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# FOOD SAFETY MODERNIZATION ACT (FSMA): IMPLEMENTATION AND BEST PRACTICES

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# ABSTRACT

The purpose of this legislative summary and analysis of the 2011 Food Safety Modernization Act (FSMA) is to outline best practices for its implementation in companies engaging in the sale of final goods for human consumption. The best practices were identified through the consideration of compliance with the regulations, cost-effectiveness of implementation, and guaranteeing food safety.

Foodborne illness currently affects one in six Americans annually, making food safety a significant issue of national concern (Overview FSMA, 2015). Information on the nature and requirements of the act, as well as its impact on relevant businesses, is discussed through the application of academic research. Two major companies in the food industry were interviewed firsthand regarding their experience implementing FSMA, with topics of discussion ranging from physical execution to present and future challenges. Furthermore, a case study on the 2015 Chipotle Mexican Grill E. coli outbreak was conducted to further understand the challenges of food safety and its potential repercussions.

In summary, the following subjects were identified as critical components in ensuring food quality and safety: comprehensive and effective preventive controls, with emphasis on security and accountability; strong supplier relations, with a bilateral commitment to honesty, safety and openness; safe and well-monitored transport of raw materials and finished products; and a swift and efficient response network in the event of a necessary recall.

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# Chapter 1

## Introduction

Foodborne illness in the United States affects about one in six Americans annually, resulting in about 128,000 hospitalizations, 48 million sick and 3,000 deaths, according to recent data from the Centers for Disease Control and Prevention. These are afflictions that generally can be easily prevented. The Food and Drug Administration (FDA) is responsible for promoting the health and well being of the United States by setting standards and regulations for the production, distribution and sale of food, drugs and cosmetics. FDA regulations to monitor food quality have historically been focused on manufacturing facilities. However, on January 4th, 2011 President Barack Obama signed into law a major piece of reform legislation that placed more stringent requirements on transportation carriers and distribution centers. Thus, the Food Safety Modernization Act (FSMA) was born. The purpose of this act was to place a heavier emphasis on the prevention of food contamination, rather than the response to it (Overview FSMA, 2015).

The Food Safety Modernization Act includes five key features: Preventive Controls, Inspection and Compliance, Imported Food Safety, Response, and Enhanced Partnerships. Its implementation is still ongoing and shaping the future of the food industry. The purpose of this paper is to identify best practices in the implementation of the Food Safety Modernization Act, which most successfully achieve the act's purpose (food quality and safety), while remaining practical and cost-effective for the company. The focus will be on companies using or selling food as its final product, such as restaurants and retail chains. An interview guide was prepared

to research how various companies are employing these new requirements, with the goal of discovering what is working well and what can be improved on. The findings from this research, partnered with case studies on events such as the 2015 Chipotle E. coli outbreak, led to the resulting best practices identified in this paper.

# Chapter 2

## Methodology

In order to provide valuable and meaningful recommendations for the implementation of the Food Safety Modernization Act, it was important to gain a complete understanding of both the history of food regulation and the components of the act itself. Secondary sources, primarily from governmental agencies such as the FDA, were used for this background research. Detailed information on the progression of food safety regulation, culminating in a discussion on the components and consequences of FSMA itself, can be found in Chapter 3.

A case study on the recent 2015 Chipotle E. coli outbreak was conducted to further understand the challenges of food safety. Key lessons and takeaways from these events were incorporated into the best practices and recommendations section of this paper, as well as utilized in preparation for interviews with two companies.

Based on this initial research, an interview guide was prepared to further explore the impact of the Food Safety Modernization Act in practice through primary research. The complete interview guide can be found in Appendix A. The interview guide was prepared to address pre-FSMA conditions, the implementation of FSMA, the successes and challenges of FSMA, and best practices. Two major companies in the food industry, to remain anonymous, were selected for interviewing. These firms were selected because of their broad experience with issues in food safety. They procure, produce, package, distribute, and sell food products. Because these companies are actively in contact with food throughout the entire supply chain, there was endless possibility for discussion.

The findings from secondary research, case studies, and first-hand interviews are summarized in Chapter 6 – Best Practices.

# Chapter 3

## Background: Food Safety Modernization Act

### History of Food Safety Regulation

Prior to the enactment of the Food Safety Modernization Act, food safety regulations were historically focused on reactive measures, rather than preventative. According to Darin Detwiler, a senior policy coordinator for the advocacy group STOP Foodborne Illness: "Up until now, everything has been reactive. This is the most sweeping food regulation passed within the last 70 years" (FDA Consumer Updates, 2015).

The modern era of the FDA as a law enforcement organization began in 1906 with the Pure Food and Drug Act (which would later be expanded and revised.) Upton Sinclair's *The Jungle* also prompted the passing of the Meat Inspection Act that year, due to the book's details on the unsanitary conditions of a meatpacking house in Chicago. The majority of regulations over the next several decades pertained to drugs, label requirements, and quality standards.

A major precursor to FSMA was the introduction of hazard analysis and critical control points (HACCP) in 1997, the creation of which was sparked by an E. coli outbreak. HACCP shifted food safety and inspection from a "sight, smell and touch" approach to more science based in nature (HACCP Principles, 2014). HACCP required: assessment and identification of potential hazards in food from farm to table, determination of critical control points to control these identified hazards, and establishment of a system to monitor these control points (HACCP Principles, 2014). However, HACCP was not mandatory; it was more of a recommendation.

Over the years, many companies began to practice HACCP on their own, but there was no way to enforce its recommendations. Smaller companies, with less resources, often ignored various HACCP provisions.

