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A current state analysis of preventive control requirements and traceability infrastructure in small U.S. food facilities

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A current state analysis of preventive control requirements and traceability infrastructure in small U.S. food facilities

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The student author, whose presentation of the scholarship herein was approved by the program of study committee, is solely responsible for the content of this thesis. The Graduate College will ensure this thesis is globally accessible and will not permit alterations after a degree is conferred.

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NOMENCLATURE

CDC	Center for Disease Control and Prevention
cGMPs	Current Good Manufacturing Practices
CIRAS	Center for Industrial Research and Service
ERP	Enterprise Resources Planning System
FDA	U.S. Food and Drug Administration
FSMA	Food Safety Modernization Act
IFT	Institute of Food Technologists
KDEs	Key Data Elements
MES	Manufacturing Execution System
MRP	Materials Requirement Planning System
PCQI	Preventive Control Qualified Individual
SME	Small and Medium Sized Enterprises

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ABSTRACT

In 2011, the U.S. government enacted the Food Safety Modernization Act (FSMA). The goal of the new legislation was to reduce the 48 million people per year in the U.S. who are affected by food borne illnesses through the requirement of preventive controls in food supply chains. Compliance dates for small food businesses started in 2017, when the new preventive control measures were required to be implemented.

The following research focuses on understanding the current state of FSMA preventive control requirements in relationship to small food facilities. Also, an assessment of the traceability infrastructure within small food facilities was performed. A questionnaire based survey was developed from using the FDA's FSMA Final Rule for Preventive Controls for Human Food and Animal Food along with the Institute of Food Technologist pilot study for FSMA traceability. The questionnaire was distributed to small food facilities in the state of Iowa. Fourteen different factors were analyzed from the questionnaire data: (i) food allergen controls, (ii) verification activities, (iii) current good manufacturing practices, (iv) food safety plan, (v) training records (vi) standard operating procedures, (vii) hazard analysis, (viii) recall plan, (ix) preventive controlled qualified individual, (x) operational control, (xi) accounting programs, (xii) inventory records, (xiii) lot coding, (xiv) business management software. Results were compared against the type of manufacturing, the size of the company, and how many years the company has been in business. A significant factor affecting the adoption of FSMA within the small business category proved to be company size. Chi-square analysis revealed significant results in preventive control practices and traceability infrastructure at divisions of 0-24 employees, and 25-499 employees. Companies that had 25-499

employees showed better preparation in implementing preventive controls for distinct FSMA compliance requirements. Also, companies that had 25-499 employees showed a leading advancement in technology adoption for establishment of traceability infrastructure versus companies that had 0-24 employees. The small business class distinction for FSMA spans a large range of employee sizes (499 or less). The results indicate that a special focus may be needed on businesses with less than 25 employees for FSMA preventive control requirements to be successful in small businesses.

CHAPTER 1. GENERAL INTRODUCTION

Introduction

The Center for Disease Control and Prevention estimates that in the U.S. food borne illness is contracted by 48 million people per year and results in 3,000 deaths annually (Scallan et al., 2011). Contamination of food products can happen during production, processing, distribution, and preparation throughout the food supply chain (Center for Disease Control and Prevention, 2017). A *Salmonella* outbreak in peanut butter, from 2008 to 2009 throughout the United States, resulted in 714 people becoming ill and nine deaths (Centers for Disease Control and Prevention, 2009). The outbreak was initiated from lack of process controls at one peanut processing facility. After FDA investigation, in excess of 3,000 different peanut products were identified as possible transmission vehicles for the food borne illness originating from ingredient usage of the identified facility (Centers for Disease Control and Prevention, 2009). In 2010 there were 31 documented outbreaks connected to FDA controlled ingredients (Califf, 2016). From 2011 to 2012 a multistate *Salmonella* outbreak caused 22 people to become ill from exposure to dry pet food (U.S. Food and Drug Administration, 2014). The bacteria was discovered to be introduced into the pet food from lack of preventive controls at one processing facility (U.S. Food and Drug Administration, 2014). Due to the high number of Americans sicken with food borne illness yearly, one out of every six, a new law was established that included for the first time ever, required preventive controls for food facilities (U.S. Food and Drug Administration, 2018).

In 2011, to help reduce food borne illnesses, the U.S. government enacted the Food Safety Modernization Act (FSMA) (U.S. Food and Drug Administration, 2017). The law

requires the food industry to move from a system that responds to food contamination to a system that prevents food contamination (U.S. Food and Drug Administration, 2017). FSMA allows the Food and Drug Administration (FDA) to have stricter controls on food facilities by enforcement through audits and determining audit recurrence based on associated risk. Major changes to how food facilities operate include but are not limited to: (i) registration with the FDA, (ii) a food safety plan that focuses on prevention through hazard analysis, (iii) a food defense plan that has strategies to identify sensitive spots in the supply chain, and (iv) the integration of a Preventive Control Qualified Individual into facility operations (Kennedy, Myhre Errecaborde, & Hueston, 2014).

Preventive controls are the cornerstone of FSMA. King & Bedale (2018), argue that CGMPs, hazard analysis, and risk-based preventive controls will potentially have the greatest impact on food safety. In order for FSMA to be successful it is important to understand the costs associated with integrating the new law into food facilities. The implementation costs for the preventive control requirements alone are estimated to be $381 million per year (U.S. Food and Drug Administration, 2015). In order for the preventive control measures to be cost effective, they need to eliminate a predicted 157,000 food borne illnesses a year in the U.S. (U.S. Food and Drug Administration, 2015).

The Food Safety Modernization Act consists of 89 pages, including 4 titles and 41 sections. Under section 204 of the act, the FDA has promulgated traceability and recordkeeping requirements with direction to explore traceability technology throughout food supply chains (Califf, 2016). One of the requirements under Section 204 was to perform pilot studies to evaluate the current practices of the food supply chain system. The Institute of Food Technologist (IFT) completed such pilot studies in 2013 and found that the one back

and one forward tracing method of the Bioterrorism Act might be ineffective as farms and restaurants are exempt from the rule (Bhatt, Hickey, & McEntire, 2013). This leads to gaps in critical traceability information throughout a supply chain, especially during food outbreak investigations (Bhatt et al., 2013).

