FOOD SAFETY CULTURE AND TECHNOLOGY ENCHANCE FOOD SAFETY MODERNIZATION ACT

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ABSTRACT

After multiple foodborne illness outbreaks, the government needed to develop a system that would protect the public health and prevent consumers from losing trust in the supply chain. The rules and regulations in place were established nearly a century ago were no longer adequate to address the modern-day problems in the food industry. As a result, in 2011, President Obama implemented the Food Safety Modernization Act (FSMA) that would modernize the outdated rules and regulations to protect public health and consumer's trust in the food supply chain. FSMA shifted the food safety approach of companies from a reactive state to a preventative, which required more inspections, documentations, trainings, and certifications. However, at the end of the day, the efficacy of these regulatory updates relies on the management and employees of food companies and their prioritization of food safety in their daily operations. Thus, establishing a strong food safety culture in a company is vital component to protect public health from foodborne illnesses. Food safety culture is strengthened by educating the management team and employees about the importance of each segment of the company's food safety plan and supplemented with consistent training. Utilization of technology allows for the automation of laborious tasks required by FSMA, such as maintaining records, and also reduces human errors to enhance company's compliance to FSMA.

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CHAPTER 1

INTRODUCTION

The future of the food industry is largely dependent on the food safety culture within the company and in the industry as a whole. Food safety can make an impact in many different aspects of the food industry. The premier aspect of food safety is to provide quality food that is safe for human consumption. Developing and implementing a strong food safety plan protects the consumers from foodborne illnesses and prevents them from losing trust in the supply chain of the food industry. Secondary to human health is societal impacts such as reduction of annual costs associated with foodborne illnesses and reduction of food waste associated with food adulteration and improper sanitation, all of which can put the health and trust of the consumers at risk.

In the early 1900s, Upton Sinclair exposed the filthy, unsanitary environments of slaughterhouses and meat-packing facilities in Chicago that caught the attention of the consumers and federal government. As a result of this appalling revelation, the government responded by enacting the Pure Food and Drug Act (PFDA) and Meat Inspection Act (MIA) in 1906. These two regulations were meant to govern the meat industry to ensure that the food being produced and sold was safe for human consumption. To further protect the health of the public, stricter food safety laws were needed. In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDC), which expanded the power of Food and Drug Administration (FDA) to regulate food

safety. The FDC authorized the FDA to conduct more inspections, determine tolerance levels for toxic substances, and set the required standard for product labeling. Since then, the government has added new regulations and issued amendments to existing laws as the food industry began to shift from small and medium enterprises to large processing facilities.

At the turn of the century, there were multiple foodborne illnesses outbreaks caused by various agents in multiple food types. In 2006, one of the largest and deadliest outbreak in the country affected people from 26 different states resulting in three deaths, 204 illnesses, and 104 hospitalizations. The outbreak was caused by the contamination of *Escherichia coli* O157:H7 (E.coli O157:H7) linked to spinach grown in a California produce farm (Obolensky, 2012). In 2008, following this devasting event were multiple outbreaks caused by Salmonella from different food sources. There was a Salmonella outbreak that was originally associated with tomatoes as the source of contamination, however further investigation traced back the outbreak to jalapenos (2012). Inevitably, the tomato industry suffered a total cost of $200 million due to false accusations (2012). Consequently, another Salmonella outbreak occurred which was linked to peanuts that were processed to peanut butter and incorporated into a wide range of food products. The investigation traced back to Peanut Corporations of America (PCA) processing plants in Georgia. The same plant linked to the outbreak has been inspected by the state officials over nine times between 2006 and 2008 (2012). However, no actions were taken to remedy the conditions and the safety violations noted during inspection. Even worse, some officials of PCA falsified the results of the

microbiological tests of the peanuts that tested positive for Salmonella. Thus, thousands of Americans suffered foodborne illnesses that cost the industry around $1 billion. In response, the US Department of Justice sentenced two officials and one broker of PCA to prison.

