with the new laws.[66] In meeting the domestic inspection requirements, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other

[65] U.S. Food and Drug Administration, 'Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)' (2014) <https://www.fda.gov/food/guidanceregulation/fsma/ucm395105.htm> accessed 15 November 2018

[66] C. Waldrop, '*Chapter 13 – Protecting Consumers through New Regulations, Inspection, and Verification under the U.S. Food Safety Modernization Act*' in S.F. Halabi (eds), Food and Drug Regulation in an Era of Globalized Markets' Elsevier Inc., Washington 2015) p. 163

obligations.[67] Having enhanced partnerships and putting reliance on inspections by other agencies that meet standards improves state and local capacity building and foodborne illness surveillance, and make it easier to find recall information.[68] Hence, enhanced partnerships should have a positive effect on the food safety in the U.S.

Inspection resources are established in section 201 of FSMA, whereas the FDA, working under the HHS, identifies high-risk facilities, increases the frequency of inspection of domestic and foreign facilities, identifies and conducts inspections at ports of entry and improving coordination and cooperation with USDA and the Department of Homeland Security (DHS). In March 2012, the FDA issued information on how it will categorize high-risk facility.[69] In February 2014, the FDA published a draft methodological approach for designating high-risk foods as required by section 204. After that, there was the possibility for stakeholders to comment, while the FDA gathered scientific data and information from stakeholders to revise the draft. [70] FDA has still not succeeded in refining this draft of classifying high-risk foods and has failed to implement this provision in time (see chapter 5), while foodborne illnesses could have been prevented when implemented. [71]

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[67] Food Safety Modernization Act 2011, section 201

[68] J. Reardon, 'Food Safety Modernization Act' (PowerPoint presentation, 2011) <https://www.aafco.org/Portals/0/SiteContent/Meetings/Presentations/Food_Safety_Modernization_Act-Joseph_Reardon-2011_Annual.pdf> accessed 14 January 2019

[69] R. Johnson, 'Food Safety Issues for the 113th Congress' (2014) <https://www.everycrsreport.com/files/20140203_R42885_3f73bfc76447fa66b3bc6a994e90a1a08a92c5df.pdf> accessed 15 November 2018

[70] C.F. Lin, 'FDA's Draft Methodological Approach to Identifying High-Risk Foods' (2014) <http://blog.petrieflom.law.harvard.edu/2014/03/06/fdas-draft-methodological-approach-to-identifying-high-risk-foods/> accessed 15 November 2018

[71] Center for Food Safety, 'Food Safety Groups Sue FDA Over Failure To Address Foodborne Illness Outbreaks' (October, 2018) <https://www.centerforfoodsafety.org/healthy-home/3274/healthy-home/press-releases/5430/food-safety-groups-sue-fda-over-failure-to-address-foodborne-illness-outbreaks> accessed 16 October 2018

Section 201 of FSMA includes HHS issuing an annual report with information about food facilities. Not later than February 1 of each year, the HHS has to submit an annual report to Congress (21 U.S.C. §393). Up to now, HHS has sent Congress three annual reports on food facilities, food imports, and foreign offices including efforts to cooperate with other agencies from 2011 until 2013. Reports for subsequent years have not been submitted. [72]

During an inspection, investigators identify potential violations of applicable laws and regulations, document their findings and recommend a classification in an inspection report to assess food safety. If regulatory action is necessary by the facility after an inspection, the investigator classifies the inspection as official action indicated (OAI). Official action indicated includes warranting an advisory action, whereas a warning letter is issued or a regulatory meeting is set, or an enforcement action, requiring facilities to correct the violations. Whenever there is a less significant violation, the investigator classifies the inspection as voluntary action indicated (VAI) or, in case of no action is necessary by the facility, the inspection is classified as no action indicated (NAI).[73] From 2009 to 2017, the amount of VAI's issued during an inspection reduced from an average of 3960 a year to 3696 a year, a decrease of 8%. In the same time period, the number of NAI issued increased from a mean of 6725 to 7694 (+15%), and the OAI increased as well from 348 to 415 (+19%) (Figure 1).[74] These outcomes could indicate that the authority is stricter and goes more often straight from no action indicated to an official action indicated, or that facilities are more often violating the law resulting in an official action. Another

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[72] FDA, 'Reports & Studies' (2017) <https://www.fda.gov/food/guidanceregulation/fsma/ucm271961.htm> accessed 15 November 2018

R. Johnson *supra* note 28

Food Safety Modernization Act 2011, section 201

[73] D. R. Levinson, 'Challenges remain in FDA's Inspections of Domestic Food Facilities/ (2017) <https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf'> accessed 12 October 2018

[74] U.S. Food & Drug Administration, 'Inspection Classification Database Search' <https://www.accessdata.fda.gov/scripts/inspsearch/results.cfm> accessed 7 January 2019

suggestion might be the amount of inspection has increased and hence, the amount of NAI and OAI increased. Unfortunately, FDA is not as transparent with the amount of inspections as it is with its inspection classification database. For this reason, it is hard to drawn firm conclusions if the food safety has deteriorated by the increasing OI and it remains just an indication.

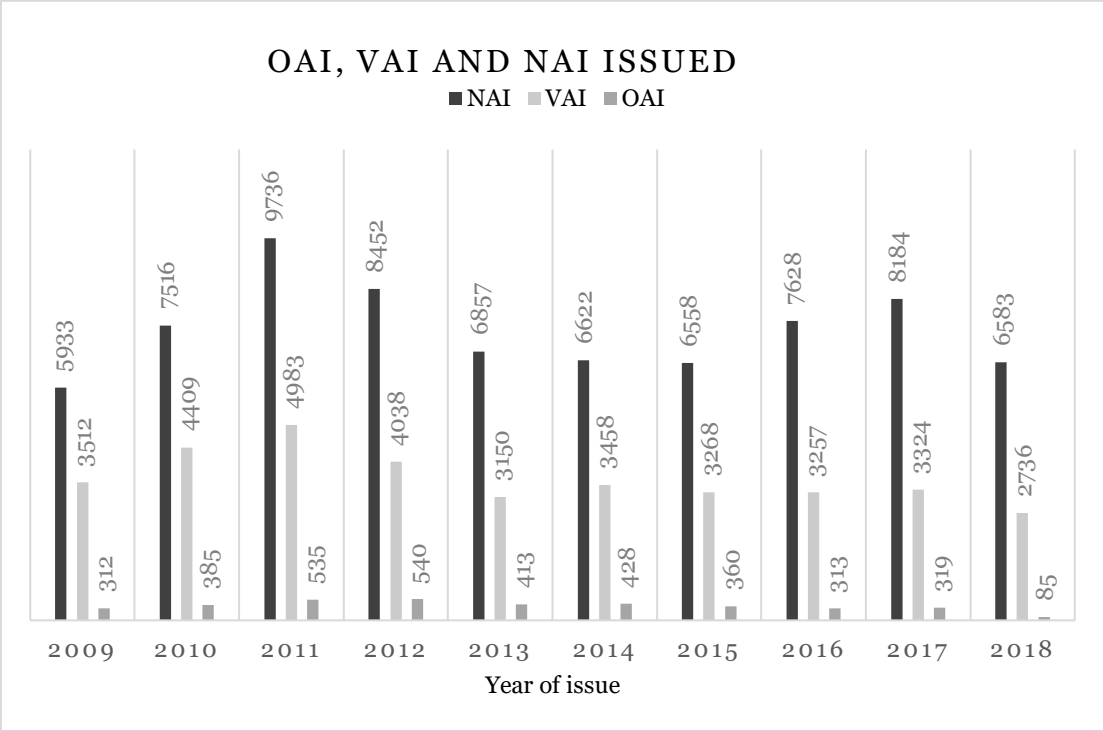

Figure 1: Number of OAI, VAI and NAI issued during an inspection between 2009 through December 11, 2018. For the calculations in the text, 2018 is not used since there was no full data of the whole year available. The project area used in the database search is the Center for Food Safety and Applied Nutrition, including foodborne biological hazards; pesticides and chemical contaminants; molecular biology and natural toxin; food and colour additives petition review; technical assistance: food and cosmetics; food composition, standards, labelling; and colour and cosmetic technology in all available districts and states. Inspections Classifications listed reflect the compliance status of firms when the report was generated. These inspections classifications may or may not represent the final agency determinations of compliance for these firms. **Reference**: U.S. Food and Drug Administration *supra* note 82