In 2005, the Sanitary Food Transportation Act (SFTA) was passed, giving the FDA authority to regulate the sanitary transportation of food. Various safeguards that SFTA envisioned are incorporated in FSMA under Sanitary Transportation (Final Rule on Sanitary Transportation, 2016).

However, even after a century as a law enforcement body, the FDA has been largely unsuccessful in containing foodborne illness in the United States. In recent years, the Center for Disease Control and Prevention (CDC) has been able to identify the contaminated ingredients in fewer than half of all multistate outbreaks. There are still 128,000 hospitalizations and 3,000 deaths annually in the United States due to foodborne illness (Burden of Foodborne Illness, 2016). FSMA seeks to more aggressively combat this issue.

The Food Safety Modernization Act is the culmination of over a century of food safety regulation. FSMA is significant for three reasons: 1) it incorporates the diverse concerns, rules and guidelines developed by the FDA since its establishment into a single far-reaching piece of legislation; 2) FSMA requires what HACCP had only recommended; and 3) it expands the FDA's authority to step in during issues of food safety.

**Fundamental Elements of FSMA**

The Food Safety Modernization Act was signed into law on January 4th, 2011 by President Barack Obama. As of April 2017, it is still in the process of being implemented, with some aspects having compliance dates into 2019.

FSMA has five major elements, which represent the areas in food safety that the act seeks to improve, monitor and regulate. These five elements include: Preventive Controls, Inspection and Compliance, Imported Food Safety, Response and Enhanced Partnerships.

*Preventive Controls*:

These are steps taken to prevent or significantly minimize the likelihood of food safety issues arising in a company. The object is to identify and combat an issue before it occurs.

*Inspection and Compliance*:

The industry is held accountable through mandated inspections, increased record keeping, accountability procedures and potentially severe consequences for noncompliance (Overview FSMA, 2015).

*Imported Food Safety*:

This goal seeks to ensure that imported food meets U.S. standards. Importers are responsible for ensuring this from foreign suppliers by auditing their facilities for compliance with U.S. safety standards and proving that the supplier has satisfactory preventive controls in place (Overview FSMA, 2015).

*Response*:

In the event that a food safety issue occurs, it is important that the response is swift and effective in order to contain the threat. Response was improved by granting the FDA mandatory recall authority for all food products (after giving opportunity for the responsible party to cease distribution and recall itself), and allowing for potential suspension of a food facility's registration (Overview FSMA, 2015).

*Enhanced Partnerships*:

The goals of FSMA can be better accomplished when there are more trusted people and organizations monitoring its provisions. This ranges from enhanced training of food safety officials to certifying new auditing agencies (Overview FSMA, 2015).

These five objectives are represented in the seven specific rules of the bill, called the Seven Foundational Rules. These rules include: Preventive Controls for Human Food, Preventive Controls for Animal Food, Produce Safety, the Foreign Supplier Verification Program, Third Party Certification, Sanitary Transportation and Intentional Adulteration. There are various requirements within each. Note that the purpose of this legislative summary and analysis is to identify best practices for safety and cost-effectiveness in the sale of final goods for human consumption. Thus, details such as precise types of crop exemptions from a rule or specific clerical procedures will be intentionally excluded from the report. This level of detail can be accessed on the FDA's official website. Therefore, this paper will not touch on Preventive Controls for Animal Food. It will also only briefly touch on Third Party Certification and Produce Safety.

Third Party Certification accredits third-party auditors (foreign government or private) to monitor food safety certifications for foreign facilities, which helps to ensure subsequent food safety in the U.S. This rule sets the specific structure and processes for foreign accreditation and certification bodies to be recognized by the FDA. Although their presence and responsibilities are certainly important to ensuring food quality and safety, this research is not concerned with the specifics of their formation.

Produce Safety (which largely applies to growing and harvesting crops) will also only be analyzed in brief. Food starts with produce; if the produce is not safe, the final product may not be safe. However, because the focus of this paper is on the sellers of final goods, these requirements will be discussed at a high-level, only relating to how compliance generates food safety. There are so many exceptions to these rules, such as agricultural commodities identified by the FDA as rarely consumed raw (i.e. asparagus, sweet corn and eggplants.) Rather than get caught up in these fine details, this research is concerned is with general requirements that impact safety down the supply chain.

## Seven Foundational Rules

### *Preventive Controls for Human Food*

This rule requires that food facilities have a written plan for preventing and identifying potentially hazardous issues; it must include sections on hazard analysis, preventive controls and oversight, and management of preventive controls (Final Rule Preventive Controls, 2015).

A hazard analysis must be conducted to identify all known or foreseeable hazards of natural or artificial means. Companies were typically aware of three types of hazards prior to

FSMA: physical (i.e. foreign materials such as glass in the product), chemical (i.e. pesticide residues or heavy metals) and microbiological (i.e. pathogenic organisms.) These hazards were identified under HACCP. The Food Safety Modernization Act forced companies to pay attention to a fourth, lesser known hazard: radiological (i.e. uranium content.) During a hazard analysis, a company considers all four types of hazards and seeks to identify where and how these hazards can be introduced.

Preventive controls are the steps taken to prevent these foreseeable hazards from being introduced. For example, it is common to have little stones mixed in with beans that are harvested (Company A interview). This would be identified in the hazard analysis, and a machine to separate the stones and inspect the final product could be a preventive control.

Although similar to critical control points (CCP), which were introduced under HACCP, preventive controls have a broader scope. CCPs represent a point where the product has the possibility to become extraordinarily hazardous. Preventive controls are utilized for even mild potential hazards. Thus, all critical control points are preventive controls, but not all preventive controls are critical control points. Although a company may have adequately met the critical control points required under HACCP, the Food Safety Modernization Act may require additional preventive controls at other, less hazardous, steps. Note that the requirement for a hazard analysis and preventive controls applies to both suppliers and in-house processes.