CHAPTER 2

FOOD SAFETY MODERNIZATION ACT

The increase in frequency of foodborne illnesses was a major concern for government public health officials and to the consumers. The fact that FDC was nearly 100 years old, thus didn't account for modern day problems, necessitated an update. In an effort to mitigate the occurrence of foodborne illnesses, President Obama signed into law the Food Safety Modernization Act in 2011 (Schneider, 2011). Food Safety Modernization Act (FSMA) shifted the food safety strategy of companies from being reactive to foodborne illness outbreaks to being preventative of outbreaks to occur (2011). This law required food companies to develop and implement formal written and documented food safety plans, and obligated more trainings for their employees (Obolensky, 2012). Prior to FSMA, Hazard Analysis Critical Control Point (HACCP) was the most commonly utilized food safety paradigm to protect public health from foodborne illnesses. Upon enactment of FSMA, food safety plans required not only the inclusion of concepts of HACCP plans, but formally added new elements to ensure a more holistic approach to food safety. FSMA requires preventative controls (e.g. process controls, sanitation, allergen, and supply chain), process monitoring, corrective actions, verifications procedures, a recall plan, and training, including a trained Preventative Control Qualified Individual (PCQI) with responsibility for overseeing the food safety plan (2012). These requirements need to be accompanied with proper documentation to demonstrate successful implementation of the written plan.

1. Preventative Controls

    In 1972, some in the food industry adopted a systematic approach to hazard identification, assessment of risks, and control from the National Aeronautics and Space Administration (NASA). This systematic approach was known as Hazard Analysis Critical Control Point (HACCP) and was the system used to analyze the different stages of production and identify where sources of contamination could be introduced during processing. The implementation of FSMA in 2011 required food companies to revamp their HACCP plan to become HARPC compliant, which is Hazard Analysis Risk-Based Preventative Control (FDA, 2019). HARPC requires facilities to evaluate potential hazards, monitor performance of the controls, and maintain records of monitoring. The hazards to be analyzed at every step of the production when building food safety plans are biological, chemical, and physical hazards. In addition, radiological hazards, natural toxins, pesticides, drug residues, allergens, parasites, unapproved food and color additives, and any naturally occurring and unintentionally introduced hazards need to be identified and noted as part of the food safety plan (FDA, 2019). For every hazard identified, there must be a control put in place to minimize or eliminate the likelihood of that hazard from affecting the product unsafe for human consumption. The food safety plan and the records of monitoring will then be presented to FDA officials during inspections of the facility.

2. Recalls

As stated in the Code of Federal Regulations, Title 21, Section 7 (21 CFR 7), recall is an action that manufacturers and distributors are must undertake to protect the public health from products that present a “risk of injury or gross deception or are otherwise defective.” Thus, FSMA requires manufacturers and distributors to have a written recall plan for any product for which a hazard has been identified. The recall strategy should address these topics:

- Depth of the Recall. This component addresses who among the consumers need to return the product and at what part of the distribution chain did the product reach.
- Public Warnings. The recall plan needs to include a strategy of how to notify the public if a recall is needed. Although not every recall must be accompanied with a public warning, depending on the severity of the situation.
- Effectiveness Checks. This component is to ensure that the recall strategy can account for all the contaminated product shipped out and all the contaminated product that was returned and/or destroyed as part of the recall. This is a way to assess the effectiveness of a recall plan to remove potentially hazardous food from the market.
- Disposal of Product. When a recall is issued, the recall plan must also include the procedures to be taken with the product that is recalled, whether the product gets reconditioned or salvaged.

Recalls are rather expensive for companies to execute, which may deter them to conduct when needed, as it is voluntary. In order to prevent foods not safe for human consumption to reach the market, FSMA grants the FDA authority to make decisions on the spot if the facility's production environment is deemed unfit to produce safe and quality food, such as mandating a recall (Schneider, 2011). Other authorities granted by FSMA to the FDA are expanded administrative detention, suspension of registration, enhanced product tracing abilities, and additional recordkeeping for high-risk foods (2011). The FDA also has the authority to cease distribution order to any producer and/or distributor if the FDA determines there is a reasonable probability of food adulteration or misbranding.

3. Documentation

Proper documentation is necessary to be in compliance with FSMA. Companies need proof that the food safety plans are being followed. While often a daunting task for manufacturers and distributors, FDA officials are strict with records that prove the products are safe for human consumption. These documents are signed off by certified employees of the companies who have received the appropriate trainings to ensure proper steps are followed during processing to prevent contamination.

