

MPH 622
Research Paper One

Public Health Law and the Food Modernization Act

Jacqueline DiFulvio

MPH 622: Environmental Health Law, Governance, and Justice

"I pledge that I have neither given nor received any aid on this work."

Public Health Law and the Food Modernization Act

Food safety is not a new concern in the world, especially combating foodborne illness. The first foodborne illness death in history has been believed to be Alexander the Great, who is believed to have died from Salmonella poisoning (Jarvie, 2018). The Minnesota Department of Health defines foodborne illness as an illness caused by consuming contaminated food or beverages (Minnesota Department of Health, n.d.). Foodborne illnesses are of concern due to their wide range of symptoms as well as the vast differences in incubation time, the time between exposure and symptom onset, depending on the pathogen (Minnesota Department of Health, n.d.). The Federal government has emphasized the importance of modern laws and regulations to help protect food safety and the best interest of the American people. Countless Americans are fearful of foodborne illnesses and want to believe that food manufacturers and companies are doing their part in protecting their consumers. And when companies are not valuing food health and safety, legal battles arise. To modernize and protect food safety, on January 4, 2011, President Barack Obama signed into the Food Safety Modernization Act (FSMA), giving the Food and Drug Administration (FDA) new authorities.

The FSMA gave the FDA the ability to regulate how foods are grown, harvested, and processed, in turn giving the FDA more power to focus on preventing foodborne illness (U.S. Food and Drug Administration, 2018). Additionally, the FDA website states the following concerning the FSMA:

The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities. (U.S. Food and Drug Administration, 2018).

Within the act comes protections to employees and citizens who speak up to protect food safety. Foodborne illnesses are a major threat to public health, and their threat to society will never end due to mutations and human error, but the FSMA can help steer the United States on a path for preserving public health. This paper addresses some of the successes and challenges the FSMA has faced in recent years within public health law, and how the act continues to make a difference in society.

Current State of Food Safety in Public Health Laws

Congress designed and enacted the Food Safety Modernization Act to combat the increasing threat of foodborne illnesses in the United States. The Centers for Disease Control and Prevention (CDC) estimates that 48 million people get sick each year due to foodborne illnesses, with 128,000 hospitalized and 3,000 dying (Centers for Disease Control and Prevention, 2018). The FDA currently regulates food safety under the Federal Food, Drug, and Cosmetic Act (21 U.S. Code Chapter 27). Additionally, it is important to note that the FDA is responsible for overseeing over 80 percent of the United States' food, minus meat and poultry which is regulated through the U.S. Department of Agriculture (USDA) (Strauss, 2011, p. 354). The FSMA gives the FDA the power to mandate prevention controls, including mandatory prevention controls for food facilities, mandatory produce safety standards, and the authority to prevent intentional contamination (U.S. Food and Drug Administration, 2018). With seven major rules within the FSMA, the FDA has ensured that the safety of food supply is a shared responsibility among multiple points in the global supply chain rather than a single party (Center for Food Safety and Applied Nutrition, 2021a). The act was specifically designed and made to include specific actions at each step of the chain to help prevent contamination and reduce the risk of contamination (Center for Food Safety and Applied Nutrition, 2021a). However, when there are rules and procedures, there will be people and businesses that break them.

Current Legal Issues

Federal and local courts have handled and seen multiple cases related to the Food Safety Modernization Act and protections included within the act, with many of the cases and future cases being grouped into a single category: infringement of whistleblower protections. A whistleblower is defined as one who reveals something covert or who informs against another; an employee who brings wrongdoing by an employer or by other employees to the attention of a government or law enforcement agency (Merriam-Webster, n.d.). Below discusses various whistleblower cases and the rulings that have come out of them.

Infringement of whistleblower protections

The Occupational Safety and Health Administration (OSHA) has a program titled the Whistleblower Protection Program. Within the program, employees are protected from retaliation from their employers for reporting violations of workplace health and safety. This applied directly to the FSMA, as the following is stated within the act:

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). (21 U.S.C. § 399d(a); Legal Information Institute, n.d.).