Although FDA is on track to meet the FSMA inspection mandates during the initial cycles, the overall number of food facilities that FDA inspected since the adoption of FSMA has decreased with 3,000 facilities between 2011 and 2015. In addition, FDA did not always take action when it revealed significant

inspection violations classified as OAI during an inspection. When FDA did take action, it commonly relied on facilities to voluntarily correct the violations and it was not always timely or it did not always result in correction of violations. FDA rarely took advantage of the new administrative tool to a mandatory recall provided by the FSMA and failed to conduct timely follow-up inspections to ensure correctives by facilities with significant inspection violations: [75] since the adoption of FSMA, the FDA has used its mandatory recall power only three times, arguing that most companies collaborate and hence voluntarily recalls violated food products.[76]

The inspector's concerns discovered during an inspection are kept on a FDA Form 483. On this form, observed conditions or practices indicating that an FDA-regulated product may be in violation of FDA's requirement are listed. Before the adoption, between FY 2006 until FY 2010, the average of 483 forms issued had an estimated number of 2256 for food products. After the adoption, the average has increased with more than 19% to 2700 issued forms (Figure 2). [77] Considering the increase in FDA Form 483 issued, it could be suggested that the violations of food facilities during an inspection has increased since the adoption of the FSMA in 2011 and the food safety has been more at risk.

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[75] D. R. Levinson *supra* note 73

[76] C. Beach 'FDA puts its mandatory recall cards on the table – face up' Food Safety News (November, 2018) <https://www.foodsafetynews.com/2018/11/fda-puts-its-mandatory-recall-cards-on-the-table-face-up/?fbclid=IwAR1nQUPFOC2qm-kzVyQvKQtvDwSL_qzLd0ZOhu5WBQXiikDNJOBR8cO8UJw> accessed 6 November 2018
E. Shaffer 'F.D.A. vows 'more robust use' of recall authority' Food Business News (July 2018) https://www.foodbusinessnews.net/articles/12834-fda-vows-more-robust-use-of-recall-authority accessed 8 November 2018
U.S. Food and Drug Administration, 'Food Guidance Documents' (2018) https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm accessed 8 November 2018

[77] U.S. Food and Drug Administration, 'Inspection Observations' (2018) <https://www.fda.gov/ICECI/Inspections/ucm250720.htm> accessed 15 November 2018

After a Form 483 is issued and the inspector completes his or her report, the agency may decide to issue a Warning Letter, indicating a serious violation. This formal notification allows the violating food facility to take voluntary and prompt correction action. [78]

FDA is expected to conduct timely reinspections of facilities with significant inspection violations, to ensure compliance and corrections to violations of the facility in case. The goal for these reinspections is to be conducted within six months after an OAI classification has been finalized and any actions taken. Follow-up inspections are not seen as advisory or enforcement actions. [79] In section 107 of FSMA, FSMA authorizes HHS to assess and collect fees for reinspection, recall and importation activities (21 U.S.C. §379j (31)). [80]

[78] J. Lehnman, 'FDA Warning Letters and Form 483: What's the Difference?' (2013) <http://www.imarcresearch.com/blog/bid/280993/fda-warning-letters-and-form-483-what-s-the-difference> accessed 15 November 2018

[79] Food and Drug Administration, Office of Regulatory Affairs 'FMD 86: Establishment Inspection Report Conclusions and Decisions' (2014) <https://www.fda.gov/downloads/iceci/inspections/fieldmanagementdirectives/ucm382035.pdf> accessed 4 November 2018

[80] D. R. Levinson *supra* note 73

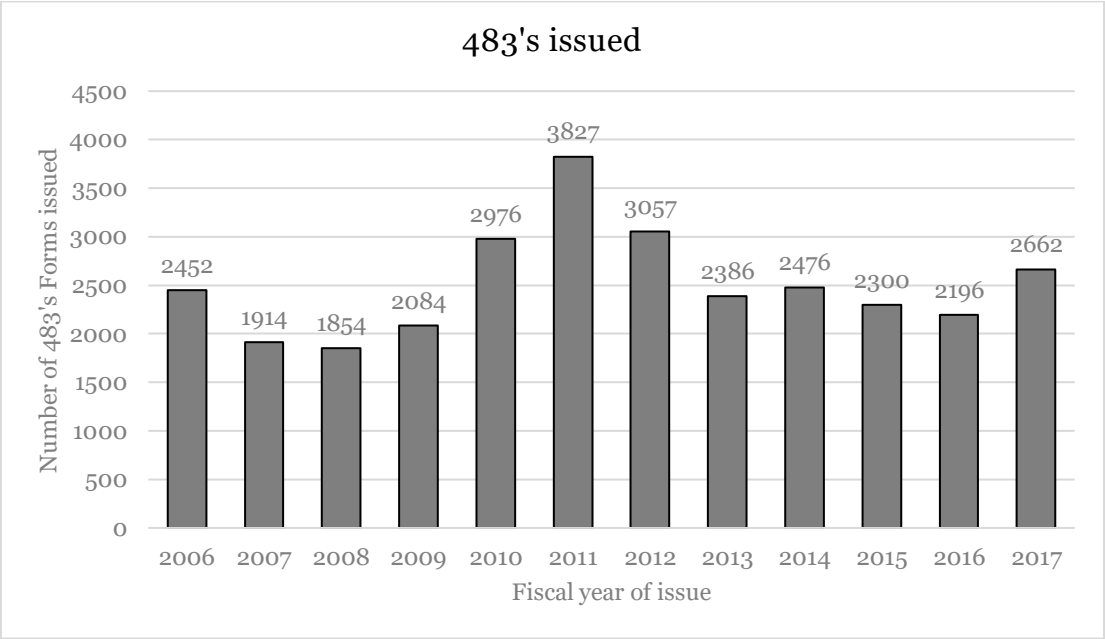

Figure 2: Number of 483 forms issued before and after the adoption (FY 2006- FY 2017). Years were defined as fiscal years including periods between 1 October 12:00:00 AM of the previous year and 30 September 12:00:00 AM.This figure does not represent the complete set of 483's issued during the fiscal years as some 483 forms were manually prepared and not available in this format, hence it is just an indication.[81]

Laboratory Accreditation for analyses of foods

In section 202 of the FSMA, requirements about laboratory accreditation for analyses of foods were established (21 U.S.C. §350k). HHS should establish a program for the testing of food by accredited laboratories no later than two years after the adoption[82], intended to help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program.[83] By the development of setting standards which laboratories must adhere, FSMA provides a feeling of assurance of testing results and hence food safety for food facilities and the consumer. Food testing

[81] U.S. Food and Drug Administration *supra* note 6

[82] Food Safety Modernization Act 2011, section 202

[83] U.S. Food and Drug Administration, 'FSMA Final Rule on Accredited Third Party Certification', <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm> accessed 22 December 2018

should be conducted by accredited laboratories within 30 months – 2,5 years – after the adoption, unless otherwise exempted. Additionally, HHS should submit a progress report on implementing a national food emergency response laboratory network within 180 days after adoption and biennially thereafter.[84]

The FDA FSMA rule on accredited third party certification was finalized a little later than two years after the enactment in November 2015, establishing a voluntary program for the accreditation of third-party certification bodies. This program includes a framework, requirements and procedures for accreditation bodies seeking recognition by the FDA; promotes international consistency and is closely monitored by the FDA. In June 2017, the FDA launched a website where organizations can apply to be recognized as an accreditation body, and at the same time implementing the program. [85] In September 2011 and in November 2013 FDA issued its biennial report as required; reports for subsequent years have not been submitted or not been available for the public.[86] Reasoning behind these missing biennial reports remains unclear.