4. Imported Food Safety

The FDA estimates that fifteen percent of the total U.S food supply is imported, including 50% of fresh fruits, 20% of fresh vegetables, and 80% of

seafood (Obolensky, 2012). In order to regulate the safety of the food imported into the US from different countries, the Foreign Supplier Verification Act (FSVA) was established. The FDA enacted this law to verify that the foreign suppliers are producing food in a manner that provides the same level of public health protection as the preventative controls or produce safety regulations, as appropriate. FSVA also ensures that the supplier's food is not adulterated and is not misbranded with respect to allergen labeling. FSVA required importers to perform certain risk-based activities to verify that the food imported into the U.S. has been produced in a manner that meets the U.S. safety standard. An industry-recognized program to support the FSVA is Global Food Safety Initiative (GFSI) which is established and managed by the international trade association. While the GFSI is not part of FSMA, the main goal of GFSI is to "harmonize food safety standards across differing national food safety regulations" (Percy, 2011).

5. Enhanced Partnerships

In order to protect consumers from foodborne illnesses, the governing body for food safety has to be expanded to other sectors of the government. Under the FSMA regulation, the FDA is required to consult with other agencies, such as the Department of Health and Human Services, the Department of Homeland Security, and foreign government agencies (FDA, 2019). The enhanced partnerships permitted by the FSMA regulation provides a more holistic approach in protecting the public from foodborne outbreaks.

The implementation of FSMA was an immense step forward in the food industry to protect the public health from foodborne illnesses. After multiple outbreaks, the consumers were starting to lose trust with the food supply chain. Consumers needed reassurance that the food they purchase at retail stores and restaurants were safe to consume. In response, President Obama implemented a law that will revitalize the regulations within the food industry, enforcing food manufacturers to abide to stricter rules that aim to reduce foodborne outbreaks. The implementation of FSMA, however, is just one segment of improving food manufacturing and processing. Compliance to the law can only be proven during audits, which often occurs annually while some companies opt self-audit their facilities multiple times each year. Compliance to FSMA, solely, does not guarantee safe quality foods. In addition to compliance, companies should adopt and establish a strong food safety culture. In doing so, management and employees will embody food safety practices that will result in safer, higher quality foods, and more importantly, less recalls. Establishing a strong food safety culture within the company is another component in efforts to protecting the consumers from foodborne illnesses.

CHAPTER 3

FOOD SAFETY CULTURE

The Food Safety and Modernization Act strives to serve as a guideline for food companies to produce safe quality foods for human consumption. FSMA requires employees to receive more training and certifications on proper food handling for processing of foods. Consequently, some companies in the food supply chain require supplier companies to go through third-party audits as another verification that the food they are selling are produced under plans that are designed and executed to protect public health. However, stricter regulations and higher standards of distributors are only one aspect of food safety.

In 2007, a study was conducted on food safety and food hygiene training in commercial sector. The study concluded that approximately 97% of all food service-related illnesses could be traced back to employees improperly handling food (Egan et al., 2006). While this study was prior to the enactment of FSMA, it is important to note that there were still regulations in place to address Good Manufacturing Practices (GMPs) and HACCP for producers, and the Food Code for retailers (2006). Though these regulations were in place at the time, 97% of foodborne illnesses are still traced back to employees as the source of contamination, which suggested that regulation alone was inadequate to protect public health from foodborne illnesses. Proper education and training of employees are needed to prevent food contamination.

Food safety plans require a combination of proper education, training of employees, and an understanding of the importance of food safety to protect consumer health. Education is defined as the learning of the theory and information about a subject while training provides employees experience and skills through application of theoretical knowledge gained from education (Tracey & Cardenas, 1996). Communication is an integral part when educating employees. It is important to consider the level of employees' education to ensure they understand the main idea and the goal of the training they are receiving. A strong foundation in education and training about food safety should translate to employees having better perceptions of the importance of food safety to protect public health (Powell et al., 2011). Thus, it is ideal for companies to have certain incentives, whether it be low-value gifts such as gift cards or a bonus to their monthly salary, to motivate employees to do the best they can in preventing food contamination. By doing so, employees in food production and processing would claim the responsibility as the first line of defense in preventing foodborne outbreaks.