Traceability allows for the forward and backward tracking of products as they move from one place in the food supply chain to another (Bhatt et al., 2013). When there is a food recall situation, traceability is a fundamental element for minimizing exposure and preventing the spread of illness throughout a population (Bhatt et al., 2013). The forward movement in the supply chain is how a product is tracked and the backward movement is how a product is traced (Bhatt et al., 2013). In order for a comprehensive traceability system to be in place, a product must be able to be tracked, traced, and historic information about the product must be accessible at all times (Bosona & Gebresenbet, 2013).

The FDA reports that smaller businesses primarily use paper records for traceability documentation (Califf, 2016). A report to the U.S. congress was issued in 2016 which reviewed the proposals from the pilot projects. The FDA reported five major suggestions focused on keeping consistent data elements for traceability throughout a supply chain: (i) a set of homogeneous information needed for product tracing should be identified by the FDA, (ii) food firms should internally maintain records that can identify all products from the receipt locations to the distribution locations, (iii) food businesses should develop ways to advance accuracy and quality of electronic data submitted to the FDA, (iv) the FDA should consider the establishment of key data elements (KDEs) and how the retrieval process of such data should exist, and (v) a documented plan should exist where food firms describe their process for tracking and tracing raw materials and products one step in each direction

(at a minimum) of the supply chain (Califf, 2016). KDEs include but are not limited to; supplier identification, product identification, purchase order number, number of items, and the receipt date for products (Bhatt et al., 2013).

Purpose

The purpose of this study was to identify challenges that small businesses face with implementing the new FSMA regulations. Being able to identify the current preventive control and traceability practices in food facilities will help with understanding the status of the new food safety law. Even though the law was established in 2011, compliance dates for small businesses did not start until September of 2017. Because the law requires radical changes in how food supply chains operate, it is important to understand the current level of regulation implementation. Success of FSMA is dependent upon the success of the food industry's abilities to make changes to their supply chain systems. The questions addressed in this thesis are: Are there differences in FSMA preventive control implementation within the small business group? What type of traceability infrastructure do small businesses have in place for food manufacturing? What challenges do small businesses face with FSMA implementation?

Thesis Organization

This thesis follows format for journals and conference proceedings where these manuscript have already been be submitted. Each chapter in this thesis is self-contained. Chapter 1 is a general introduction of the topic highlighting the overall research objectives with references (this chapter). Chapter 2 and 3 include an abstract, introduction along with literature review, methodology with figures and tables, results, discussion with limitations

and future work, conclusions and references followed by chapter 4 which includes a general summary and conclusions for the thesis.

Chapter 2 titled “Food Safety Modernization Act: A Current State Analysis of Preventive Control Requirements and Traceability Infrastructure in Small Food Facilities” is a research paper modified from the manuscript already submitted to the journal “Food Control” and is currently under review. Chapter 3 titled “Food Safety Modernization Act: A Lean Six Sigma Approach to Traceability in Small and Medium Sized Enterprises” is a conference paper modified from the manuscript published in the conference proceedings of the Seventh International Conference on Lean Six Sigma titled “Leading the Culture of Operational and Service Excellence through Lean and Six Sigma methodologies”.

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CHAPTER 2. FOOD SAFETY MODERNIZATION ACT: A CURRENT STATE ANALYSIS OF PREVENTIVE CONTROL REQUIREMENTS AND TRACEABILITY INFRASTRUCTURE IN SMALL FOOD FACILITIES

Manuscript under review in *Food Control* journal

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Abstract

In 2011, the U.S. government enacted the Food Safety Modernization Act (FSMA). The goal of the new legislation was to reduce the 48 million people per year in the U.S. who are affected by food borne illnesses through the requirement of preventive controls in food supply chains. Compliance dates for small food businesses started in 2017, when the new preventive control measures were required to be implemented. This research focuses on understanding the current state of FSMA preventive control requirements in relationship to small food facilities. Also, an assessment of the traceability infrastructure within small food facilities was performed. A questionnaire based survey was developed from using the FDA's FSMA Final Rule for Preventive Controls for Human Food and Animal Food along with the Institute of Food Technologist pilot study for FSMA traceability. The questionnaire was distributed to small food facilities in the state of Iowa. Fourteen different factors were analyzed from the questionnaire data: (i) food allergen controls, (ii) verification activities, (iii) current good manufacturing practices, (iv) food safety plan, (v) training records (vi) standard operating procedures, (vii) hazard analysis, (viii) recall plan, (ix) preventive controlled qualified individual, (x) operational control, (xi) accounting programs, (xii) inventory records, (xiii) lot coding, (xiv) business management software. Results were

compared against the type of manufacturing, the size of the company, and how many years the company has been in business. A significant factor affecting the adoption of FSMA within the small business category proved to be company size. Chi-square analysis revealed significant results in preventive control practices and traceability infrastructure at divisions of 0-24 employees, and 25-499 employees. Companies that had 25-499 employees showed better preparation in implementing preventive controls for distinct FSMA compliance requirements. Also, companies that had 25-499 employees showed a leading advancement in technology adoption for establishment of traceability infrastructure versus companies that had 0-24 employees. The small business category spans a large range of employee sizes (499 or less). The results indicate that a special focus may be needed on businesses with less than 25 employees for FSMA preventive control requirements to be successful in small businesses.

Introduction

Food Safety Modernization Act

The Center for Disease Control and Prevention estimates that in the U.S. food borne illness is contracted by 48 million people per year and results in 3,000 deaths annually (Scallan et al., 2011). Contamination of food products can happen during production, processing, distribution, and preparation throughout the food supply chain (Center for Disease Control and Prevention, 2017). A *Salmonella* outbreak in peanut butter, from 2008 to 2009 throughout the United States, resulted in 714 people becoming ill and nine deaths (Centers for Disease Control and Prevention, 2009). The outbreak was initiated from lack of process controls at one peanut processing facility. After FDA investigation, in excess of 3,000 different peanut products were identified as possible transmission vehicles for the food

borne illness originating from ingredient usage of the identified facility (Centers for Disease Control and Prevention, 2009). In 2010 there were 31 documented outbreaks connected to FDA controlled ingredients (Califf, 2016). From 2011 to 2012 a multistate *Salmonella* outbreak caused 22 people to become ill from exposure to dry pet food (U.S. Food and Drug Administration, 2014). The bacteria was discovered to be introduced into the pet food from lack of preventive controls at one processing facility (U.S. Food and Drug Administration, 2014). Due to the high number of Americans sicken with food borne illness yearly, one out of every six, a new law was established that included for the first time ever, required preventive controls for food facilities (U.S. Food and Drug Administration, 2018a).