Finally, Oversight and Management of Preventive Controls requires companies to continuously monitor them and take corrective actions as necessary.

*Produce Safety*

Prior to the Produce Safety rule, there were no required science-based standards for growing, harvesting, packing and holding produce on domestic or foreign farms for human consumption (Final Rule Produce Safety, 2015). The rule sets standards for: agricultural water quality and testing; soil, manure and compost; sprouts; domesticated and wild animals; workers health and hygiene; and equipment, tools and buildings. These standards help prevent contamination and ensure quality.

Many food facilities selling final goods do not harvest the produce themselves; it is common to be supplied with the produce for production. Even if the company is not directly responsible for following the requirements laid out in the Produce Safety rule, it is important that their suppliers do. Hazard analysis and preventive controls can help identify and control these risks.

*Foreign Supplier Verification Program (FSVP)*

We live in a global economy. Fifteen percent of the U.S. food supply is imported (Overview FSMA, 2015). With so much of our food coming from other nations, we must be vigilant that it meets the same U.S. standards of food safety. FSMA seeks to accomplish this through its Foreign Supplier Verification Program requirement.

A FSVP must be developed and maintained for every foreign supplier. A FSVP includes a hazard analysis of the supplier, evaluation of food risk and supplier performance, supplier verification, and corrective actions (if needed.) Supplier verification may include on-site audits, sampling and testing of products, a review of the supplier's relevant food safety records, etc. It is the responsibility of the importer to meet these requirements. An importer may work with the

supplier directly to conduct this analysis, or another certified entity may do it and provide the importer with the results (Final Rule FSVP, 2015).

*Third Party Certification*

This rule establishes the process for accrediting third-party auditors (foreign government or private) to monitor food safety and issue certifications for foreign facilities. These certified third parties can help with the Foreign Supplier Verification Program process. Accreditation bodies (which certify these third-party auditors) must monitor performance of these parties, as well as their own, and submit assessment reports to the FDA. The FDA reserves the right to revoke an accreditation body's recognition and certification if there is cause (Final Rule Third-Party, 2015).

Third-party certification bodies must perform unannounced facility audits and provide information on any potential health concerns to the FDA. They must also continually assess their own performance and improve as necessary (Final Rule Third-Party, 2015).

*Sanitary Transportation*

Keeping food safe during production is not enough. The product must reach the final consumer safely, as well. This rule aims to prevent risks to food safety during transport, such as ineffective hygienic practices, cross-contamination and improper refrigeration. Its focus is on minimizing and preventing risks to safety, not quality. It "builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act" by introducing various sanitary requirements across transportation services and providers (Final Rule Sanitary Transportation, 2016). Documentation of training in sanitary transportation practices for the carrier personnel deemed responsible

during transport is now required. The FDA requires written records of these procedures, agreements and training (Final Rule Sanitary Transportation, 2016).

Note that this rule does not apply to transport by ship or air due to limitations in the law.

*Intentional Adulteration*

Facilities must identify and address any vulnerable processes that could be used to cause intentional wide-spread harm; this is accomplished through a "Food Defense Plan." A firm's Food Defense Plan must be written and identify potential risks, possible corrective steps, risk-reducing strategies and procedures for food defense monitoring, corrective actions, and verification. Analysis must be conducted again every three years (Final Rule Intentional Adulteration, 2015).

For example, a company may install security cameras or require swipe cards to access certain areas of the facility. Measures such as these would deter intentional adulteration and increase accountability for the responsible parties.

**Potential Challenges of FSMA**

- The principles and standards required under FSMA apply to a wide range of commodities and processes across a very diverse food industry. As companies continue to implement FSMA and subsequently challenge themselves for continuous improvement, they will turn to the FDA for advice and guidance. The FDA must be able to accurately assess each distinct situation to provide the appropriate support. This requires thorough and effective technical training of its inspectors and compliance staff, as well as corollary staff in the states. Various regulations under FSMA have a multitude of options for compliance.

Thus, assessing compliance requires regulators to make well informed judgments based on comprehensive training and expertise. This lack of precise standards for compliance could pose problems for regulators (Technical Staffing, 2015).

- The Food and Drug Administration is an agency residing under the Department of Health and Human Services. The enactment of the Food Safety Modernization Act has placed a significant additional burden on the FDA, with limited resources to match. The outgoing 2016 Obama Administration requested a budget increase for HHS to supply the resources necessary to enforce FSMA. However, the March 2017 budget blueprint released under the Trump Administration includes a 16.2% decrease for the Department of Health and Human Services (Kopan, 2016). Without proper funding, it is likely that proper regulation of FSMA compliance will not be possible.

# Chapter 4

## Interviews

### Company A

Prior to the enactment of the Food Safety Modernization Act, this company was already challenging itself to effectively meet all safety provisions outlined under HACCP. The implementation of FSMA mandated many procedures which were already in place; however, the company was still able to improve and tighten its measures. A representative cited the "tightness and organization" of the firm's system as its biggest improvement since FSMA. Some of the company's practices were ahead of its time, and some (not specifically required under FSMA) are identified as best practices in Chapter 6.

*Preventive Controls*

Prior to FSMA, Company A was actively identifying potential hazards that were physical, chemical or microbiological in nature. Potential hazards were identified by considering historical experiences in the industry for each raw material (i.e. carrots are known to pick up lead or other metals from the ground), as well as by identifying potential hazards more specific to the company's operation. FSMA now requires the company to identify potential hazards of a fourth kind: radiological (i.e. seafood off the coast of Japan.) The firm has had no issues with radiological hazards thus far, but it remains cognizant of the possibility due to FSMA.