A combination of both comprehensive education and intuitive training sessions provide employees a better understanding of what it takes to produce safe quality foods (Grover, Chopra, and Mosher, 2016). Providing knowledge without training will not translate to employees properly executing the knowledge they learned. The food safety culture embodied by the management and employees of the company is the overarching defense to pathogen contamination in a processing facility (Grover et al., 2016).

Above all of the regulations, trainings, and certification requirements to mitigate foodborne illness, it is the food safety culture within each company that will truly make a difference in producing safe quality foods. A strong food safety culture needs to be established within a company to change the way employees work and improve food safety performance (Jespersen, Griffiths, and Wallace, 2017). Food safety culture is defined as "a behavior-based food safety management system, that has a foundation in the scientific knowledge of human behavior as well as organizational culture and food safety" (Neal, Binkley, and Henroid, 2012). Organizational culture, such as food safety culture, is shared from top-to-bottom of the hierarchal structure within the company. Food safety culture has to be embodied by all employees of the company, not just by the management or just by the front-line employees alone.

Education and training serve as the foundation for employees' understanding of food safety. However, communication is vital in order to convey the ultimate message of the importance of food safety. The education program should begin with a pre-assessment of each employee to find out what they currently know about food safety practices (Charalambous et al., 2015). In doing so, the management will be able to better tailor the education and training program to the level in which all of the employees will understand and comprehend. For example, while microbiology plays an integral part in understanding characteristics of pathogens, it may be that not all employees have background in microbiology. Thus, it is ideal for the education program to also include information about the pathogens of concern for the products being produced and how

the different processing steps addresses these pathogens to mitigate its growth and proliferation.

Frank Yiannis described food safety culture as “how and what the employees in a company or organization think about food safety…behaviors employees routinely practice and demonstrate” (Yiannas, 2008). In order for employees to think progressively about food safety, they must understand the reason behind the daily tasks they execute on the processing floor which can be done by providing employees comprehensive education on food safety. Education provided by the management, as for an example, should consist of more than just the need to wash their hands frequently. Rather, in addition to reminding employees to wash their hands, companies should also educate employees on the reasons why they should do so (e.g. most contamination occur through hand-to-hand) (2008). Further, education on food safety should be more than just informing employees about the different chemicals to use to sanitize various equipment. It is also important to include the reasons why there are specifications for the concentrations of different cleaning chemicals as these concentrations show the highest effectiveness cleaning and sanitizing (2008). Moreover, employees should learn why certain sanitizing chemicals are not effective for all types of pathogens and how they are designed to kill only certain types of pathogens.

Consequently, there are specific parameters set at different stages of production. Thus, the message that should be communicated to employees concerning these parameters are the potential outbreak that could result if parameters are not met. For example, one of the most important steps in milk processing is the pasteurization step

which reduces the bacterial load in milk. Effectiveness of pasteurization is dependent on time and temperature. The education should be more than just relaying the message of the different time and temperature requirements (Charalambrous et al., 2015). Employees should also understand the reason behind the set parameters (e.g. per Pasteurized Milk Ordinance (PMO), High Temperature Short Time (HTST) pasteurization of raw milk requires to reach 161°F for at least 15 seconds to reduce the bacterial load such as *Listeria monocytogenes* in the product). Yiannis emphasized that education about food safety should be "more than just the topic of the month" (Yiannas, 2008). Rather, food safety education should be embodied by every employee of the company.

Furthermore, as employees understand the theoretical aspects of food safety, it is imperative for them to apply their knowledge into practice. An intuitive training program is the next step to developing a strong food safety culture. All processing plants are different. Plants will vary depending on the product being produced, the method of production, their geographic locations, the education of employees, and the risks associated with these variables. Therefore, the training of the employees should be a continuation of the education program provided by the company. The training should be tailored to the layout of individual processing plants. While the concept of food safety remain universal across different processing plants, the procedures to ensure food safety within each processing plant will vary. Thus, it is important for the management to provide employees the proper training to ensure practices executed by the employees are in line with the food safety plan of the company.