The FSMA protects employees from unfair treatment. In *Chase v. Brothers Intern. Food Corp.*, Colin Chase, the plaintiff, argues that his former employer, Brothers International Food Corporation, unlawfully fired him after raising food safety concerns (*Chase v. Brothers Intern. Food Corp.*, 3 F. Supp. 3d 49 (W.D.N.Y. 2014)). Brothers International Food Corporation is a large distributor of packaged foods, having hands-on many products made from consumer purchase. As previously stated, food safety is a major public health concern, so this court case directly interacts with public health law. Chase raised two different concerns over the corporations handling of two different food products, and when he refused to sign a non-disclosure agreement without discussing the agreement with an attorney, he was fired (*Chase v. Brothers Intern. Food Corp.*, 3 F. Supp. 3d 49 (W.D.N.Y. 2014)). Chase argued this was in direct violation of his protections under the FSMA and the court agreed, denying the defendant's motion to dismiss the case (*Chase v. Brothers Intern. Food Corp.*, 3 F. Supp. 3d 49 (W.D.N.Y. 2014)).

This case was not the first nor the last time the courts will see a corporation or company under fire for refusing to acknowledge their practices threatened food safety, therefore threatening the health of their customers. Instead, some businesses rather try to remove the employee voicing these concerns, and if the people are not aware of their protected rights, then many more companies will fly under the radar of public health law. The FSMA protection is brought up in cases that even directly related to food safety – in *Alexander v. Pharmerica Logistics Servs., LLC*, Nikki Alexander was terminated from her job as pharmacy director following her obtaining an injury on the job (*Alexander v. Pharmerica Logistic Servs., LLC*, No. 2:20-cv-03389-DCN (D.S.C. Jan. 21, 2021)). Alexander's administration cited the FSMA in that her former company violated the whistleblower provisions within the act, and the case is still open with a ruling pending. And yet another example is seen in *Brown v. Choice Prods., LLC*, where the courts rule to dismiss the defendant's demand for dismissal (*Brown v. Choice Prods., LLC*, 20-cv-046-wmc (W.D. Wis. Feb. 26, 2021)).

Implications for the Future

When it comes to public health and safety, the courts tend to agree with the side that is fighting to protect public health and safety. Food contamination, foodborne illness, and improper handling procedures have happened countless times in the past and will continue to happen countless more times. Under the Food Safety Modernization Act, workers are protected when they raise concerns, but this still does not get to the root of the problem in that businesses and corporations are still mishandling food products. For example, under the FSMA, facilities that handle high-risk foods must be inspected within five years of enactment and no less than three

years afterward, but three years is still a substantial time frame (U.S. Food and Drug Administration, 2018). How many food packages have the potential of being contaminated in a facility within one year, never mind three years? The large gaps in time leave room for error in human handling, thus possibly increasing the risk of malpractice and contamination, potentially leading to an outbreak.

However, there have been benefits and improvements to the food system thanks to the establishment of the FSMA. First, the Federal government has given a clear standing on public health and safety relating to food – they want to protect the people from products that can potentially cause harm. Second, the Act gives the Food and Drug Administration more power; before the FSMA, the FDA could not mandate food recalls and had to rely on the manufacturers to voluntarily recall their products which was no easy task (Center for Food Safety and Applied Nutrition, 2018). Now, the Act gives the FDA the power to enforce recalls of adulterated or misbranded foods, and with no longer having to wait on companies to act themselves, it gives the FDA more power to protect public health and safety.

Furthermore, the food system is expanding past the thought of just food and food products. The FDA passed the Produce Safety rule, which went into effect in 2016. This rule created the first science-based minimum standards for the safe growing and harvesting of fruits and vegetables, food products that can be eaten raw, which includes water quality testing (Center for Food Safety and Applied Nutrition, 2021b). Furthermore, this new rule requires the testing of agricultural water quality for generic *Escherichia coli* (*E. coli*), which is a pathogen known for its association with foodborne illnesses and outbreaks (Rock et al., 2019, p. 4). Testing of water used for agricultural purposes sounds great and makes sense, as contaminated water sources can lead to contaminated food products, but it adds a whole new level to the equation. Businesses needed time to establish plans and practices to meet the new regulation's standards. Along with time, businesses also needed to reevaluate financial plans to count for the new testing. In 2017, the FDA extending compliance dates for this new requirement, giving large farms a deadline of January 26, 2022, small farms January 26, 2023, and very small farms a deadline of January 26, 2024 (Rock et al., 2019, p. 13). The deadline extension may have been viewed as essential from an economic and enforcement viewpoint, but it poses the same issues as mentioned above: how many foodborne illness outbreaks can occur in the meantime?

There is no right answer with how quickly new regulations should be enforced, and there will also be people who argue whatever decision the government makes. At the end of the day, the Food Safety Modernization Act gives the Federal government the blueprint to expand its food protection regulations and to continue to protect the American people.