Preventive controls are then designed around the identified hazards. Due to FSMA's requirement, the firm documents every preventive control in detail. This measure increases accountability.

Some preventive controls in the firm vary depending on the nature of the finished good and its packaging. For example, the spice industry is known to have a risk of salmonella contamination. When using garlic in a canned product, a preventive control for the garlic itself may not be necessary, as the hazard will be killed during the canning process. However, garlic used in a spice blend for potato chips must be tested. In this case, the company may require its supplier to complete the testing prior to shipment. FSMA requires companies to record and prove that preventive controls are in place. Due to this requirement, the firm documents every preventive control in detail. This measure increases accountability.

Sometimes a hazard is not able to be consistently minimized to a safe level. Within the company, this was the case for morel mushrooms. It is almost impossible to farm this type of mushroom, so most are supplied from China where they grow in the wild. Poisonous mushrooms look a lot like morels, and the company would receive them dried, making the distinction even more difficult. Ultimately, the firm decided that feasible preventive controls were not effective enough, so they did not go forward with the project.

### *Foreign Supplier Verification Program*

A representative from the company explained that many importers are a business entity and not a technical resource. Various importers may not know about FSMA or fully understand its provisions to a qualified level. In these instances, the company works with the importer's supplier upstream to ensure that they have all the necessary controls in place. The firm might send representatives to audit the supplier's facility and perform extra inspection of the product upon arrival. When particular hazards are identified, such as carrots carrying lead from the ground, the company requires a certificate of analysis before it will take the product.

However, some importers are very competent at FSMA. They maintain high expectations for food safety and may even visit the suppliers upstream themselves. For these importers, the company will exercise less control.

*Transportation*

For Company A, the first step in ensuring safe transportation is the product's packaging. Finished goods are usually packed very tightly, and some products (such as vegetables) are packaged in multiple layers. Proper packaging helps protect the product's integrity in the event of an unforeseen hazard.

Before loading products for outbound delivery, a trained employee checks every truck for rodents, insects, unusual smells, or other unhygienic practices. A black light is used to determine if rodents have been present. These creatures tend to constantly urinate as they move, and the black light will illuminate any evidence of this. Upon being cleared for loading, the products are always placed on a pallet, which holds them off the floor of the truck.

Inbound delivery procedures are similar. A trained employee will check the truck for the same hazards, including the use of a black light. Some produce, such as a truckload of cucumbers, might come in open boxes, making inspection even more critical. Suppliers are made aware that this inspection will always occur, keeping them proactive and accountable.

Shipments may not arrive in a truck that previously carried trash or anything foul, such as raw chicken. Shipments by tanker truck, such as milk, must arrive with a wash ticket proving it was washed before being loaded. Milk shipments must also come with assurance that the truck only carries milk.

Employees receiving and loading goods are trained well to identify all these potential issues.

*Facility and Employees*

The company has required standard hygienic practices of its employees (such as hair nets and glove wearing) since before FSMA, and employees who are sick are asked not to come into work. However, the firm explained that sick employees often still feel inclined to go to work out of a desire to "look good." Attendance policies can worsen this problem. To combat this, all company employees are trained to know that they should not go to work sick, especially if they are a food handler. They are made aware that reporting sick will not be counted against them. If an employee is observed displaying symptoms of sickness (i.e. coughing, sweating or sneezing), they may be asked not to work on the line for that day.

In an effort to prevent intentional adulteration and improve security in general, the company tightened access to its facilities through bigger fences, barbed wire, security cameras, and swipe cards for access to various areas. The cameras and swipe cards also increase the accountability of the firm's employees. For example, by policy only a few designated people can enter a mixing tank room. Only the operator can be by the tank, so it is obvious if an unauthorized person is present. Swipe access histories can also be used to determine which parties were present when an issue occurred.

*Visitors*

Visitors of any company facility must be escorted at all times. They cannot handle or approach products like an employee. Every visitor must wear a hair net and a lab coat to prevent

introducing contaminants from their head or clothes. Shoes are washed prior to entering by scrubbers or a foam sprayer that sanitizes the shoes.

If the visitor is working at the facility (such as a contractor), he or she will receive a brief training that includes mandatory hygeniec practices. However, all visitors (working or not) must read and sign a Good Manufacturing Practice Checklist (GMP) that explains things like the importance of washing hands before entering a production area.

*Response*

To ensure the company can quickly and effectively act in the event of a recall, meticulous records are kept throughout production. Each batch of product has a batching sheet attached to it. The batching sheet contains precise information on the lot number and supplier of each ingredient used in production. This sheet becomes part of a permanent record.

For each day of manufacturing, there is a unique lot number put on the product. This number can tell the company where it was produced, on what days, which specific lot of each ingredient was used, and where the product was shipped to. The company is able to accurately reach this level of detail in about two hours.

However, to prevent an issue from escalating that far, employees are trained to immediately put production on hold if even suspicious of an issue. Escalation protocol also requires that the employee report the concern to his or her supervisor immediately. If it is determined that a real issue may be present, the company says it will always “throw a bigger net” when pulling product. The firm believes it is better to throw away extra product than to risk the safety, PR, and financial implications of needing to do it later.

**Company B**

Similar to Company A, this firm had also been following HACCP guidelines prior to FSMA. Upon its enactment, the company evolved and refined its practices. One of the biggest differences post-FSMA is the company's new focus on identifying and preventing potential radiological hazards. Prior to FSMA, the firm was concerned with only physical, chemical or microbiological hazards. In addition, relevant procedures that were trained and memorized are now written and documented so that anyone can follow them. A representative from the company noted that FSMA has raised awareness beyond quality assurance and shifted the focus across the industry to product safety.