Whistleblower protection

FSMA's provision on whistleblower protection took effect immediately after the adoption of the FSMA in 2011, hoping to reduce violations and hence enhancing the food safety. Whistleblower complaints are managed for the FDA by the Occupational Health & Safety Administration (OSHA). Since the adoption of the FSMA, there have been 361 complaints filed by OSHA (2011-2018). However, many complaints were eventually withdrawn (22%) or dismissed (50%) for various reasons. Only 26% of the complaints had a positive outcome for the complainant, showing that this provision did not have the posstive effect expected. The remaining 2% of the complaints were 'kicked-out',

[84] Food Safety Modernization Act 2011, section 202

[85] U.S. Food and Drug Administration *supra* note 83

[86] R. Johnson *supra* note 28

U.S. Food and Drug Administration *supra* note 6

Food Safety Modernization Act 2011, section 202

U.S. Food and Drug Administration *supra* note 72

which occurs when the complainant brings an action for *de novo* (Latin for "from the new") review of the complaint in a U.S. district court,[87] meaning a court decision without reference to any legal conclusion or assumption made by the previous court to hear the case. [88]

4.2 General requirements of the Food Safety Modernization Act on the domestic and foreign industry, regarding the key provision inspection and compliance

FSMA shifted the food safety system from reactive to more preventive, meaning that the FDA is more inspection-oriented and enforcement-minded than before the adoption. Under the FSMA, the FDA has to conduct more inspections, FDA has to use a system-based approach to conduct inspections, and FDA has increased access to records during routine inspections. Additionally, FDA has to put more focus on ensuring consistency among inspections conducted by the FDA or states on behalf of the FDA. [89] It is anticipated that during an inspection inspectors are more assertive and comprehensive, focusing more on detailed observations and more prone to list an observation on Form 483, resulting in an increased amount of Form 483 since the adoption of FSMA (see section 4.1). Moreover, instead of collecting product samples of finished product, inspectors nowadays are conducting extensive environmental testing throughout facilities

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[87] United States Department of Labour, 'Whistleblower Docketed Cases Received: FY2008-FY2018' (Informationsheet, n.d.) <https://www.whistleblowers.gov/sites/default/files/3DCharts-FY2008-FY2018.pdf> accessed 21 January 2019

Tracegains, 'The Trump Administration or Whistleblowers: Which Might Have More Impact on FSMA Compliance?' (2017) <https://www.tracegains.com/blog/the-trump-administration-whistleblowers-which-might-have-more-impact-fsma-compliance> accessed 5 November 2018

[88] Cornell Law School, 'De Novo' <https://www.law.cornell.edu/wex/de_novo> accessed 21 January 2019

[89] L. H. Ziemba, 'FDA Inspections & Recordkeeping Post-FSMA' (2015) <http://www.wifoodprotection.org/docs/110415/RecordsandInspectionsLeahZiemba.pdf> accessed 4 November 2018

which is more likely to detect a problem than finished product testing. [90] While focusing on prevention during inspections, FDA is hoping to prevent foodborne illness outbreak and eventually enhance the food safety.

When a food facility registers with FDA, it grants permission to FDA to inspect the facility at any given time. The possibility that regulators could knock on the door at any reasonable time, should raise the importance of an enhanced food safety system in the facility.[91] Initial FDA food facility inspections are of no cost for the food facility and may occur due to routine reasons, a facility's level of potential risk to public health, or as a response to a complaint or problem. If the inspectors discover certain food safety violations during an initial inspection, the FDA might decide to return at a later date to evaluate if the food facility implemented appropriate corrective actions during a reinspection.[92] Food facilities undergoing a reinspection, will be subject to reinspection fees since the adoption of the FSMA. These reinspection fees include any follow-up laboratory testing and inspection preparation time, travel time and the time it takes to write a follow-up report.[93] Fees for FY 2018 are $248 per hour for domestic food facilities, an increase of $27 from FY 2017, and $285 per hour for a foreign facility, the same as in FY 2017. Proper preparation of the facility for an initial inspection, may prevent such expensive reinspections and reputation damage[94] and would increase food safety in the facility.

[90] J. A. Levitt and V.S. Knapp 'FDA's Changing Culture: What Every Food Company Needs to Know' (2013) FoodSafety Magazine <https://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2013/fdae28099s-changing-culture-what-every-food-company-needs-to-know/> accessed 8 November 2018

[91] R. Talbott *supra* note 23

[92] Registrar Corp, 'U.S. FDA Announces Reinspection Fees Fiscal Year 2018' (2017) https://www.registrarcorp.com/u-s-fda-announces-reinspection-fees-fiscal-year-2018/ accessed 16 November 2018

[93] J. A. Levitt and V.S. Knapp *supra* note 90

[94] Registrar Corp *supra* note 92

When Form 438 observations have occurred during an inspection of a facility, it is of great importance that the food facility has an appropriate response. Companies should pay attention to report all corrective actions taken, or set a timetable for further corrective actions, and the facilities' commitment to comply the law for an enhanced food safety. Considering the facilities response to a Form 483 and the violations issued at the 483 Form, the FDA reviews whether to send a Warning Letter or not.[95]

The broad access granted to the FDA is another major provision for facilities. If the FDA requires a record to be kept, they have access to those records under the FSMA. FDA is going to be looking at the adequacy of facilities program: what do the records say about how the facilities food safety system is designed.[96] Hence, proper preparation of an initial inspection includes a well-designed food safety system.

4.3 FDA appropriations

FDA is responsible for the oversight of more than $2.5 trillion in consumption of food, medical products and tobacco, accounting about 20 cents of every dollar spent by an American consumer. [97] FDA's responsibility is to protect the public health and in order to do so, they need a yearly budget. [98] FDA's total budget, also called FDA's total program level, is composed of discretionary appropriations from two different sources: the budget authority and the collection of user fees. Between FY 2014 and FY 2018, FDA's total program level increased from $4.387 billion to $5.269 (+20%). The budget authority

[95] J. A. Levitt and V.S. Knapp *supra* note 90

[96] S. Lewis, "FSMA Inspections: What To Expect When the FDA Knocks On Your Door' (2017) <https://www.foodonline.com/doc/fsma-inspections-what-to-expect-when-the-fda-knocks-on-your-door-0001> accessed 10 November 2018

[97] U.S. Food and Drug Administration, 'What is FDA's Budget and What is Its Impact?' <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm553033.htm#cost> accessed 19 December 2018

[98] U.S. Food and Drug Administration, 'Fact Sheet: FDA at a glance' (2018) <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm553038.htm> accessed 20 December 2019

increased by 12% while the collection of user fee increased more than 31%. FY 2019 request consists of a total program level of $5772 billion, an increase of $503 million (+10%) over the FY 2018 enacted amount.