A strong food safety culture within a company is crucial to produce safe quality foods because ideally it will be the driving factor that motivates employees to learn and execute the proper food safety behaviors (Jespersen et al., 2017). Through such culture, employees will have a sense of belonging within an organization that prioritize food safety. Employees working together have the same attitude and beliefs concerning a practice (Jespersen et al., 2017). Therefore, there is a higher chance of conformity amongst co-workers as they execute their daily routine on the processing floor (Jespersen et al., 2017). Often, within companies that have a weak food safety culture, the conformity of the standards is sub-par to the food safety standards established by management. As a result, it is imperative to establish a strong food safety culture within an organization to ensure that the standards employees abide to are up to par with the standards that will result in producing safe quality foods for human consumption.

CHAPTER 4

SUPPLEMENTAL WORKSHOPS, SEMINARS, AND CERTIFICATION CLASSES

Workshops, seminars, and certification classes are offered by extension agents from land grant universities and third-party organizations to assist companies build their food safety plans. FSMA may seem daunting to the management and employees of the production facilities because of the many rules and regulations. While larger companies have the ability to hire employees, specifically managers and supervisors, with tremendous experience in food safety, small to mid-size producers are often limited by resources. More importantly, larger corporations have the budget to provide education and training to their employees that small to mid-size companies lack thereof. Thus, small to mid-size companies are at a disadvantage when it comes to understanding and implementing FSMA requirements.

A major challenge for the management and employees of food companies is how to get started on their food safety plan. Another concern is determining the various limits and requirements needed to be met to ensure the food produced is safe for human consumption. A prime example is artisan cheese makers. The layout design of each artisan cheese processing facility will vary across cheesemakers and their procedures of manufacturing cheese will also differ greatly. Thus, each of their food safety plan will not resemble the other and therefore may have different processing limits at different stages of production. These small cheesemakers, whether they are owners or employees, are in search of consultation from industry experts on best practices and

procedures to ensure that their food safety plan are not only in compliance with FSMA, but effective given their resources. More importantly, processing facilities will greatly depend on their food safety plan to prevent recalls or outbreaks that will put the brand of the company at risk.

In order to alleviate the overwhelming experience employees may face when building their food safety plans, workshops are held to assists with establishing the company's food safety plan. Through these workshops, employees are able to ask industry experts about specific questions they may have concerning their unique food safety plan. These workshops allow employees to work through the various steps of their processing with the guidance of well-versed food safety instructors. As a result, the attendees of these workshops gain a holistic understanding of the requirements of FSMA and more importantly, gain confidence in building their food safety plan that will then be implemented in their facilities. With a better understanding of the reason behind each step of processing and the limitations/requirements set at those steps, employees are better equipped in sharing their knowledge to the rest of their company.

As part of the FSMA regulation, companies are required to show employees have been appropriately trained for the tasks or positions they are responsible for in the facility. Certifications are often used to show that employees have received the proper food safety training. Certification classes allow employees to gain more knowledge about food safety and help them gain more confidence in building and abiding to food safety plans. Different certifications include Preventative Control Qualified Individual (PCQI), HACCP certification, and Safe Quality Foods (SQF) certification. 21 CFR

117.18 Subpart C of FSMA requires all processing facilities to have at least one employee that is PCQI certified to prepare the food safety plan, validate the preventative controls, review the records, and reanalyze the food safety plan in place for any updates needed. In addition, juice and seafood processing facilities are required to have at least one employee that is HACCP certified. While not required by the FSMA regulations, companies can hire third-party SQF auditors or have an employee get certified as an SQF auditor to prepare reports detailing quality, safety, and product issues. SQF auditors can also assist in correcting product and safety defects as well as collaborate with in-house employees to improve new and existing products.

Workshop/Certification Courses at Cornell University

As part of the extension program, Cornell University offers various workshops and certification courses to assist producers and processing facilities meet the requirements of FSMA. The courses are tailored for different segments of the food industry which includes fruits and vegetables, dairy, food manufacturing, packing, and processing. Ultimately, there are also regulatory certification classes that includes PCQI and GMPs.