*Preventive Controls*

The firm identifies potential hazards for a product in a team setting. Members of this team have knowledge and technical backgrounds in diverse areas. For example, an employee from the manufacturing facility can provide the best information on the operation of a line, including points where contaminants may be introduced. Someone with a background in microbiology can provide expertise related to those hazards. Collectively, the team can create the best hazard analysis and preventive controls.

*Foreign Supplier Verification Program*

According to a company representative, the firm does not differentiate between domestic and foreign suppliers except when logistically necessary. All suppliers are held to the same standards and must meet the same requirements. The company works directly with its suppliers overseas, just as it would domestically, to help these suppliers conduct their hazard analysis.

Suppliers are managed by a Supplier Quality Management team, with members from the corporate level and each regional level. The firm was able to leverage FSMA to upgrade its systems to support this improved supplier management and detailed database.

*Transportation*

All carriers are subject to inspection upon arrival and prior to loading at company facilities. Carriers are made aware of this to ensure that they maintain the conditions necessary to pass inspection. Specific requirements vary based on the type of vehicle and product. For example, bulk liquid transportation vehicles are required to prove kosher status, as well as provide evidence of being washed before loading. Goods that require refrigeration also require a temperature and humidity report at both loading and unloading.

*Facility and Employees*

All employees are required to follow Good Manufacturing Practices, such as sterile hand washing, that are explicitly outlined for them. Employees are expected to self report illnesses and not attend work when sick. The company also requires hair nets in production areas and gloves when handling product.

Although the company is still in the process of assessing its facilities for additional Intentional Adulteration controls, it put basic controls in place years ago under the Bioterrorism Act of 2002. Various areas of the facility are restricted to a limited number of employees with access. This measure improves both security and accountability of employees. To further protect the integrity of its products, facilities are equipped with cameras, security guards, and sensors.

*Visitors*

Non-working visitors must be escorted at all times, and the identity of each must be reviewed and confirmed prior to entry. Upon admittance, visitors are informed of the company's visitor policy and their presence is documented. Visitors are required to wear hair nets and smocks to identify them as visitors; they are prohibited from wearing jewelry and touching products or equipment.

Working visitors are expected to follow the same rules as manufacturing personnel. These expectations are communicated to them upon arrival.

*Response*

Company B has full traceability of all products, from all facilities, in the event of a recall. Every incoming ingredient is coded and tracked so that the firm has complete visibility to the contents of every finished product. The company also tracks where these finished goods are shipped, so they know who to contact if an issue arises.

To ensure that the company is maintaining efficient and effective recall ability in all channels, a mock recall is conducted at least once annually. The mock recall checks the accuracy and timeliness of the recall system in both directions. Recalls are handled by a collection of three committees: global recall, regional recall, and manufacturing. Depending on the country or region of the concern, the recall is managed by the appropriate team. The manufacturing committee is in charge of fact-finding (such as which batch of products was affected), as well as taking corrective action.

A representative explained that the mock recalls continue to get more challenging as the company expands globally, but says they will not stop challenging themselves.

# Chapter 5

## Food Safety: In the News

### 2015 Chipotle E. coli Outbreak

*Background*

Founded in July of 1993 by CEO Steve Ells, the official tagline of Chipotle Mexican Grill is "Food with Integrity." For the company, this entails a commitment to "responsibly raised animals, classic cooking techniques, whole ingredients, the environment, [and] local produce" (Chipotle Food with Integrity). These guiding principles have been engrained in the company's marketing over the years, including short animated films about the evils of industrial agriculture. Chipotle differentiates itself from competitors through these initiatives.

Individual restaurant locations are set up in a standard model, utilizing: an open kitchen, fresh ingredients, "real" cooking in the back and an assembly line in front, allowing customization and speed (Berfield, 2015). The company has a complex supply network of about one hundred suppliers for its sixty-four ingredients, a number which doesn't include local farms. Local farms are designated as those within 350 miles of a restaurant, and these farms supply only ten percent of its produce during peak season. This wide range of suppliers is what helps Chipotle maintain its "fresh" promise in every location nationwide (Berfield, 2015).

Food safety issues began for Chipotle in 2008 after a norovirus outbreak, sickening 450 people, was linked to the company's supply chain (Berfield, 2015). Chipotle was able to quickly recover from the incident with minimal damage to its reputation. However, a similar norovirus

outbreak was repeated in August and November of 2015. Over sixty people in Minnesota were also infected between August and September of that year due to Salmonella in the chain's tomatoes (Berfield, 2015).

Chipotle culminated its difficult year with two highly publicized E. coli outbreaks, which occurred between October and December 2015. In the initial, larger outbreak, fifty-five people were infected in a total of eleven states. There were twenty-one hospitalizations and no deaths. A smaller outbreak occurred in November due to a different strain of E. coli. There were five resulting infections, one hospitalization, and no deaths. (Multiple Outbreaks, 2016).

E. Coli is present in animal or human feces. The bacteria can be spread to produce through irrigation water, animals defecating in crop fields, or by improperly treated manure. Through proper sanitization or cooking at high temperatures, E. coli in food can be killed. However, produce eaten raw that is difficult to clean properly is considered high-risk. Much of what gives Chipotle its "fresh" advantage, including tomatoes, lettuce and cilantro, are included in this high-risk category (Berfield, 2015).