FDA's total budget includes all its program areas, e.g. foods, human drugs, biologics, animal drugs and feeds, devices and radiological health, tobacco products. Just looking at the budget for the food area, FDA's budget increased from $900 millions to $1053 millions between FY 2014 and FY 2018 (+17%). During this period, the budget authority increased from $883 millions to $1042 millions, while the collection of user fee reduced from $17 million to $12 million. In FY 2019, a budget of $1041 millions is requested (-2%)[99], including budget authority and fees, of which $1,029,863,000 is budget authority and $10,871,000 is user fees (Table 1). Budget authority would increase compared to FY 2018, whereas user fees would remain nearly the same. In FY 2019, the foods program would continue its statutory mission of promoting and protecting. [100]

[99] A. Dabrowska and V.R. Green, 'The Food and Drug Administration (FDA) Budget: Fact Sheet' (Congressional Research Service, 2018) < https://fas.org/sgp/crs/misc/R44576.pdf> accessed 16 November 2018

[100] FDA, 'Narrative by Activity' (2018) <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM617769.pdf> accessed 3 December 2018

Program Area	FY 2014 Enacted	FY 2015 Enacted	FY 2016 Enacted	FY 2017 Enacted	FY 2018 Enacted	FY 2019 Request
Foods	900	914	999	1037	1053	1041
BA	883	903	987	1026	1042	1030
Fees	17	10	12	12	12	11
Total Budget Authority	2561	2597	2730	2791	2872	3254
Total User Fees	1826	1909	2017	1954	2397	2519
Total Program Level	4387	4507	4747	4745	5269	5772

Table 1:FDA appropriations between FY 2014 and FY 2018; FY 2019 is still requested. The numbers are in dollars in millions. [101] The amounts used were provided in legislation passed by Congress and signed into law by the President, obtained from Congressional budget documents rather than FDA budget documents. Discrepancies in numbers with actual budget spend might occur. [102]

Trump's administration proposed a FDA total budget authority of $1.89 billion for 2018, a cut of $854 million for budget authority (-31%) and an increased user fees with $1.3 billion.[103] The cut in budget authority is not surprising, since President Trump temporarily uploaded a fact sheet during his campaign of 2016 mentioning reducing food safety regulations and even eliminating the so called 'FDA Food Police'. [104] However, in 2019 the total budget increased

[101] A. Dabrowska and V.R. Green *supra* note 99

[102] A. Dabrowska and V.R. Green, 'The Food and Drug Administration: Fact Sheet' (E-mail contact, December 2018)

[103] R. Robbins, 'Trump wants to cut billions from the departments that regulate drugs, stop infections, and research cancer' Business Insider (21 May 2017) <https://www.businessinsider.com/trump-proposed-2018-budget-cuts-to-nih-cdc-fda-hhs-2017-5?international=true&r=US&IR=T> accessed 5 December 2018

L. Ramsey, 'Former Obama administration officials blast Trump's proposed health budget cuts' Business Insider Nederland (23 May 2017) <https://www.businessinsider.nl/trumps-2018-budget-health-2017-5/?international=true&r=US> accessed 5 December 2018

[104] L. Wheeler, 'Trump floats rolling back food safety regulations', The Hill (15 September 2016) <https://thehill.com/regulation/healthcare/296152-trump-says-he-would-eliminate-food-safety-regulations> accessed 5 December 2018

again, allowing better oversight.[105] Nonetheless, the proposed budget of the administration is often different from what Congress decides to provide (Table 1), since the Constitution gives Congress the power of the purse. [106]

Even though FDA's budget has increased during the last few years, many factors have led to tighter budget constraints and inadequacy in meeting its numerous responsibilities. The U.S. budget sequestration in 2013 is one of these factors, referring to the automatic spending cuts to the federal governments for years 2014 until 2021. [107] Additionally, the number of facilities has grown (Figure 3). According to the FDA, there were about 76,000 food processing facilities in 2011, while in 2015 there were more than 86,000, an increase of 13%. As already mentioned in section 4.1, the overall number of food facilities that FDA inspected since the adoption has decreased with 3,000 facilities between 2011 and 2015 according to an OIG report (Figure 3). Additionally, FDA did not always take the appropriate actions when necessary. Some Congress members have seized the OIG report as evidence food safety programs are underfunded. In 2015, Michal R. Taylor – deputy FDA

A. Swerdloff, 'We Asked Food Policy Experts What They Thought of Trump's Plan to Dissolve The FDA' (2016) <https://munchies.vice.com/en_us/article/pgv37z/we-asked-food-policy-experts-what-they-thought-of-trumps-plan-to-dissolve-the-fda> accessed 5 December 2018

'', 'Donald Trump campaign pitches, then deletes food safety changes', CBS News (Washington 16 September 2016) https://www.cbsnews.com/news/donald-trump-campaign-pitches-then-deletes-food-safety-changes/ accessed 5 December 2018

[105] M. Noltemeyer 'Group applouds 2019 F.D.A. budget', FoodBusiness News (Silver Spring 14 February 2018) https://www.foodbusinessnews.net/articles/11347-group-applauds-2019-fda-budget accessed 4 December 2018

Department of Health and Human Services, 'Fiscal Year 2019) (2019) <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm603315.pdf> accessed 5 December 2018

[106] A. Dabrowska and V.R. Green *supra* note 102

House Budget Committee, 'Budget Process Reform: FAQs' (n.d.) https://budget.house.gov/initiatives/budget-process-reform/faqs/ accessed 5 December 2018

[107] J. Alphonose and others, 'The FDA Funding Crisis' (2013) 30(2) Journal of Pharmacy Technology, p.57, p. 58

commissioner for foods and veterinary medicines – said in an interview: "We have good plans for moving forward. The problem is we don't have enough money."[108] Even some food-safety experts are wondering whether the federal food safety funding has kept pace with the expansion of the agency's mission.[109] Considering the growing number of facilities and the available budget, it seems that FDA is indeed underfunded for moving forward.

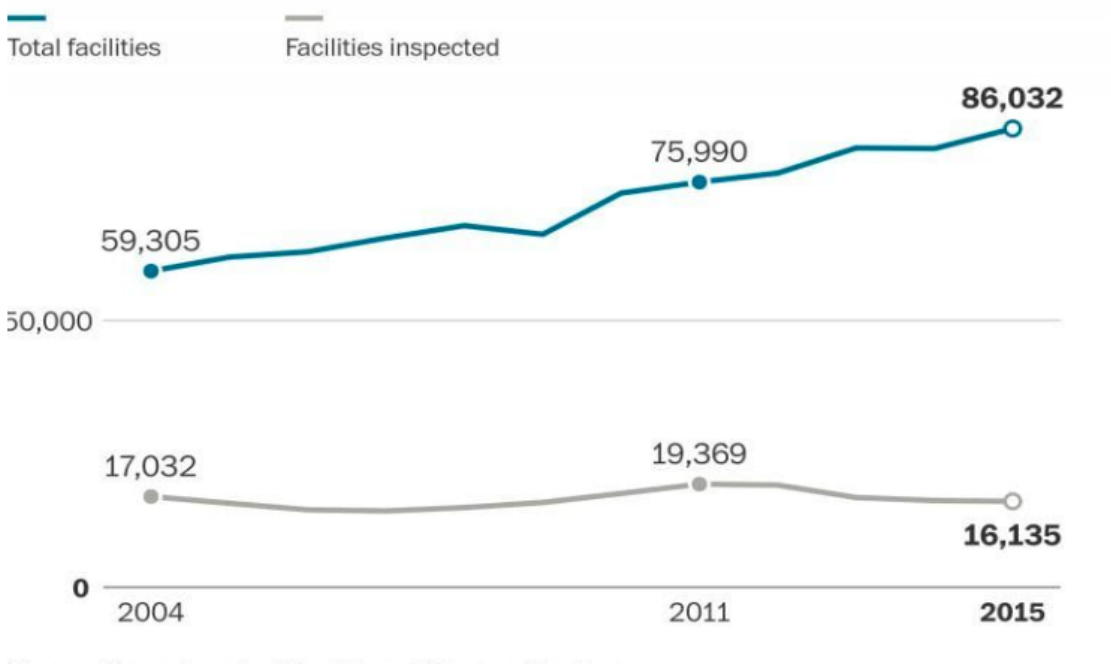

Figure 3: Number of total facilities and number of facilities inspected between 2004 and 2015. FDA inspectors are visiting fewer food facilities than they did 10 years ago. Meanwhile, the number of facilities has grown. **Reference**: C. Dewey, *supra* note 109