<u>Fruits and Vegetables</u>

a. Good Agriculture Practices (GAP)
    i. This course is in collaboration with third-party, e.g. USDA, Primus, Global GAP, and is intended to assist employees of fresh produce farms to assess risks and implement practices to reduce hazards

by understanding GAPs. Completion of the course results in GAP certification of the attendee's farm.

b. Produce Safety Alliance (PSA) Grower Training

    i. Section 112.22 (c) of Title 21 in the Code of Federal Regulations requires at least one supervisor or responsible party of the farm to receive training for food safety that is equivalent to that of the curriculum recognized as adequate by the FDA. This course fulfills the requirement to satisfy the FSMA Produce Rule requirement.

<u>Dairy Foods</u>

a. HACCP/Food Safety Plans/SQF

    i. This course is to enhance HACCP and other food safety systems by providing an extensive training on building HACCP based foods safety plans for dairy operations that is also applicable to juice and other foods. This program also meets the core requirements of the National Conference of Interstate Milk Shipments (NCIMS) Voluntary HACCP program for Grade "A" Dairy processors.

b. Dairy Science and Sanitation

    i. This workshop educates dairy processing personnel on the composition of milk, dairy microbiology, dairy food safety, and provides an overview of the dairy regulations. Participants gain a

basic understanding of the principles of dairy science, safety, and sanitation that should be applied to their processing facilities.

c. HTST Pasteurizer Operator Workshop

    i. The workshop is beneficial for pasteurizer operators as well as Quality Assurance/Quality Control and maintenance personnel as it encompasses different required regulatory tests for HTST pasteurizers and provides hands-on activities to meet training requirements for performing HTST system testing under the NY State Broken Seal Policy.

d. Dairy Product Workshops

    i. There are various dairy product workshops that covers the Science of Cheese Making and Vat Pasteurization and Science of Yogurt and Fermented Dairy Products. These workshops are offered from beginners to advanced skill levels to assist manufacturers interested in adding a new product line to their facility or improving their current product quality.

<u>Regulatory</u>

a. Preventative Control Qualified Individual (PCQI)

    i. Cornell Extension offers workshops for interested individuals to be PCQI certified. This workshop is through the Food Safety Preventative Controls Alliance and Association of Food and Drug Officials (AFDO).

Food Manufacturing, Packing, and Processing

a. This program is to provide assistance to ensure safety and stability of food products entering the supply chain. Various assistance includes lab analysis for pH levels, water activity, and Brix of food and beverage products. The program also offers process authority and scheduled process for product review, documentation, and process validation.
b. Processors of low-acid or acidified foods must operate with a certified supervisor present at all times during processing. Under this program, the Better Process Control School allows supervisors to be certified for thermal processing systems, acidification, and container closure evaluation programs for low-acid and acidified canned foods.

CHAPTER 5

UTILIZATION OF TECHNOLOGY FOR COMPLIANCE TO FSMA

The Food Safety Modernization Act requires more monitoring and documentations at each stages of production. Companies that produces many different products may opt to utilize software management systems to reduce the manual tasks of record-keeping to remain in compliance with FSMA. Different technologies have emerged to automate record-keeping that encompasses supplier compliance, risk management, and processing controls such as monitoring time and temperature of different equipment when producing certain products.

Appropriate and complete documentation can be hard to maintain, especially for small and medium enterprises, as most of their record-keeping is done manually. However, while manual record-keeping is often labor intensive in many cases, it is a more cost-effective option especially for small and medium enterprises as automation will often require a purchase of new equipment, more training to the employees, and introduce a learning curve for all (Kelepouris, Pramatari, and Doukidis, 2007).

While automation is making a positive impact within the food industry, it is important to note that currently larger companies are the ones most able to take full advantage of these emerging technologies. Often, implementation of such technologies requires large investment in which small and medium companies are unable to afford.

Amongst the technologies available today are software such as enterprise resource planning (ERP) and quality management systems (QMS). These two systems

have different functionalities but can be integrated to build a more efficient production management system. The goal of ERP systems is to streamline business operations through automation and consolidation of business data into one single source. The data refers to business functions such as planning, purchasing, inventory, sales, marketing, finance, and human resources. Examples of ERP systems are NetSuite, Microsoft Dynamics, ADP, and Sage. In contrary, QMS is a system that helps to design and manage quality activities that allows quality team to set policies, processes, and procedures required for planning and executing all of the business functions from research and development, stages of production, and customer service. Each system provides its own unique functionalities depending on the nature and requirements of the companies to remain in compliance with FSMA.