In 2011, to alter the urgent need to reduce food borne illnesses, the U.S. government enacted the Food Safety Modernization Act (FSMA) (U.S. Food and Drug Administration, 2017b). The law requires the food industry to move from a system that responds to food contamination to a system that prevents food contamination (U.S. Food and Drug Administration, 2017b). FSMA allows the Food and Drug Administration (FDA) to have stricter controls on food facilities by enforcement through audits and determining audit recurrence based on associated risk. Major changes to how food facilities operate include but are not limited to: (i) registration with the FDA, (ii) a food safety plan that focuses on prevention through hazard analysis, (iii) a food defense plan that has strategies to identify sensitive spots in the supply chain, and (iv) the integration of a Preventive Control Qualified Individual into facility operations (Kennedy, Myhre Errecaborde, & Hueston, 2014). Table 2.1 summarizes some of the major changes that human food facilities faced from the Bioterrorism Act of 2002 to the enactment of the Food Safety Modernization Act of 2011

(FSMA). FSMA did not replace the Bioterrorism Act of 2002, the new regulations were written to build off of the already established regulations.

Table 2.1: FSMA preventive control additions

	Bioterrorism Act of 2002	**Food Safety Modernization Act of 2011**
Preventive Control Requirements	None	Education and training requirements for all personnel Preventive Control Qualified Individual (PCQI) Food safety plan with hazard analysis
Facility Registration	One Time	Biennial
Record Keeping	One back (source) and one forward (recipients) identifiable	No change*
Administrative Detention of Food Products	Product can cause serious adverse health consequence or death	Product believed to be adulterated or misbranded
Food Defense Plan against Intentional Adulteration	None	Written plan with employee training and records
Mandatory Recall	None	FDA has authority

*Section 204 of FSMA is an open section for the improvement of traceability and recordkeeping. Information summarized from the (U.S. Food and Drug Administration, 2018d). Adapted from (Schultz & Chopra, 2018). Table is not inclusive of all new FSMA requirements.

Within the regulations of FSMA, the FDA has established 3 different business classifications for Preventive Control Requirements for Human and Animal Food; Very

Small Business, Small Business, and Other Business. Table 2.2 shows the differences between the classification structures for human and animal food facilities centering around preventive control requirements. Human and animal food facilities have very similar preventive control requirements, with the main difference being how the units are classified and compliance dates.

Table 2.2: Classification of Human and Animal food facilities.

Business Size	Human Food	Animal Food
Very Small	Averages < $1 million in sales plus market value of no-sale products held per year during a 3 year period foregoing the current year **Compliance Date:** September 17, 2018	Averages < $2.5 million in sales plus market value of no-sale products held per year during a 3 year period foregoing the current year **Compliance Date:** September 17, 2019
Small	< 500 full-time comparable employees **Compliance Date:** September 18, 2017	< 500 full-time comparable employees **Compliance Date:** September 17, 2018
Other	Averages ≥ $1 million in sales during a 3 year period foregoing the current year and ≥ 500 full-time comparable employees **Compliance Date:** September 19, 2016	Averages ≥ $2.5 million in sales during a 3 year period foregoing the current year and ≥ 500 full-time comparable employees **Compliance Date:** September 18, 2017

Information summarized from (U.S. Food and Drug Administration, 2018e).

Preventive controls

"The term `preventive controls' means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, or holding at the time of analysis." - U.S. Food and Drug Administration, (2017a)

A hazard may be a biological, chemical, physical, or radiological substance that can either be naturally occurring or accidently introduced into a food product (U.S. Food and Drug Administration, 2017a). The *Salmonella* outbreak in peanut butter was an example of a biological hazard being introduced into a food facility. The new requirements of FSMA are directed at having controls in place to minimize or eliminate these hazards. Understanding the possible hazards linked to each ingredient in a food product is a necessity in order to implement effective preventive controls (King & Bedale, 2018b). Table 2.3 lists the preventive controls of FSMA and why they are important in ensuring food safety.

The FDA classifies eight food allergens as "major food allergens" because they account for 90% of all allergic reactions (U.S. Food and Drug Administration, 2018f). The major food allergens are: (i) milk, (ii) eggs, (iii) fish, (iv) shellfish, (v) tree nuts, (vi) peanuts, (vii) wheat, and (viii) soybeans (U.S. Food and Drug Administration, 2018f). Controlling food allergens is crucial because exposure to such ingredients can be fatal. The FDA estimates that exposure to a food allergen results in 30,000 emergency room visits and 150 deaths per year in the U.S. (U.S. Food and Drug Administration, 2018f).

Preventive controls are the cornerstone of FSMA. King and Bedale (2018a) argue that CGMPs, hazard analysis, and risk-based preventive controls will potentially have the greatest impact on food safety. In order for FSMA to be successful it is important to understand the costs associated with integrating the new law into food facilities. The implementation costs for the preventive control requirements alone are estimated to be $381 million per year (U.S. Food and Drug Administration, 2015). In order for the preventive control measures to be cost effective, they need to eliminate a predicted 157,000 food borne illnesses a year in the U.S. (U.S. Food and Drug Administration, 2015).