[108] R. Nixon, 'Funding Gap Hinders Law for Ensuring Food Safety' The New York Times (Washington, 7 April 2015) <https://www.nytimes.com/2015/04/08/us/food-safety-laws-funding-is-far-below-estimated-requirement.html> accessed 31 January 2019

J. Firger, 'Food safety measures severely underfunded' CBS News (7 April 2015) https://www.cbsnews.com/news/food-safety-policies-severely-underfunded/ accessed 30 January 2019

[109] C. Dewey, '20 percent of serious food safety violations ignored, new report finds' The Washington Post (29 September 2017) <https://www.washingtonpost.com/news/wonk/wp/2017/09/29/20-percent-of-serious-food-safety-violations-go-ignored-new-report-finds/?utm_term=.6eef0023ca39> accessed 1 December 2018

Chapter 5 - Effect of The Food Safety Modernization Act on The U.S. Food and Drug Administration's Role and Responsibilities in Terms of Inspection and Compliance

The adoption of the FSMA expanded FDA's powers, establishing more responsibilities for the FDA. During the last years, FDA failed to comply with some deadlines ancillary of its expanded authorities, leaving all Americans vulnerable to foodborne illness and decreasing the food safety in the U.S. Nonetheless, FDA is on track meeting the FSMA inspections mandates, but not without criticism.

5.1 FDA's responsibilities

FDA is responsible to "protect the public health by ensuring that … foods are safe, wholesome, sanitary, and properly labeled" (21 U.S.C. §393(b)(2)).[110] Additionally, FDA is responsible for protecting the public from electronic product radiation; assuring cosmetics and dietary supplements are safe and properly labeled; regulating tobacco products; and advancing the public health by helping to speed product innovations.[111] Hence, the FDA is the agency with most responsibility for U.S. food supply, regulating approximately 80 percent of both domestic and foreign food products. USDA oversees the other 20 percent, consisting of meat, poultry and egg products. [112] FDA's responsibilities extend to the 50 United States, the District of Colombia, Puerto Rico, Guam, the Virgin Island, American Samoa, and other U.S. territories and possessions.[113]

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[110] *In Re Breast Cancer Prevention Partners et al.* v *United States Food and Drug Administration and Scott Gottlieb supra* note 43

U.S. Food and Drug Administration, 'What does the FDA do?' (2018) <https://www.fda.gov/aboutfda/transparency/basics/ucm194877.htm> accessed 4 November 2018

[111] U.S. Food and Drug Administration *supra* note 110

[112] C. Belden and D. Orden *supra* note 8

[113] U.S. Food and Drug Administration *supra* note 110

FSMA enables FDA to better protect public health by strengthening its ability to regulate and granting the agency enhanced preventative authority by new enforcement tools, such as mandatory recall authority, and the ability to prescribe additional recordkeeping requirements, such as for facilities handling "high-risk" foods. It was Congress's intent that implementation of these measures by the FDA would result in lives being saved, illnesses prevented, and spare even more people from being infected in the first place, by shoring up and dramatically improving the way the food system is regulated. However, these positive public health outcomes could only be realized if the FDA complies with the new law by promulgating regulations, completing required actions, and enforcing provisions mandated by Congress.[114]

5.2 FDA's failure of meeting deadlines

In the last years, FDA has failed to comply with the law by not meeting two important food safety FSMA action deadlines: classifying and designating which foods are classified as 'high-risk' for foodborne illness purposes, and creating additional record keeping requirements for facilities handling such foods (21 U.S.C. §§ 2223(d)(1)-(2)).[115] Congress required FDA to designate high-risk foods by January 2012 and to propose recordkeeping requirements for facilities that handle high-risk foods by January 2013. Over five years later, FDA was not even close in meeting those deadlines.[116] In the years that FDA has failed to complete the requirements, devastating foodborne illness outbreaks have unfortunately continued and spread across the country, killing hundreds and hospitalizing thousands of Americans. These foodborne illness

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[114] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human Services supra* note 1

[115] D. Flynn, 'Civil action asks judge to order FDA to name 'high risk' foods as mandates' Food Safety News (Washington, 17 October 2018) <https://www.foodsafetynews.com/2018/10/civil-action-asks-judge-to-order-fda-to-name-high-risk-foods-as-mandated/> accessed 4 November 2018-11-08

[116] Center for Food Safety *supra* note 71

outbreaks might have been prevented or lessened if these FSMA measures were in place. Some have argued that FDA's failure to implement FSMA's critical food safety regulations by their statutory deadlines is an abdication of the agency's fundamental responsibilities. Moreover, the agency's unlawful withholding is putting millions of lives at continued risk of contracting foodborne illnesses, contrary to Congress commands. The lawsuit therefore seeks to require FDA to complete the high-risk food actions FSMA requires by Court-established deadlines.[117]

BACKGROUND: FOOD SAFETY MODERNIZATION ACT SECTION 204(d)

- FSMA required FDA to designate "high-risk" foods by January 4, 2012 and to publish a notice of proposed rulemaking to establish recordkeeping requirements by January 4, 2013. (Id. §2223(d)(2)(A), 2223(d)(1).
- Pursuant to the FSMA, FDA must "designate high-risk foods for which [ ] additional recordkeeping requirement … are appropriate and necessary to protect the public health." (21 U.S.C. § 2223(d)(2)(A)).
- Pursuant to the FSMA, FDA must publish the list of "high-risk" foods on its website at the time its promulgates the final rule for the additional recordkeeping requirements. ID. §223(d)(2)(B).

Reference: Food Safety Modernization Act, 2011

Unfortunately, FDA's failure of meeting these two deadlines were not the first ones. In 2012, FDA was sued of missing at least seven statutory Congressional deadlines. The Court held that the FDA's failure to promulgate the mandated regulations by their statutory deadlines constituted a failure to act under the Administrative Procedure Act (APA) and unlawful withholding of the regulations in violation of FSA and the APA. The Court granted relief, establishing a new timeline for FDA to promulgate final regulations. On May

[117] D. Flynn *supra note* 115

Center for Food Safety and Center for Environmental Health v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human Services supra* note 1

27th 2016, four years later than intended, the FDA met the last deadlines and promulgated the rules. FDA argued that regulations are novel and complex, and that during the period that it has been working on new regulations, it has also continued to monitor food safety. [118]

BACKGROUND: ADMINISTRATIVE PROCEDURE ACT – SECTION 2; SECTION 10

- The APA's definition of "agency action" includes an agency's "failure to act" (Id. §551(13)).
- Pursuant to the APA: "Person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action… is entitled to judicial review thereof" (U.S.C. § 702)
- Pursuant to the APA, a reviewing court "shall compel agency action unlawfully withheld or unreasonably delayed." Id. §706(1).

Reference: Administrative Procedure Act 1946

Before the adoption of the FSMA, some already questioned if FDA was sufficiently qualified and resourced to make such scientifically difficult regulatory decisions. They argued that the country needed an FDA with better oversight, and procedures, not increased regulation and food safety laws. [119] Instead, FSMA increased FDA's responsibility and role, which the FDA, considering the case law and the numbers of inspections, cannot handle completely with the available budget.

[118] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human Services supra* note 1

[119] C. Belden and D. Orden *supra* note 8

Chapter 6 - Impact of The Food Safety Modernization Act on the foodborne illness outbreaks

To assess the effect on the food safety of the provisions on inspection and compliance, the number of foodborne illness outbreaks after the adoption of FSMA will be given in this chapter.