Conclusions and Personal Reaction

Foodborne illnesses and outbreaks have plagued the human race for years, with plenty of undocumented cases throughout history, and they will continue to circulate within society. The Food Safety Modernization Act was created to protect public health and safety. The goal of the act is to strengthen the food safety system by providing detailed guidelines and procedures while giving the FDA more regulatory power. In an article published at the beginning of the FSMA, Taylor (2011) is hopeful of the new system outlined in the FSMA, describing the act as an investment in science and an opportunity to build a system to protect against foodborne illness outbreaks (p. 18(3)). However, it is almost impossible to predict how this act and its regulations will change in the future, as the worldwide food system continues to change and evolve every day.

Taking my previous and newly gained knowledge of the threat of foodborne illnesses and how the Federal government created the FSMA in the interest of public health and safety, I believe the act will continue to grow and be modified to adapt to an ever-changing food landscape. However, I do believe that with the unknown changes in the future that perhaps the FSMA may become outdated and replaced with a new act that would better address the food system at the time. Regardless, the Federal government will continue to place importance on protecting the American population from easily preventable foodborne illness outbreaks. However, an act that is destined to change is guaranteed to face legal pushback. People do not like change, especially if the change is sudden and drastic. To ensure that the food system is protected, thus meaning that people are protected, education of the changing food landscape is necessary.

Additionally, no matter what changes are to come to both the food system and the FSMA, the act cannot lose its section on protecting people. If companies and businesses are not following the current or new regulations of the act, employees and citizens must continue to be protected for speaking out in public health's best interest. There will be countless other court cases of violations of whistleblower protections, which may come across as time and money, but these cases cannot be dropped. American citizens have the right to fight for their safety, and the FSMA gives the protection people deserve.

References

- Center for Food Safety and Applied Nutrition. (2021a, January 4). *Food Safety Modernization Act (FSMA)*. U.S. Food and Drug Administration. <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>.
- Center for Food Safety and Applied Nutrition. (2018, November 18). *FDA Finalizes Guidance on Mandatory Recall Authority*. U.S. Food and Drug Administration. <https://www.fda.gov/food/cfsan-constituent-updates/fda-finalizes-guidance-mandatory-recall-authority>.
- Center for Food Safety and Applied Nutrition. (2021b, March 10). *FSMA Final Rule on Produce Safety*. U.S. Food and Drug Administration. <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.
- Centers for Disease Control and Prevention. (2018, November 5). *Estimates of Foodborne Illness in the United States*. Centers for Disease Control and Prevention. <https://www.cdc.gov/foodborneburden/index.html>.
- Jarvie, M. (2018, October 4). *History of food safety in the U.S. – part 1*. MSU Extension. https://www.canr.msu.edu/news/history_of_food_safety_in_the_us_part_1.
- Legal Information Institute. (n.d.). *21 U.S. Code § 399d - Employee protections*. Legal Information Institute. <https://www.law.cornell.edu/uscode/text/21/399d>.
- Merriam-Webster. (n.d.). Whistleblower. In *Merriam-Webster.com dictionary*. Retrieved June 21, 2021, from <https://www.merriam-webster.com/dictionary/whistleblower>
- Minnesota Department of Health. (n.d.). *Causes and Symptoms of Foodborne Illness*. Minnesota Department of Health. <https://www.health.state.mn.us/diseases/foodborne/basics.html#:~:text=Foodborne%20illness%20is%20caused%20by,bacteria%2C%20viruses%2C%20and%20parasites>.
- Rock, C. M., Brassill, N., Dery, J. L., Carr, D., McLain, J. E., Bright, K. R., & Gerba, C. P. (2019). Review of water quality criteria for water reuse and risk-based implications for irrigated produce under the FDA Food Safety Modernization Act, produce safety rule. *Environmental research*, 172, 616-629.
- Strauss, D. (2011). An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business. *Food and Drug Law Journal*, 66(3), 353-376. Retrieved June 14, 2021, from <http://www.jstor.org/stable/26661214>.
- Taylor, M. R. (2011). Will the Food Safety Modernization Act help prevent outbreaks of foodborne illness? *New England Journal of Medicine*, 365(9), e18.

U.S. Food and Drug Administration. (2018, January 30). *Background on the FDA Food Safety Modernization Act (FSMA)*. U.S. Food and Drug Administration.
<https://www.fda.gov/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma>.