Table 2.3: FSMA Preventive Controls

Preventive Control	Purpose	Example
Food Allergen Controls	Measures taken by a facility to prevent cross contamination of allergens and make sure packaged foods are correctly identified.	Labeling allergen containing ingredients from suppliers during receipt.
Verification Activities	Process of ensuring that steps taken to minimize an identified hazard are effective and tools utilized to monitor hazards are routinely check for accuracy.	Checking to make sure a temperature probe is providing accurate measurements.
Current Good Manufacturing Practices (cGMPs)	Company policies and training procedures to make sure food production is free of contaminants and safe for distribution.	Using sanitary water to clean a food processing vessel.
Food Safety Plan	Document that includes a hazard analysis, preventive controls, and the management plan for such preventive controls.	(Purpose)
Training Records	Documents that show employees are educated and qualified to perform specific job functions.	Recorded date, time, signature, and activities of an individual who has learned how to receive raw material.
Standard Operating Procedures	Documents that contain information as to how a specific job function is performed, with a focus on food safety and cleanliness.	Directions for how to correctly clean a processing vessel.
Hazard Analysis	Recognition of physical, chemical, and biological threats that could impact the safety of the food product and countermeasure to mitigate such threats.	Identifying that a broken mixing blade could introduce metal fragments into product, reduce threat by using metal detection.
Recall Plan	Written method for how the food product will be retrieved in the event of adulterated product in the supply chain.	Written procedure for notifying supply chain partners of potential adulterated food.
Preventive Control Qualified Individual (PCQI)	Individual who has completed specific training centered on hazard identification, prevention, and control or is someone considered qualified through career maturity. Must be involved in the creation of the food safety plan.	(Purpose)

Preventive control and purpose sections are summarized from FSMA Final Rule for Preventive Controls for Human Food (U.S. Food and Drug Administration, 2018b, 2018d). Examples are taken from the FDA's Draft Guidance for Industry: Hazard Analysis and Risk

Based Preventive Controls for Human Food (U.S. Food and Drug Administration, 2018c) The list is not inclusive of all required preventive control activities for food facilities.

Traceability infrastructure

Traceability allows for the forward and backward tracking of products as they move from one place in the food supply chain to another (Bhatt, Hickey, & McEntire, 2013). When there is a food recall situation, traceability is a fundamental element for minimizing exposure and preventing the spread of illness throughout a population (Bhatt et al., 2013). The forward movement in the supply chain is how a product is tracked and the backward movement is how a product is traced (Bhatt et al., 2013). In order for a comprehensive traceability system to be in place, a product must be able to be tracked, traced, and historic information about the product must be accessible at all times (Bosona & Gebresenbet, 2013).

Bosona & Gebresenbet (2013) recognize five classifications that have led to the development of traceability in food supply chains: (i) safety and quality interests, (ii) regulations, (iii) social impacts, (iv) financial affairs, and (v) the progression of technology. The implementation of new laws and regulations drives demand for traceability (Mahalik & Nambiar, 2010). The new regulations of FSMA have required food supply chains to audit current methods of operations and transform company policies to improve food safety measures (U.S. Food and Drug Administration, 2017).

The Food Safety Modernization Act is made up of a total of 89 pages, including 4 titles and 41 sections. Under section 204 of the act, the FDA has established a need for traceability and recordkeeping requirements with direction to explore traceability technology throughout food supply chains (Califf, 2016). One of the requirements under Section 204 was to perform pilot studies to evaluate the current practices of the food supply chain system. The Institute of Food Technologist (IFT) completed such pilot studies in 2013 and found that the

one back and one forward tracing method of the Bioterrorism Act can be ineffective as farms and restaurants are exempt from the rule (Bhatt et al., 2013). This leads to gaps in critical traceability information throughout a supply chain, especially during food outbreak investigations (Bhatt et al., 2013).

IFT found that the use of electronic tracking systems were more adequate and reduced product tracking times led to $18K to $14M depending on the case investigated (Bhatt et al., 2013). The cost associated with changes from paper based tracking systems to electronic systems were a major concern for some businesses (Bhatt et al., 2013). The FDA reports that smaller businesses primarily use paper records for traceability documentation (Califf, 2016). A report to the U.S. congress was issued in 2016 which reviewed the proposals from the pilot projects. The FDA reported five major suggestions focused on keeping consistent data elements for traceability throughout a supply chain: (i) a set of homogeneous information needed for product tracing should be identified by the FDA, (ii) food firms should internally maintain records that can identify all products from the receipt locations to the distribution locations, (iii) food businesses should develop ways to advance accuracy and quality of electronic data submitted to the FDA, (iv) the FDA should consider the establishment of key data elements (KDEs) and how the retrieval process of such data should exist, and (v) a documented plan should exist where food firms describe their process for tracking and tracing raw materials and products one step in each direction (at a minimum) of the supply chain (Califf, 2016). KDEs include but are not limited to; supplier identification, product identification, purchase order number, number of items, and the receipt date for products (Bhatt et al., 2013). Table 2.4 lists different traceability components

for capturing KDEs. The congressional report concluded with next steps that stated a need to understand the product tracing practices in small businesses (Califf, 2016).

Table 2.4: Traceability infrastructure for tracking KDEs

Infrastructure	Purpose
Operational Control (MES)	Manufacturing Execution Systems (MES) are computer based programs that are utilized in operations to track information about production quality and efficiency (Mahalik & Nambiar, 2010).
Accounting Programs	Allow for an organization to digitally record information on product quantities, costs, and labor associated with production (Meade, Kumar, & White, 2010) .
Inventory Records	Documents that allow for an organization to keep track of goods that are received, manufactured, and shipped (Bhatt et al., 2013).
Lot Coding	Exclusive identifier for products that were produced under like conditions and in defined quantities (American Society for Quality, 2018).
Business Management Software	Enterprise resources planning (ERP) system allows an organization to direct all activities of a business and share information throughout separated business units (APICS, 2011). A materials requirements planning (MRP) system controls the bill of materials requirements needed for production (APICS, 2011).