With the goal of strengthening the food safety system and improving the public health, the impact of the FSMA on the foodborne illness outbreaks is of great relevance: reducing the foodborne illness outbreaks is important to enhance food safety for the consumer. However, data of foodborne illness after the adoption of the FSMA are showing that the foodborne illnesses have not reduced and have even gone up.[120]

6.1 Estimated foodborne illness outbreaks

Centers for Disease Control and Prevention (CDC) is one of the major operating components of the Department of Health and Human Services. CDC's mission is to protect America from health, safety and security threats, in- and outside the U.S. It estimates foodborne illness outbreaks in the U.S. every year to provide an accurate picture of known pathogens and unspecified agents causing foodborne illness in the U.S.[121] CDC provides both a database on multistate foodborne outbreaks from 2006 to 2018[122] and an even broader national outbreak reporting system (NORS), including also illnesses reported that are not considered part of a multistate outbreak from 1998 to 2017. [123]

[120] Center for Food Safety *supra* note 71

[121] Centers for Disease Control and Prevention, 'Estimates of Foodborne Illness in the United States' (2016) https://www.cdc.gov/foodborneburden/index.html# accessed 13 October 2018

[122] Centers for Disease Control and Prevention *supra* note 11

[123] Centers for Disease Control and Prevention, 'National Outbreak Reporting System (NORS)' <https://wwwn.cdc.gov/norsdashboard/> accessed 10 December 2018

Table 2: Number of foodborne illness outbreaks; number of foodborne illnesses; number of hospitalizations; and number of deaths occurred between 2006-2017. In 2011, FSMA was signed by President Obama. **Reference**: Centers for Disease Control and Prevention *supra* note 123

Year	Outbreaks	Illnesses	Hospitalizations	Deaths
2006	1256	28881	1169	10
2007	1098	21302	893	18
2008	1027	23050	1243	22
2009	668	13790	553	7
2010	853	15865	630	16
2011	796	14278	952	45
2012	834	14997	859	20
2013	829	13516	1102	25
2014	877	13443	745	25
2015	924	15541	990	18
2016	849	14367	892	21
2017	839	14471	822	21

According to the numbers of foodborne illnesses and foodborne illness outbreaks from NORS, the change of the regulatory food safety system was a much-needed overhaul. From 2006 to 2008, the foodborne illness outbreak numbers were extremely high. In these years, the suggestion of a new regulatory system came by in Congress. Since the adoption of FSMA, numbers of foodborne illness outbreaks decreased and varied just a little afterwards. However, looking at the number of foodborne illnesses, the rate went up from 2013-2017, with a peak of 15.541 in 2015 (Table 2/ Figure 4) resulted by a major Salmonella outbreak.

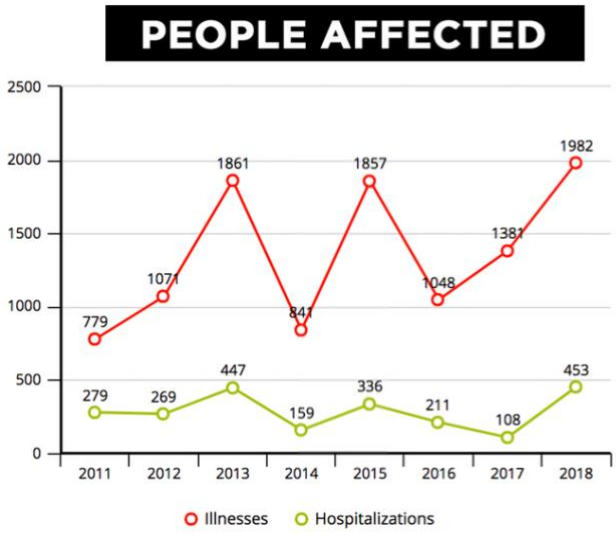

Figure 4: Number of illnesses and hospitalizations due to foodborne illness outbreaks in the U.S. since the adoption of FSMA (2011-2018). In 2015, an outbreak of Salmonella Poona from cucumber lead alone to an illness rate of 838 sick people, resulting a peek in the table.

The Center for Science in the Public Interest (CSPI) examines reported foodborne illnesses from 2004 to 2013 using data of NORS, and published some interesting findings in their "Outbreak Alert! 2015". Since 2009, the average number of foodborne illness outbreaks appears to have decreased by about a third, compared to the average of the six preceding years. From 2010 to 2013, CDC reported that the number of outbreaks varied little from year to year (Figure 5), this is in line with recent data directly from the NORS database (Table 2). Small differences between the finding of the "Outbreak Alert! 2015" and the recent NORS data might occur: state agencies can modify their past outbreaks reports at any time as new information becomes available, years even after an outbreak has occurred. Previously published CDC data are subject to change. [124]

To establish risk-based interventions and design the most effective food safety hazard controls, solved outbreaks are important. Between the years 2013 and 2014, the majority of the outbreaks reported and published were only partially investigated due to understaffed and underfunded departments and overwhelmed by the volume of illness reports. While more than half of the outbreaks remain unsolved, 2013 marks an improvement in the number of solved outbreaks (Figure 5). Unfortunately, recent data (2013-2018) about solved and unsolved outbreaks are not available.

[124] Center for Science in the Public Interest 'Outbreak Alert! 2015: A Review of Foodborne Illness in the U.S. from 2004-2013' (2015) <https://cspinet.org/sites/default/files/attachment/outbreak-alert-2015.pdf> accessed 13 October 2018

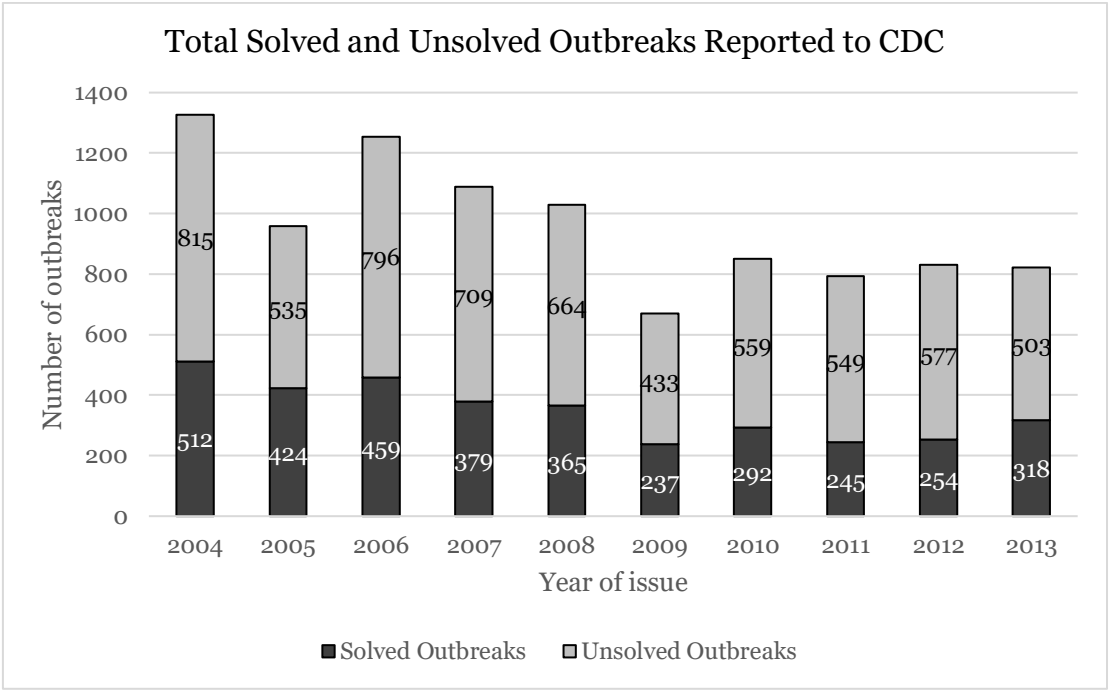

Figure 5: Total solved and unsolved foodborne illness outbreaks reported to CDC between 2004 and 2013, n = 9625. **Reference**: Center for Science in the Public Interest *supra* note 124

According to "Outbreak Alert! 2015" of the CSPI, FDA-regulated foods were implicated in over two-third of the foodborne illness outbreaks. The other one-third is linked to USDA-regulated food, or both agencies (Figure 6). [125] FDA is responsible for 80 percent of the safety of nation's food[126] and hence it is expected that most of the outbreaks are linked to their regulated food products.