During the outbreaks' subsequent investigation, the following governing bodies were involved: the Center for Disease Control, the Food and Drug Administration, the U.S. Department of Agriculture's Food Safety and Inspection Service, and public health officials across several states. It was found that almost 500 people became sick in 2015, from July on, due to eating at Chipotle. This number is only representative of those who actually went to a doctor and were properly diagnosed; experts believe that with any outbreak the total number affected is at least ten times the reported number (Berfield, 2015).

*Potential Causes and Related Issues*

According to the Center for Disease Control's report on the E. coli outbreaks, "the epidemiologic evidence collected during the investigation suggested that a common meal item or ingredient served at Chipotle Mexican Grill restaurants was a likely source of both outbreaks" (Multistate Outbreaks, 2016). However, although the CDC stated that Chipotle was "very cooperative" in the investigation, the chain had trouble informing the agency which batches of ingredients went to which stores and at which times (Berfield, 2015). Ian Williams, the chief of the CDC's outbreak response and prevention branch at the time, explained: "The system they have is not able to solve the problem we have at hand. It's not granular enough." This is an issue that permeates much of the food industry, not just Chipotle restaurants. Williams added that "traceability from the farm to the point of service" needs improvement throughout the industry. In recent years the CDC has only been able to identify the contaminated ingredients in less than half of all multistate outbreaks, not just those related to Chipotle (Berfield, 2015).

Although the specifics of which ingredients were contaminated, how they were contaminated, and from which supplier they were sourced are unknown, it is highly probable that the issue originated from one of Chipotle's bigger suppliers. Because restaurants from the East to the West Coast were affected, it is very unlikely that a local farm contributed to such widespread contamination (Berfield, 2015).

As for the chain's two norovirus outbreaks, representatives largely attributed the cause to sick employees present at the affected restaurants. This revelation comes despite the company's new paid sick-leave policy enacted in June (Berfield, 2015).

Another possible cause of contamination may be related to employee hand washing. In every Chipotle restaurant, there is an hourly alarm which alerts workers to wash their hands and

replace their latex gloves with new ones. Three former managers were interviewed about this policy but asked to remain anonymous in order to speak openly about their experiences. According to these former employees, the alarm was often ignored when the restaurant was busy. A former manager, from a location outside of San Francisco, explained that field managers visited approximately once a month to review each location. In his experience, employees were inclined to observe the hand-washing rule in the subsequent days following the visit, but they quickly returned to old habits afterward. He also added that Chipotle emphasized the safe handling of meat more than produce (Berfield, 2015).

Following these various incidents, representatives from headquarters made timely statements, both apologetic and informative in nature. Chipotle emphatically vowed to its treasured patrons, in multiple press releases, not only to alleviate the current problem but also to prevent its reoccurrence. However, the brand image of the chain, self-described as "Food with Integrity," had already taken a huge hit. The company's multiple press releases about a singular outbreak made management appear indecisive and incompetent to some consumers, as opposed to issuing a single comprehensive statement. Not only were the incidents widely publicized and nationally criticized, but also individual restaurant locations incurred further damage to the chain's brand image. Restaurants across the country sported diverse notices regarding the incident, referencing problems with the supply chain or equipment. One restaurant in Portland donned a sign reading: "Don't panic… order should be restored to the universe in the very near future." With the severity of the outbreak including the possibility of chronic illness or even death, consumers found this response smug and unremorseful in nature (Berfield, 2015).

*Corrective Actions*

In late October 2015, Chipotle hired Mansour Samadpour, head of a food safety laboratory and consulting firm in Seattle, to assist in remedying the company's food safety issues. Chipotle is confident that the team can construct an aggressive food safety plan which will "far exceed industry norms" and reduce the risk of contamination to nearly zero. According to Samadpour, "Being in compliance with industry standards is less than five percent of what companies need to do to make food safe. Company after company finds that out after they have events" (Berfield, 2015).

Key highlights from Chipotle's aggressive new food safety plan include:

- Although preparing the majority of a restaurant's food on-location is fundamental to Chipotle's "fresh" brand image, the company is shifting much food preparation into centralized kitchens. By concentrating the preparation, Chipotle can maintain greater control over the quality and safety of its ingredients (Berfield, 2015).
- After these items are prepared ahead of time at commissaries, they are transported to nineteen distribution centers and then to over 1,900 individual restaurants. Samadpour says it is an "industrial-strength plan" (Berfield, 2015).
- High-resolution DNA-based tests will be used to screen produce for pathogens before harvesting. If the produce passes, it is sent to the commissaries to be washed, sanitized and retested.
- Chipotle was using quality food processors in each individual restaurant to dice tomatoes. These enabled the tomatoes to be diced just as well as they could at a commissary, while

better retaining flavor. Under the new food safety plan, tomatoes are returning to commissaries for preparation and will arrive at a restaurant pre-diced and packaged.

- Instead of the individual restaurants, the commissaries are now responsible for cleaning and packaging cilantro, shredding lettuce, and dicing the tomatoes.
- The process of marinating Chipotle's meat has been changed to prevent cross-contamination.
- Workers will now add cilantro to higher-temperature rice on location to kill any bacteria.
- Avocados, onions, jalapenos, lemons, and limes must be blanched in boiling water for five to ten seconds to kill microbes on their surface.
- Lemon and lime juice will be added to guacamole and salsa earlier to reduce their microbe count. Steve Ells, CEO, says this step actually turns the salsa a brighter red and gives it a sweeter taste.

*Former and Lasting Impacts*

In December 2015, Chipotle released an advertisement in newspapers nationwide, signed by founder and co-chief executive Steve Ells. The ad expressed Chipotle's newfound commitment to being known as "a leader in food safety," just as it is known for using the "best ingredients in a fast-food setting." However, from August to the end of that year, Chipotle's stock value had already fallen by thirty percent (Berfield, 2015). The company also incurred many lost sales as various locations were shut down while investigating where the contaminated produce was present. Had Chipotle's system offered the granular level of visibility needed to track each batch of ingredients, the company could have saved time, money, and face. The inability to track movements within the supply chain both prolonged the event and raised

questions about the firm's competency.