Small food manufacturing facilities face many challenges with upgrading their current manufacturing practices to be in compliance with FSMA. Small to medium sized enterprises (SMEs)[1] are slow to integrate technology based supply chain management tools within their organizations because they place less emphasis on supply chain integration (Heide & Vaaland, 2007). SMEs are made up of organizational structures that differ from larger organizations including the use of manufacturing execution systems (MES) and enterprise resource planning systems (ERP) (O'Reilly, Adam, & Kumar, 2015). The

[1] Small and medium sized enterprises (SMEs) is an internationally used term to identify businesses with less than 500 employees. The FDA uses the term Small Business to identify organizations with less than 500 employees.

implementation of MES and ERP systems differs in business size categories due to cost and technological capability factors (Heide & Vaaland, 2007). A recent study on adoption of FSMA has cited six challenges that small businesses face: (i) comprehending the law, (ii) cost of complying, (iii) time to implement changes, (iv) employee preparedness, (v) lack of quality culture in the company, and (vi) employee attitude towards changes (Grover, Chopra, & Mosher, 2016). Additionally another study on FSMA in relation to produce growers found that small produce growers fear that the costs of integrating the food safety requirements will be too significant to remain in operation (Adalja & Lichtenberg, 2018).

Purpose

The purpose of this study was to identify challenges that small businesses face with implementing some of the new regulations required by FSMA. Being able to identify the current preventive control and traceability practices in food facilities will help with understanding the new food safety law's status. Even though the law was established in 2011, compliance dates for small businesses did not start until September of 2017. Because the law requires radical changes in how food supply chains operate, it is important to understand the current level of regulation implementation. Success of FSMA is dependent upon the success of the food industry's abilities to make changes to their supply chain systems. The questions addressed in this research paper are: Are there differences in FSMA preventive control implementation within the small business group? What type of traceability infrastructure do small businesses have in place for food manufacturing? What challenges do small businesses face with FSMA implementation?

Methodology

Survey participants

The research is focused on studying food manufacturing facilities that are classified as small businesses (facilities employing less than 500 employees) in the state of Iowa. The state of Iowa is a good place to study the implementation of FSMA because Iowa is the number one producer of eggs, corn, and pork in the U.S. (Iowa Economic Development Authority, 2018). Processed foods are Iowa's top manufacturing export accounting for 27.7 percent of the states total manufacturing trade, valued around $2.8 billion (Iowa State University, 2018a). Around 500 small food manufacturing facilities are located within the state of Iowa (Iowa State University, 2018a). Small business data was utilized from the Center for Industrial Research and Service (CIRAS), an economic development and industry relations organization located in the state of Iowa. Since 1963, CIRAS has worked with small businesses to improve industry performance through applied research, education, and specialized aid (Iowa State University, 2018b). Verbal approval from the agency team for data use was given. Participants in this study were industry professionals who currently work at small food manufacturing facilities in the state of Iowa.

Survey design

A survey was developed from using the FDA's FSMA Final Rule for Preventive Controls for Human and Animal Food and the Institute of Food Technologists (IFT) pilot study on food traceability. Survey questions were generated from categories of preventive control compliance requirements and traceability infrastructure. The survey was tested with two university doctoral researchers who have focused research on food safety and FSMA implementation. A field expert, one former FDA inspector who worked with small food

facilities and currently trains small businesses in FSMA regulations, was also involved in the development. Before data collection, all topic experts reviewed survey questions for technical terminology gaps and helped form objective questions. The survey was then piloted with two different small food businesses for question clarity and terminology understanding. No major changes to the survey were implemented after the pilot study. Figure 1 shows the questionnaire development flow chart, in which questions were derived from Section 103 (Hazard analysis and risk-based preventive controls) and Section 204 (Enhancing tracking and tracing of food and recordkeeping) of FSMA. The survey included multiple choice with open-ended answers, questions that had "yes" or "no" responses, and questions asking respondents to state the degree of agreement or disagreement on a seven-point Likert Scale. A seven-point Likert Scale was chosen because of previous studies showing ease of use of the scale and effectiveness for gauging participant feedback compared to other scale options (Cohen, Noone, Muñoz-Furlong, & Sicherer, 2004; Guyatt, Townsend, Berman, & Keller, 1987; O'Connor et al., 2011).