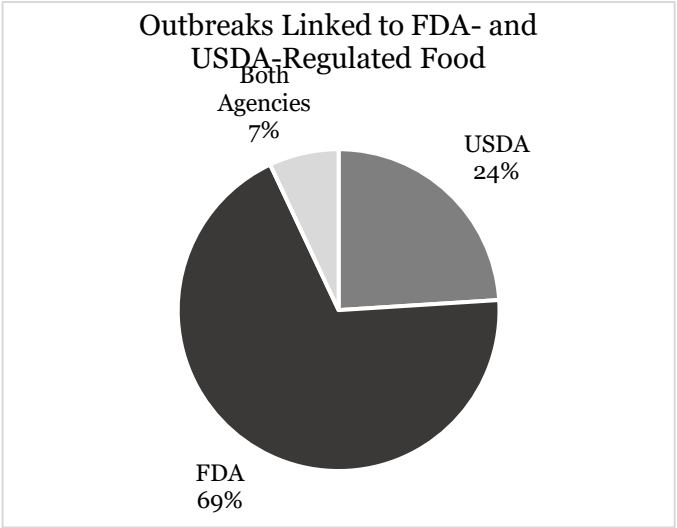

Figure 6: Outbreaks linked to FDA- and USDA- regulated food between 2004 and 2013 (n=3485). **Reference**: Center for Science in the Public Interest *supra* note 124

[125] Center for Science in the Public Interest *supra* note 124

[126] U.S. Food & Drug Administration *supra* note 4

Data of the "Outbreak Alert! 2015" and NORS database suggest that the foodborne illness outbreaks decreased, or remained consistent during the first years after the adoption of the FSMA. Nonetheless, total illnesses are not decreasing (Table 2/3), and these numbers have not stayed unnoticed for the CSF. Last October, CFS sued FDA over failure to address food borne illnesses, [127] including publishing a fact sheet with their findings based on CDC's database multistate foodborne illness outbreaks (Table 3). [128]

Table 3: Number of multistate foodborne illness outbreaks since adoption of FSMA (2011-2018), including the number of states impacted during a single outbreak. **Reference**: Center For Food Safety, *supra* note 1128

Year	Total illnesses	Most states impacted during a single outbreak
2011	779	34
2012	1071	28
2013	1861	29
2014	841	19
2015	1857	40
2016	1048	25
2017	1381	40
2018	1982	41

6.2 Addressing foodborne illnesses

Each year about 48 million people (1 in 6) become ill, 128,000 people are hospitalized and 3,000 people die from foodborne diseases in the United States, according to data of the CDC.[129] Several common types of food poisoning may cause serious long-term health effects, including kidney failure, chronic arthritis, and brain and nerve damage.[130] However, health damages are

[127] Center for Food Safety *supra* note 71

[128] Center for Food Safety, 'Foodborne Illness Outbreaks since Enactment of FSMA' (Factsheet, 2018) <https://www.centerforfoodsafety.org/fact-sheets/5428/foodborne-illness-outbreaks-since-enactment-of-fsma-on-january-4th-2011)> accessed 16 October 2018

[129] U.S. Food & Drug Administration *supra* note 6

[130] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S.*

not the only detriments of foodborne illness outbreaks: the annual cost to the U.S. economy in medical bills and productivity losses alone is over $93 billion.[131]

FSMA requires preventive measures that would decrease the impact of many illnesses caused by foodborne hazards - including the provisions on inspection and compliance - with the goal to strengthen the food safety system. Nonetheless, as mentioned above, data show that the foodborne illnesses have not decreased since the adoption of the FSMA as CSPI claims. Contrarily, the foodborne illnesses have even gone up as well as the number of states impacted during a single outbreak (Table 3).

On 15th October 2018, CFS filed a lawsuit against FDA for 'its failure to designate and establish reporting requirements for producers of foods that are 'high-risk' for food borne illness outbreaks, as required by FSMA'. [132] In CFS's opinion, FDA has not done enough preventing foodborne illness outbreaks, and FDA fails "to promulgate final regulations and complete actions by mandatory deadlines set by Congress in the FSMA", pointing at one of the deadlines of the key element inspection and compliance to designate high-risk foods for inspections. [133]

Food and Drug Administration and U.S. Department of Health and Human Services supra note 1

[131] Center for Food Safety *supra* note 71

[132] Center for Food Safety *supra* note 71

[133] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human Services supra* note 1

Part IV: Future plans

Chapter 7 – Proposed changes

The regulatory food safety system is still not working as it is supposed to, since foodborne illness outbreaks have not been decreasing significantly. President Trump proposed reshaping the safety system to provide even better food safety, by merging the FDA and USDA together into one agency, having a major impact on inspection and compliance. However, merging these two agencies into one means major provisions on FSMA. Ryan Talbott – representing CFS – advises to first follow through implementation.

7.1 Proposal reshaping the food safety system

In June 2018, President Trump released a plan to reshape the U.S. safety system to provide better food safety for the country and improve efficiency for stakeholders. It would be a significant change to the regulatory system, where one single agency would get full authority of food safety from farm to fork. Nowadays, USDA is in charge of ensuring all meat, poultry and catfish. HHS has designated FDA to oversee everything except for everything else. HHS only has to regulate food safety, while USDA is required by the government to both promote agriculture and regulate it.

President Trump's plan is not novel: his predecessor Obama also planned a reshape of the food safety system. His plan did not work out, because the Republican-controlled Congress at that time did not extend to him the authority to reshape the government. Whereas President Obama wanted to shift all authority under HHS, President Trump wants to give full authority to USDA, meaning USDA would regulate and promote the entire food system in the future and not only meat, poultry and catfish.

The shift would give USDA the clear mandate, dedicated budget, and full responsibility it needs for optimal oversight of the entire food supply in the U.S., pursuing a modern, science-based food safety system. It would reduce

duplication of inspection at some facilities, improve outreach to consumers and industry, and save budget overtime. President Trump argues that one single authority would lead to a better allocation of resources based on risk, better communication during foodborne illness outbreaks, and improved policy and program planning through development of a single strategic plan. Expectations of this proposal would lead, in the long term, to improvements in food safety outcomes, policy and program consistency and more efficient use of taxpayer resources. FDA (which would be renamed the 'Federal Drug Administration) would still remain but only focus on drugs, devices, biologics, tobacco, dietary supplements and cosmetics.[134]

However, combining the agencies would lead to a bunch of significant provisions on the FSMA again. As Ryan Talbott stated: "These agencies have been operating under separate departments for a long, long time. To all of the sudden combine them, it might cause more chaos than anything else".

Doug Powell, a former professor of food safety at Kansas State University, agrees with Ryan Talbott stating in 2015 that creating a single agency might ultimately provide less protection than the administration or lawmakers want to admit. Tony Corbo, lobbyist for an advocacy group, argues to expect that the federal government would not do well when they try to fit many agencies with different missions under one roof, with criticism of the consolidation of 22 agencies into the DHS in 2003 as example.[135] Additionally, some argue that

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[134] C. Purdy, 'Trump Wants to Reshape the US Food Safety System. The Idea is Great, and Terrible.' Quartz (22 June 2018) <https://qz.com/1312336/trumps-proposal-to-take-food-safety-regulation-away-from-the-fda-is-both-a-great-idea-and-a-terrible-idea/> accessed 28 December 2018

Executive Office of the President of the United States, 'Delivering Government Solutions in the 21st Century' (2018) <https://www.whitehouse.gov/wp-content/uploads/2018/06/Government-Reform-and-Reorg-Plan.pdf> accessed 28 December 2018

[135] T. Murse, 'Department of Homeland Security Histrory' (2018) <https://www.thoughtco.com/department-of-homeland-security-4156795> accessed 12 February 2019

FDA and USDA have been carrying out different mandates for so long, while having disputes between each other, that this would inevitably complicate effort to consolidate them.