The chain's numerous food safety incidents have hurt the brand's image beyond the contaminations themselves. The resulting shift to prepare more food in centralized locations goes directly against the founding principles that Chipotle believes in and markets to consumers. This new method increases the brand's similarity to the fast-food chains it has historically ridiculed. The company wants to maintain a fresh, local image; preparing food in a commissary and distributing it around the country directly contradicts this. Continuing to market the brand in the same manner will pose challenges.

As for the additional screening of produce prior to harvest, it is clear that safety is Chipotle's main priority. However, complying with these increased demands will be difficult for smaller farms. Many smaller farms may not be able to afford the cost of the tests themselves, especially combined with the cost of throwing away sub-standard produce. Steve Ells has stated that the company will help with the costs in these instances and recognizes that for some it may not work at all. However, Jack Hartung—Chipotle's chief financial officer—explained "if it's testing and safety vs. taking a step backward on local, we would do that and hope it would be temporary" (Berfield, 2015).

As for Chipotle itself, there has been no public disclosure on an estimated cost of these new programs. Steve Ells admits it is going to be "very, very expensive." Jack Hartung explained, "Right now we're not trying to make this cost-effective. We're just doing it. We're likely to do it very inefficiently." What does this mean for consumers? Hartung said Chipotle will not be raising prices or decreasing portions to cover the expense of these measures. He expects the company's profits and profit margin to be "messy" for now (Berfield, 2015).

Chipotle is smart for taking this route, because the company's truly greatest issue is one

that money cannot fix: consumer trust. Between Chipotle's several related lawsuits and damaged national image – building that trust and loyalty back will be an uphill battle.

# Chapter 6

## Best Practices

The following best practices were compiled through academic research, first-hand interviews with companies in the food industry, and food safety related case studies.

*Preventive Controls*

- Form a hazard analysis team with diverse backgrounds to conduct the facility's hazard analysis and determine preventive controls. For example, manufacturing personnel can provide knowledge on when and how contaminants may be introduced to a product. An employee with a background in biology will have expertise in identifying potential biological hazards.
    - Form a temporary hazard analysis team (or temporarily add members to the existing team) for all new product development. Consider and identify any and all hazards – big or small.
- Require swipe access to critical areas of the facility where raw materials or product can be tampered with to increase accountability. Limit those with access.
- Reinforce to employees that they are prohibited from coming in to work sick (especially if working with products directly) and do not penalize them for taking a sick day. Offer paid sick days to avoid workers arriving ill.
    - Send home any employee visibly ill.

- Require all manufacturing personnel to wear gloves at all times. Have fresh gloves readily available around the facility.
- Require workers to wash their hands with warm water and soap before working with products and after touching any unsanitary objects. Provide visual reminders of the importance of this practice and have managers/supervisors perform daily observations of commitment to this protocol.
- Clean kitchen surfaces often and always before introducing new ingredients with the possibility of cross-contamination. Use disposable paper towels or wash cloths which are washed in hot water between uses.
- Install security cameras throughout the facility to increase accountability.
- Develop a strong food safety culture within the company that resonates with all employees. Reinforce these ideals continuously.

*Product*

- Package food multiple times to ensure safety during transport (i.e. food in a sealed bag, thirty bags in a box, boxes stacked and wrapped on a pallet.)
- Include a control, when possible, that can indicate to the consumer if the item has been opened or tampered with (i.e. safety button on sealed jars that pops out when opened.)
- Do not move forward with product development if all potential hazards cannot be reliably and effectively prevented.

*Suppliers*

- Rationalize suppliers regularly to avoid an overly complex supply network. A complex supply network increases opportunities for the introduction of safety issues, as well as makes monitoring and identifying the source of contaminated goods more difficult.

- Manage suppliers with a Supplier Quality Management Team.
    - Do not differentiate between domestic and foreign suppliers in food safety requirements and standards.
- Imported Goods:
    - Research/interview the importer on their competency with FSMA before working with them.
        - Work with foreign suppliers directly to conduct a hazard analysis and other requirements if there are any concerns with the importer. Consider working with the supplier directly regardless, to increase accountability and confidence.
        - Exercise less control for knowledgeable, reputable importers.
- Require suppliers to share their hazard analysis and preventive control plan to confirm that there are no identifiable "holes" or areas for recommended improvement.

*Transportation*

- Every inbound and outbound vehicle should be subject to inspection.
    - Make every supplier aware of the requirements to pass inspection in their contract.
    - Train workers extensively to identify any problems with inbound/outbound vehicles (i.e. noticeable odor, cleanliness, etc.)
    - Inspect every vehicle before loading/unloading for evidence of rodents or insects; use a black light to detect urine from rodents.
- Prohibit carriers from using a vehicle which previously held trash or anything foul (such as raw chicken.)

- Place all outbound goods on a pallet to prevent products from touching the floor of the trailer.
- Require a wash ticket before loading any bulk liquid containers.
- Require assurance that a tanker truck has not previously carried anything toxic or anything that could contaminate the liquid being loaded (i.e. petroleum.)
- For items with temperature or humidity requirements during transport, use a carrier with the ability to track and provide a report of the value of each throughout the duration of the trip.