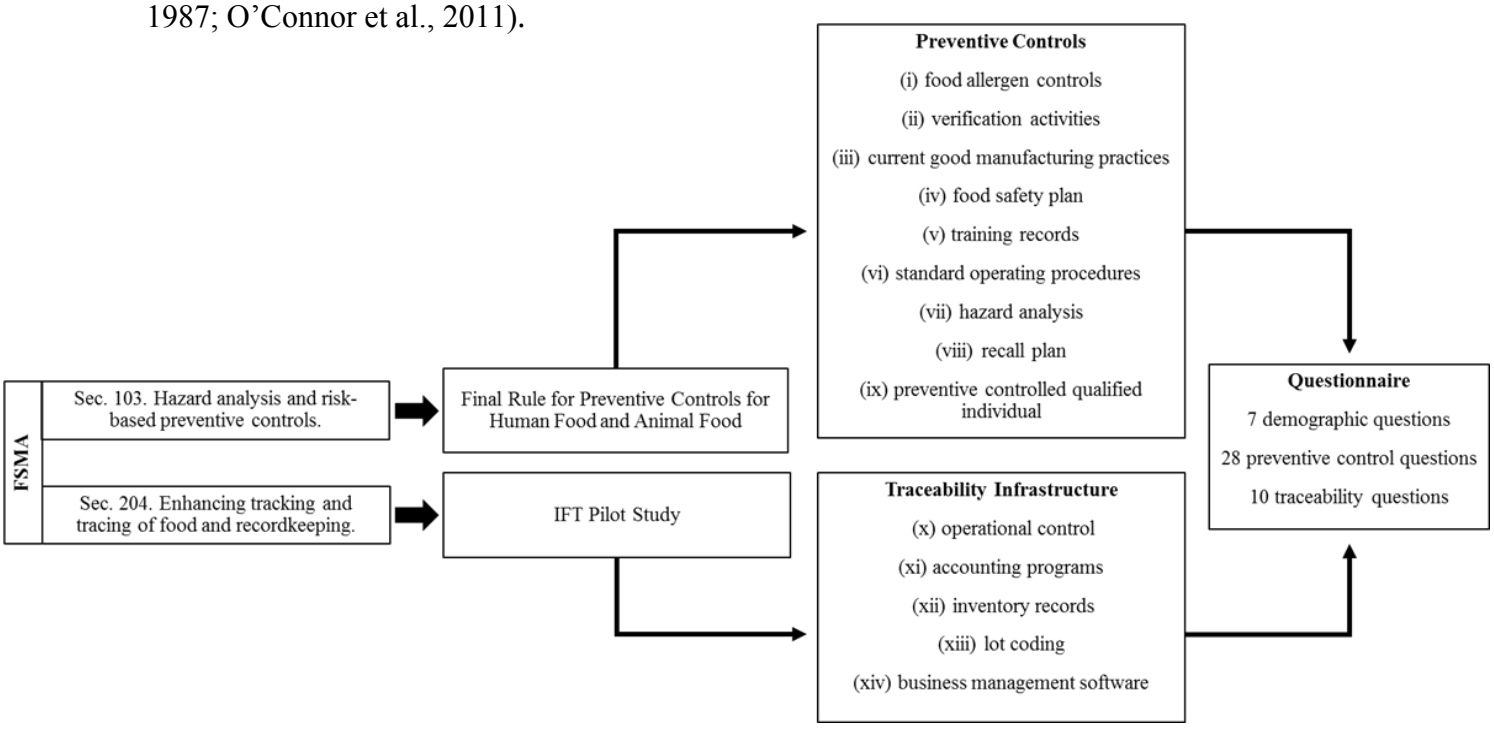

Figure 2.1: FSMA questionnaire development flow chart

Survey dissemination and analysis of data

The survey was distributed at free FSMA 'lunch and learn' sessions across the state of Iowa organized by CIRAS. The lunch and learn updates were provided to human and animal food companies and were led by CIRAS and Iowa State University's Agricultural and Natural Resources Extension. The events were two-hours long and provided a general overview of the new law. The survey was also distributed through email to human and animal food facilities using Qualtrics®. The paper-based version and electronic-base version of the survey were identical.

The data analysis tool JMP® 14 2018 was utilized to make statistical conclusions about the information collected. JMP® is a data analysis software tool developed by SAS. Pearson's chi-squared tests of independence was used to statistically analyze the manufacturing type, company size, and years in business versus different traceability infrastructure and compliance requirement responses. The three comparison categories utilized with chi-square analysis were: manufacturing type (human food versus animal feed), company size (0-24 versus 25-499), and years in business (10 or less versus more than 10). Based on responses to the questionnaire, 14 different factors were analyzed: (i) food allergen controls, (ii) verification activities, (iii) current good manufacturing practices, (iv) food safety plan, (v) training records (vi) standard operating procedures, (vii) hazard analysis, (viii) recall plan, (ix) preventive controlled qualified individual, (x) operational control, (xi) accounting programs, (xii) inventory records, (xiii) lot coding, (xiv) business management software.

Because of the smaller sample size (N=57) of this study, the seven-point Likert Scale questions were collapsed to a dichotomous scale for chi-square analysis. The objective of the

analysis was to determine if the 14 different factors showed dependence on the three different categories (manufacturing type, company size, and years in business). Collapsing of Likert Scale data has been recognized as an approach to eliminate skewness in responses when the scale is lacking numerous data points for each level on the scale (Harpe, 2015; Jeong & Lee, 2016). A dichotomized scale was obtained by moving (strongly disagree, disagree, somewhat disagree, and neither agree nor disagree responses) into one disagree category, and (somewhat agree, agree, and strongly agree) into one agree category for chi-square analysis. The collapsing of the scale points follows the recommendations of the Safety-Attitudes Questionnaire (SAQ) for categorizing agree and disagree categories (Jeong & Lee, 2016).

Results

Participant and company demographics

A total of 57 food manufacturing facilities completed the survey. 45 human food manufacturing facilities, and 12 animal food manufacturing facilities. 78% of the participants classified themselves as a Supervisor/Manager or Company Owner in food operations. 54.4% of the survey participants had more than 5 years of experience working in food manufacturing (45.6% 5 years or less). All companies surveyed had less than 500 full-time equivalent employees. Table 2.5 shows the percentage of participant and company profiles. All participants surveyed were currently working in a food manufacturing facility in the state of Iowa.

Table 2.5: Participants and company profiles

Participant Profiles (N=57)		Company Profiles (N=57)	
Job Function		**Facility Type**	
Owner	35.1%	Human	78.9%
Manager/Supervisor	43.9%	Animal	21.1%
Operator	8.8%		
Other: (Regulatory, Compliance, Auditor)	12.3%	**Size**	
		0-9	29.8%
Education Level		10-24	22.8%
PhD	1.8%	25-99	24.6%
Masters	15.8%	100-499	22.8%
Bachelors	50.9%		
Associates	5.3%	**Years in Business**	
High School	26.3%	Less than 1	8.8%
		1-5	14.0%
Experience (Years)		6-10	7.0%
0-5	45.6%	More than 10	64.9%
6-10	15.8%	No Answer	5.3%
11-15	10.5%		
16-20	21.1%		
More than 20	7.0%		
Age (Years)			
18-25	7.0%		
26-35	24.6%		
36-45	17.5%		
46-55	31.6%		
56-65	17.5%		
No Answer	1.8%		

Food Allergen Controls

Participants were asked to answer a question that asked if their company had food allergen controls in place to prevent mishandling of allergenic ingredients. 54 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the Likert Scale response percentage for food allergen controls based on manufacturing type, company size, and years in business. See

Table 2.6 for Pearson's chi squared test results. Significant differences in responses were affirmed for the manufacturing type (Table 2.6). 36% of animal food companies had food allergen controls in place compared to 77% for human food companies.