Examples of Quality Management Systems

a. SafetyChain – helps food and beverage companies improve productivity, profitability, and compliance with a flexible, user-friendly software platform that captures, manages, and analyzes real-time operations data. Functions integrated into the platform include:
    i. Food Safety Software – data collection, audit, and compliance software solution that leverages mobile data collection and program automation to make it faster and easier for food and beverage companies to comply with regulatory, non-regulatory (GFSI), and customer requirements.

ii. Supplier Compliance Software – combines robust requirements management at the supplier and item level with user-friendly portals, communication tools and powerful analytics to help food and beverage companies improve supplier onboarding, compliance, and risk management.

b. Jolt – automates and records the most vital forms, tasks, and temperatures through:

i. Active measuring – use checklists and temperature probes to monitor products and store all vital forms in the software for easy access and completion.

ii. Passive monitoring - Wirelessly and accurately measure temperatures and humidity of sensitive environments continuously and notifies personnel of any inconsistencies.

c. FoodLogiQ Connect - Allows food companies to efficiently manage their supply chain, capture all the data needed for a transparent and FSMA-compliant supply chain, and records critical tracking events to achieve real end-to-end traceability to quickly identify and address food safety issues

i. Real-time food supply chain visualization – allow for lot-level traceability to cut the costs of resolving recalls

ii. Recall and response – initiate a recall or stock withdrawal across all locations simultaneously using email, phone, and text. Monitor responses and completion of actions through live dashboards.

Technology can make a positive impact in the food industry in many different ways. The accuracy of records can be improved as the proclivity for human errors will be reduced through automated tracking (Kamath, 2018). More importantly, the records will be collected at the exact time the system is programmed to record instead of depending on an employee to make his or her rounds to record data (Kamath, 2018).

Being able to remove the laborious tasks of record-keeping will improve the daily routine of employees (Sparling and Sterling, 2004). Reducing the traffic flow of daily tasks results in careful implementation of controls such as labeling for allergens (2004). Consequently, monitoring the different steps of processing becomes easier for the employees and more reliable for the processing facility as the system will alert employees for any anomaly from the control parameters programmed in their food safety plan (Kelepouris et al., 2017). Ultimately, technology can improve the food safety culture of the company by alleviating the reliance on employees to produce safe quality foods.

Improved tracking technologies will help reduce response time to outbreaks and initiate faster product recalls, while also reducing waste. An established food safety culture that is in compliance with the stricter regulations of FSMA is the first line of defense in protecting the consumers from foodborne illnesses. While the risk of outbreaks to occur is decreased, there is still a potential for illnesses to occur. With the current system in place, it takes the federal and state officials an average of two weeks to trace the contamination from its source due to the current method used in the industry to trace product origins, which is the one up-one down method (Kamath, 2018).

Technology can also make an impact in improving recalls by storing the data collected in processing facilities in a centralized or decentralized (e.g. blockchain) database. Integration of data collected starting from the origin of the food to when the food gets to retail allows for a more efficient and faster recall process. Instead of having to go through multiple records from the processing supply chain (e.g. one up-one down method), an integrated database can reduce the time it takes to analyze the records (Kamath, 2018). A system as such can provide a more accurate way of tracing the point of contamination. As a result, it can prevent or reduce the risk of more people getting contaminated when there is an outbreak. More importantly, improvement in traceability can also reduce the amount of food that goes to landfill due to food contamination as the automated record keeping has the potential to pinpoint the specific foods that are contaminated and only those that are identified will be sent to landfill (Sparling and Sterling, 2004). Today, consumers are throwing away any implicated products that bare resemblance to the product recalled even though the product in their home was not part of the batch recalled because current methods are unable to pinpoint the contaminated products.

An effective food safety system requires the entire industry to be integrated no matter the size of the company. Integration of data from different companies is imperative in order to have an efficient way to recall products if deemed unsafe for human consumption. An integrated system allows for faster recall which saves the industry money and prevents losing consumer's trust in the supply chain (Sparling and Sterling, 2004).