*Visitors / Intentional Adulteration*

- Require a swipe card or other form of electronic pass to gain entrance to facility.
- Document all visitors, including time of entrance and exit, and require proof of identification.
- All visitors should:
    - Require an appointment and proof of identification for entrance
    - Be documented at time of entry and exit
    - Wear a hair net
    - Remove loose jewelry or other items
    - Be provided with steel toed shoes and safety goggles and/or sanitize their shoes with a spray
    - Wear something to identify them as a visitor (i.e. a lab coat or smock)
- Working visitors should:
    - Receive a brief training
    - Read and sign off on the facility's Good Manufacturing Practices (GMP)

    - Receive limited access to only required areas and must be escorted beyond those

- Non-working visitors should:
    - Watch a short video or presentation on safety and expectations
    - Be escorted at all times
    - Be prohibited from touching product (including finished) or machinery

*Response*

- Maintain a permanent, granular level of data on batches, lot numbers, and product movements to ensure complete visibility in the event of a safety issue or recall.
- Conduct mock recalls at least annually to ensure the most effective and efficient process in the event an actual recall is necessary. Use each practice to identify areas for improvement in response time, clarity, and effectiveness. Be sure to test all channels and in both directions.
    - Form committees in charge of mock recalls and actual recalls. Split them into regional, global, and manufacturing. The manufacturing committee is in charge of fact finding (i.e. which lot of products were affected, when and where they were shipped, etc.) The appropriate regional or global committee takes action depending on the location and magnitude of the recall.
    - Create and annually revise a risk mitigation plan in the event of a recall. This includes everything from logistics to Public Relations. Remain proactive and ready to act at the first sign of concern.
- Use unique lot numbers for each day of manufacturing.
- It is always better to “throw a bigger net” and recall too much than too little.

- Include on product packaging exactly how to contact the appropriate party in the event of an issue with the product.
- Train all workers to *immediately* report any and all concerns with a product's manufacturing or distribution. Create an escalation protocol so the appropriate parties are aware of any important situation.
- Stop production immediately for any food safety concern and investigate before continuing. It is always best to discard product if there is anything but 100 percent confidence in its integrity.
- In the event of a recall:
    - Share information with consumers *immediately.*
    - Be swift, honest and apologetic in the public statement.
    - Reassure consumers that the problem is contained (or update them when it is.)
    - Try to contain all information to one public statement to avoid appearing incompetent.
    - Conduct a thorough investigation to the cause of the recall and identify preventive controls that failed or are needed.

*Public Relations*

- In an era of increasing consumer awareness and concern for food safety, it is important to inform and reassure them of the company's unwavering commitment to food safety. Reaffirm this commitment through various channels, including: company websites, on site at POS locations, social media, and traditional advertising campaigns.

# Appendix A

## Interview Guide

Interview Guide: Food Safety Modernization Act
Cassandra Smith

1. There are Seven Foundational Rules for the implementation of the FSMA. My focus for this interview is primarily concerned with aspects of five of them:
    a. **Preventive Controls for Human Food:** Food facilities much have written safety plans for preventing and identifying potentially hazardous issues that must include:
        i. *Hazard Analysis*
            1. How does your company identify known/foreseeable hazards of natural or artificial means?
            2. Can you provide any examples of these potential hazards?
        ii. *Preventive Controls*
            1. How are these identified hazards minimized or prevented?

    b. **Produce Safety:**
        i. *Workers Training and Health and Hygiene*
            1. What measures are taken to prevent the contamination of produce or food-contact surfaces by sick/infected persons?
            2. What measures are utilized to prevent visitors from introducing contamination?

    c. **Foreign Supplier Verification Program:** Importers must verify that foreign suppliers meet U.S. food safety standards. A FSVP is developed for each specific supplier.

i. *Hazard Analysis* (i.e. Condition of facility and equipment, raw materials, sanitation, processing and packing procedures, etc.)

1. Does your company work with foreign suppliers?
2. Do you work with the supplier directly to conduct this analysis, or does another entity complete it for your review? How is this relationship managed?

ii. *Supplier Verification*

1. What are some methods used for supplier verification? (i.e. annual on-site audits, sampling and testing, review of supplier's relevant food safety records, etc.)

d. **Sanitary Transportation: (**This provision does not apply to deliveries by ship or air due to limitations in the law)

i. *Vehicles and transportation equipment*

1. Does your company own goods while in-transit? What measures are taken to ensure their safe transport? (i.e. temperature controls, cleanliness of vehicle, cross-contamination, etc.)

e. **Intentional Adulteration:** Facilities must identify and address any vulnerable processes that could be used to cause intentional widespread harm. Does not target specific hazards but rather requires risk-reducing strategies.

i. *Vulnerability Assessment ("Food Defense Plan")*

Interview Guide: Food Safety Modernization Act
Cassandra Smith

1. What mitigation strategies were identified to reduce the risk of intentional adulteration?

2. A major lesson to be learned from the 2015 Chipotle E. coli outbreak is the importance of supply chain traceability for all ingredients and final goods. Chipotle's data was not granular enough, so they were unable to pinpoint which batches of ingredients went to which stores and when. They were forced to shut down excess locations in the Oregon/Washington area to stop the spread.
    a) How effectively can your system trace ingredients and/or final goods from farm to the point of service? How is this accomplished? How granular is this data?

3. One of the defining characteristics of the FSMA is its focus on *preventive* measures, as opposed to *reactive* measures. However, in the event of an incident, what reactive measures does your company have in place? Is there a recall system?

4. What do you think the most significant impact of the FSMA has been for your company? What areas have seen the most improvement since its enactment in January 2011?

5. Do you have any feedback on the overall effectiveness of the FSMA and its implications for registered food facilities such as yourself?

6. Can you think of any other procedures or anecdotes that might be helpful to my research?

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