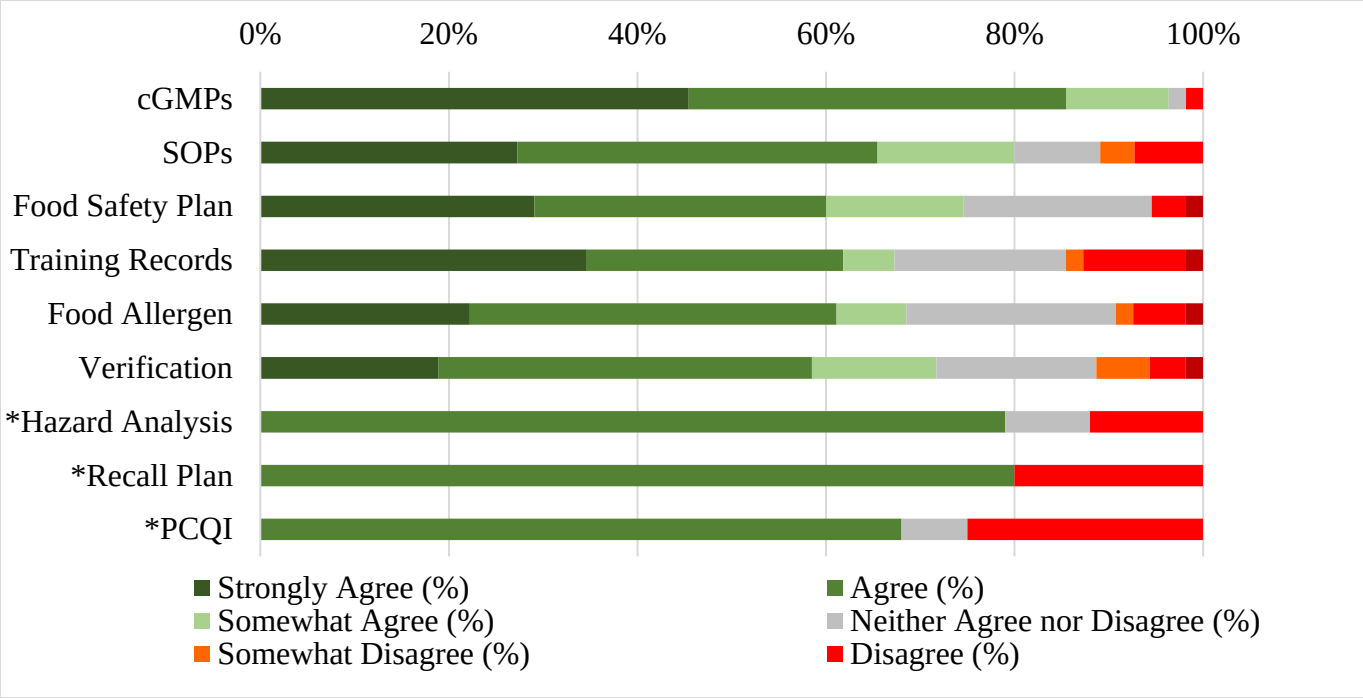

Figure 2.2: Response percentage for all participants

Table 2.6: Pearson's chi squared test results for compliance requirements

Compliance Controls	**Manufacturing Type (DF=1)**	**Company Size (DF=1)**	**Years in Business (DF=1)**
Food Allergen	6.62 (0.0101)	0.23 (0.6328)	0.71 (0.4008)
Verification	1.71 (0.1912)	9.20 (0.0024)	4.64 (0.0312)
cGMPs	0.58 (0.4466)	2.00 (0.1572)	0.28 (0.5946)
Food Safety Plan	2.37 (0.1236)	5.75 (0.0165)	1.43 (0.2322)
Training Records	4.15 (0.0417)	20.29 (<.0001)	10.10 (0.0015)
SOPs	3.84 (0.0501)	13.26 (0.0003)	6.07 (0.0137)
Hazard Analysis	1.48 (0.2238)	5.75 (0.0165)	2.80 (0.0944)
Recall Plan	3.73 (0.0533)	2.40 (0.1210)	6.35 (0.0118)
PCQI	3.97 (0.0463)	7.18 (0.0074)	1.914 (0.1665)

Note: p-values are reported in parentheses, α=0.05, DF=degrees of freedom

Table 2.7: Response percentages based on manufacturing type

Chi-Square		Agree			Disagree			
Questions	**Manufactruing Type**	**Strongly Agree (%)**	**Agree (%)**	**Somewhat Agree (%)**	**Neither Agree nor Disagree (%)**	**Somewhat Disagree (%)**	**Disagree (%)**	**Strongly Disagree (%)**
cGMPs	**Animal**	58%	34%	8%	0%	0%	0%	0%
	Human	42%	42%	12%	2%	0%	2%	0%
SOPs	**Animal**	50%	25%	25%	0%	0%	0%	0%
	Human	21%	42%	12%	11%	5%	9%	0%
Food Safety Plan	**Animal**	42%	42%	8%	8%	0%	0%	0%
	Human	26%	28%	16%	23%	0%	5%	2%
Training Records	**Animal**	50%	42%	0%	8%	0%	0%	0%
	Human	30%	24%	7%	21%	2%	14%	2%
Food Allergen	**Animal**	27%	9%	0%	55%	0%	9%	0%
	Human	21%	47%	9%	14%	2%	5%	2%
Verification	**Animal**	10%	50%	30%	0%	0%	10%	0%
	Human	21%	37%	10%	21%	7%	2%	2%
***Hazard Analysis**	**Animal**		92%		8%		0%	
	Human		76%		9%		15%	
***Recall Plan**	**Animal**		100%		0%		0%	
	Human		75%		0%		25%	
***PCQI**	**Animal**		92%		8%		0%	
	Human		61%		7%		32%	

*Non-Likert Scale question

Table 2.8: Response percentages based on company size

Chi-Square		Agree			Disagree			
Questions	**Size**	**Strongly Agree (%)**	**Agree (%)**	**Somewhat Agree (%)**	**Neither Agree nor Disagree (%)**	**Somewhat Disagree (%)**	**Disagree (%)**	**Strongly Disagree (%)**
cGMPs	**0-24**	32%	50%	11%	4%	0%	4%	0%
	25-499	59%	30%	11%	0%	0%	0%	0%
SOPs	**0-24**	14%	36%	11%	18%	7%	14%	0%
	25-499	41%	41%	19%	0%	0%	0%	0%
Food Safety Plan	**0-24**	4%	36%	21%	32%	0%	7%	0%
	25-499	56%	26%	7%	7%	0%	0%	4%
Training Records	**0-24**	14%	21%	4%	36%	4%	18%	4%
	25-499	56%	33%	7%	0%	0%	4%	0%
Food Allergen	**0-24**	7%	50%	14%	18%	4%	7%	0%
	25-499	39%	27%	0%	27%	0%	4%	4%
Verification	**0-24**	7%	37%	11%	30%	11%	4%	0%
	25-499	31%	42%	15%	4%	0%	4%	4%
***Hazard Analysis**	**0-24**		67%		13%		20%	
	25-499		93%		3%		4%	
***Recall Plan**	**0-24**		72%		0%		28%	
	25-499		89%		0%		11%	
***PCQI**	**0-24**		52%		3%		45%	
	25-499		85%		11%		4%	