CHAPTER 6

INTERNSHIP AT EMMY'S ORGANICS

The deadline for businesses to be compliant with the requirements of FSMA was dependent on the size of the business (e.g. number of employees), total annual revenue, and the type of product being produced (e.g. human food, animal feed, or produce). Companies with 500 employees or more were required to be incompliance with FSMA within one year of the date of final rule which was 2015. According to the FDA FSMA Compliance Dates, companies considered to be very small to small business, i.e. companies with less than 500 employees or a total annual revenue of less than $1 million had a deadline of until 2018 with a potential to extend until 2020 (FDA, 2019).

While the number of large production facilities increases, the majority of the food in the market still originates from small and medium enterprises. For large production facilities, it is easier for them to establish their food safety plans for they have more resources and funding to make the transition of their food safety plans to be more preventative. However, as recognized by the FDA, the small and medium enterprises are limited with funding and resources to establish a thorough food safety plan.

In order to further assist the small and medium enterprises in building their food safety plan, the FDA developed a software program that provide assistance to companies. Food Safety Builder is a great tool as it provides the framework of building a food safety plan. The software guides the user step by step in developing a plan that are specific to their facilities to be in compliance with 21 CFR Part 117 which includes:

current good manufacturing practices, Hazard Analysis, and Risk-Based Preventative Controls for Human Food regulation.

As an intern at Emmy's Organics, I had the opportunity to utilize the Food Safety Builder to update the food safety plan of the company. Emmy's Organics is a local startup company in Ithaca, New York that produces organic coconut cookies. The humble beginnings of the company started with less than ten employees producing delicious and healthy snacks in a small house kitchen. The founders started selling their cookies at different markets in Ithaca. The weekly farmer's market served as their main customer pipeline. Overtime the company gained traction and started selling their products at stores such as Starbucks, Wegmans, CVS, and Walmart. As of 2019, Emmy's is producing around 100,000 cookies per day in a local facility and have started to outsource some of the production to meet the increasing demand.

As their net sales continue to increase exponentially, it is imperative for the company to update the food safety plan to ensure they are in compliance with the rules and regulations of FSMA. The Food Safety Builder provided by the FDA was used as a starting point in updating the company's food safety plan. While the resource served as a guideline to assist in building the plan, there were some areas where further work was needed to ensure compliance with the regulations.

As an intern, one the difficulties encountered throughout the process was finding reliable resources that were specific to such an operation as Emmy's. For example, I had a hard time determining the preventative controls for the production of the cookies as it did not have a kill step at any point of processing since the cooking are not baked

but rather dehydrated. After inquiring with extension agents at Cornell University, industry expert suggested that the preventative controls for the products included supply chain controls that encompassed proper documentations of the suppliers, documentations for receiving the ingredients from suppliers, as well as a robust sanitation and allergen controls within Emmy's to prevent potential cross-contamination from the environment and cross-contact between unique allergens.

Thus, I obtained the updated documentations from suppliers, such as third party food safety audit reports, to ensure that the ingredients received for production of cookies are safe to consume. With the help of my supervisor, we then created procedures to confirm that the ingredients and suppliers producing them passed the quality and food safety inspections. I also developed sanitation procedures to ensure that the equipment and the facility is cleaned properly before and after operations, thus controlling for cross-contamination and cross-contact risks. Lastly, as the company develop new flavors or seasonal products, I checked that the allergens are properly labeled.

Emmy's Organics has strived to establish and maintain a strong food safety culture. The employees are provided with quality training that not only described what steps are needed to be done to prevent contamination, but the training also expressed the importance of each step to produce safe quality foods. The training was provided by the Food Safety Manager and Vice President of Manufacturing of the company. As a result, the employees remain cognizant of food safety throughout their daily routine and are able to report any anomaly within the production that may deem the product unsafe

for human consumption. This internship provided me an insight of the challenges of implementing food safety plans within smaller companies. Emmy's Organics is a prime example of a company successfully rising to the challenge of not only driving food safety culture but building an internal culture that truly values the importance of their work in protecting public health and delivering delicious cookies that delight consumers.

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