Not only outsiders, but even food safety inspectors at USDA are worrying about consolidating both agencies into one, by arguing that FDA's program is nowhere as near as rigorous as theirs. One single agency and consolidating inspection functions would weaken their standards. [136]

However, introducing one single food safety agency has some support. In 2008, CSPI released a report advocating for one single food safety agency, with some of the arguments being an improved coordination of food inspections and outbreak response and having one person held accountable for food safety. [137]

In 2015, a bill to create a single food safety agency (S.287/ H.R.609) was introduced by Senator Richard J. Durbin in the Senate and House of Representatives, showing support. The bill establishes the Food Safety Administration as an independent agency to protect the public health by preventing foodborne illness, ensuring the safety of food, improving research on contaminants leading to foodborne illness, and improving security of food from international contamination and for other purposes not be housed at HHS. However, after introducing the bill, there was no progress of this bill.[138]

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[136] R. Nixon, 'Obama Proposes Single Overseer for Food Safety' The New York Times (Washington, 20 February 2015) < https://www.nytimes.com/2015/02/21/us/obama-proposes-single-overseer-for-food-safety.html> accessed 13 February 2019

[137] Center for Science in the Public Interest, 'Should there be a Single Food Safety Agency?' (Powerpoint presentation, 2008) < http://www.afdo.org/Resources/Documents/4-news-and-events/past-presentations/0806101000PlunkettCaseForSingleAgencyJune.pdf> accessed 11 February 2019

[138] L. Zuraw, 'Lawmakers Introduce Bills to Create Single Food Safety Agency' Food Safety News (28 January 2015) https://www.foodsafetynews.com/2015/01/lawmakers-introduce-legislation-to-create-single-food-safety-agency/ accessed 11 February 2019

114th Congress *supra* note 118

Nonetheless, creating one single food agency is a global trend. The consolidation of food-safety authority into one single agency was adopted by Denmark, Ireland, UK and Canada in the 1990s. In 2000s, the European Union, New Zealand and India made the same move. [139]

In an attempt to improve the coordination in certain areas, including produce safety and biotechnology products, the FDA and USDA signed an agreement last year.[140] Giving the chance to FDA's new authorities under FSMA to improve their standards and enhance the nation's food supply, this agreement might seem to be an adequate solution until FSMA is completely implemented. Proper implementation and no major changes, which could lead to chaos, might currently seem best to enhance food safety.

7.2 Recommendations for improved food safety

According to Ryan Talbott, for an enhanced food safety, it would be best to follow through implementation. Since a lot of regulations of FSMA are supposed to have been implemented years ago, the food safety system is already closing in on a decade being behind. As far as the inspection and compliance, Ryan Talbott thinks inspections would be based on risk with a more give and take process: both facilities and FDA must work together for an appropriate implementation. There needs to be cooperation but, on the other side, also a pretty strict enforcement. [141]

FSMA was signed into law to enhance the food safety system. When FSMA would be completely implemented, there is the right balance of cooperation between food facilities and FDA and when FDA gets the financial support needed, it is most likely that this goal of FSMA will be fulfilled, without having reshaped food safety system in the near future.

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[139] C. Purdy *supra* note 134

[140] United States Government Accountability Office, 'Food Safety – High Risk Issue' (n.d.) <https://www.gao.gov/key_issues/food_safety/issue_summary> accessed 12 February 2018

[141] R. Talbott *supra* note 23

Part V: Conclusion

Chapter 8 – Conclusion

The aim of this thesis was to analyse the provisions of inspection and compliance of the FSMA: has these provisions improved food safety in the U.S.? In order to answer this main question, several sub questions have been answered in the chapters, summarized below.

It took some eye-opening, high-profile incidents before the recognition emerged for the need of an enhanced food safety system.[142] To strengthen the food safety system, the Food Safety Modernization Act was signed into law, adopting five key elements with one of them being inspection and compliance. Main provisions of these key elements have increased mandatory inspection frequency of facilities based on classifications of the level of risk by individual facilities, access to records, testing by accredited laboratories and protection of whistle-blowers.[143] After several years, the provisions of inspection and compliance have not all been implemented by the FDA, including failure in classifying high-risk food necessary for frequented inspections based on risk. Last autumn, CFS started a lawsuit against the FDA for 'its failure to designate and establish reporting requirements for producers of foods that are 'high-risk' for food borne illness outbreaks', claiming FDA has not done enough preventing foodborne illness outbreaks. [144]

The number of foodborne illnesses increased during the last years, leaving the long-standing problem of foodborne illnesses ongoing, even after the adoption

[142] D. M. Strauss *supra* note 3, p. 353-354

[143] N. Obolensky *supra* note 45, p. 891-895

[144] *Center for Food Safety and Center for Environmental Health* v *Alex M. Azar II, Secretary of U.S Department of Health and Human Services; Scott Gottlieb, M.D., Commissioner of U.S. Food and Drug Administration and U.S. Department of Health and Human Services supra* note 1

of the FSMA. As claimed by CFS, this increased rate could be caused by the lack of appropriate implementation of FSMA by the FDA. FDA must increase focus in promulgating final regulations and complete actions by mandatory deadlines set by Congress. Despite blaming the FDA, one must consider its circumstances. FSMA promised some major improvements by implementing new regulations, while FDA does not have the available budget to do this in an appropriate way. Scientific advancement, new legislation and new industries are continually increasing FDA's workload, necessitating a proportionate budget increase. Increasing its budget can substantially increase its performance level.[145] Additionally, Trump's administration also plays a role in FDA's performance, with a more relaxed enforcement of FSMA and some major governmental shutdowns during his presidency, including the recent shutdown in December 2018 to January 2019. During this 35-days period, FDA employees were furloughed[146] and routine inspections by the FDA were stopped,[147] resulting the American consumers being vulnerable to food safety incidents.

It is still early days in the implementation phase of FSMA, including the implementation of the specific provisions of inspection and compliance. Therefore, it would be really hard to draw any final conclusions about the link between food safety outbreaks and these specific provisions. Meeting all deadlines set by the FDA, and the fact that the industry knows that they are going to be inspected, is hopefully enough to force the industry to adjust how they are operating and finally reduce the foodborne illness outbreaks. In order to lead things in the right way, FDA has to work hand in hand with the industry

[145] J. Alphonse and others *supra* note 107, p. 57

[146] U.S. Food and Drug Administration, 'Orderly Shutdown Guidance: December 21, 2018' (2018) <https://www.fda.gov/AboutFDA/WorkingatFDA/ucm629208.htm>accessed 30 January 2018

[147] S. Kaplan, 'Government Shutdown Curtails FDA Food Inspections' The New York Times (Washington, 9 January 2019) <https://www.nytimes.com/2019/01/09/health/shutdown-fda-food-inspections.html> accessed 30 January 2019

while not being seen as their nemesis. As Ryan Talbott said: “There needs to be a cooperative process- but not a cooperative process that lets things slide.”[148]

It is of great importance that the not yet implemented provisions and rules will be implemented as soon as possible, before thinking about another major revision of the food safety system. Reshaping (again) the food safety system would mean significant provisions for the FSMA, while the current provisions have not even been implemented yet. It could lead to even more chaos while reposing is of great value now in reaching the final goal: strengthening the food safety system.

[148] R. Talbott *supra* note 23

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