*Non-Likert Scale question

Table 2.9: Response percentages based on company years in business

Chi-Square		Agree			Disagree			
Questions	**Years in Buisiness**	**Strongly Agree (%)**	**Agree (%)**	**Somewhat Agree (%)**	**Neither Agree nor Disagree (%)**	**Somewhat Disagree (%)**	**Disagree (%)**	**Strongly Disagree (%)**
cGMPs	**0-10**	35%	41%	18%	6%	0%	0%	0%
	10+	46%	43%	8%	0%	0%	3%	0%
SOPs	**0-10**	18%	29%	12%	23%	0%	18%	0%
	10+	31%	43%	14%	3%	6%	3%	0%
Food Safety Plan	**0-10**	18%	24%	23%	35%	0%	0%	0%
	10+	34%	34%	12%	11%	0%	6%	3%
Training Records	**0-10**	18%	12%	6%	35%	6%	23%	0%
	10+	40%	34%	6%	11%	0%	6%	3%
Food Allergen	**0-10**	0%	41%	18%	41%	0%	0%	0%
	10+	29%	38%	3%	15%	3%	9%	3%
Verification	**0-10**	6%	29%	18%	35%	12%	0%	0%
	10+	24%	43%	12%	9%	3%	6%	3%
***Hazard Analysis**	**0-10**		67%		5%		28%	
	10+		86%		8%		6%	
***Recall Plan**	**0-10**		59%		0%		41%	
	10+		89%		0%		11%	
***PCQI**	**0-10**		53%		6%		41%	
	10+		72%		8%		20%	

*Non-Likert Scale question

Verification Activities

Participants were asked if their company validates process controls to make sure they are effective. 53 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the Likert Scale response percentages for verification of process controls based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. Significant differences in responses were affirmed between the sizes of the companies and years in business (Table 2.6). Companies that had 25-499 employees, 92% agreed with validating process controls compared to 56% for companies with 0-24 employees. Companies in business more than 10 years, 82% agreed with validating process controls compared to 53% for companies in business 10 or less years.

Current Good Manufacturing Practices (cGMPs)

Participants were asked if their company uses cGMPs to keep the cleanliness of food-contact surfaces. 55 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the Likert Scale response percentages for cGMPs based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. No significant differences were affirmed across the categories (Table 2.6).

Food Safety Plan

Participants were asked if their company has a food safety plan that contains a hazard evaluation. 55 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the Likert Scale response percentages for a food safety plan based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. Significant differences were affirmed in the size of the company (Table 2.6). Companies that had 25-499 employees, 89% agreed with having a food safety plan compared to 61% for companies with 0-24 employees.

Training Records

Participants were asked if their company keeps training records for all employees. 55 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the Likert Scale response percentages for training records based on manufacturing type, company size, and years in

business. See Table 2.6 for Pearson's chi squared test results. Significant differences in responses were affirmed for all 3 categories (Table 2.6). 92% of animal food companies agreed with keeping training records compared to 60% for human food companies. Companies that had 25-499 employees, 96% agreed with keeping training records compared to 39% for companies with 0-24 employees. Companies in business more than 10 years, 80% agreed with keeping training records compared to 35% for companies in business 10 or less years.

Standard Operating Procedures (SOPs)

Participants were asked if their company has documented SOPs for different work duties. 55 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the Likert Scale response percentages for SOPs based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. Significant differences in responses were affirmed for the size of the company and years in business (Table 2.6). Companies that had 25-499 employees, 100% agreed with having documented SOPs for different work duties compared to 67% for companies with 0-24 employees. Companies in business more than 10 years, 89% agreed with having documented SOPs for different work duties compared to 59% for companies in business 10 or less years.

Hazard Analysis

Participants were asked if their company has ever performed a hazard analysis. 57 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size,

and years in business. Table 2.7, 2.8, and 2.9 show the response percentages for hazard analysis based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. Significant differences were affirmed for company size (Table 2.6). Companies that had 25-499 employees, 93% had performed a hazard analysis compared to 67% for companies with 0-24 employees.

Recall Plan

Participants were asked if their company had a recall plan in place in the event of product contamination. 56 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the response percentages for a recall plan based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. Significant differences in responses were affirmed for how long a company has been in operation (Table 2.6). Companies in business more than 10 years, 89% have a recall plan compared to 59% for companies in business 10 or less years.

Preventive Control Qualified Individual (PCQI)

Participants were asked if their company had a Preventive Control Qualified Individual (PCQI). 56 of the 57 participants responded to the question. Figure 2.2 shows the response percentages for each Likert category. Responses were compared against manufacturing type, company size, and years in business. Table 2.7, 2.8, and 2.9 show the response percentages for having a PCQI based on manufacturing type, company size, and years in business. See Table 2.6 for Pearson's chi squared test results. Significant differences in responses were affirmed for the manufacturing type and the size of the company (Table

2.6). 92% of animal food companies had a PCQI compared to 61% for human food companies. Companies that had 25-499 employees, 85% had a PCQI compared to 52% for companies with 0-24 employees.

Operational Control

Participants were asked if their company utilized computers for operational purposes. 57 of the 57 participants responded to the question. Table 2.10 shows the response percentages for traceability infrastructure. Responses were compared against manufacturing type, company size, and years in business. See Table 2.11 for Pearson's chi squared test results. Significant differences in responses were affirmed for the size of the company (Table 2.11). Companies that had 25-499 employees, 93% used computers in operations vs. 50% for companies with 0-24 employees.

Table 2.10: Traceability infrastructure response percentages

Chi-Square	Agree	Disagree	
Questions	**Agree (%)**	**Neither Agree nor Disagree (%)**	**Disagree (%)**
Operational Control	70%	7%	23%
Accounting	82%	9%	9%
Inventory Records	75%	9%	16%
Lot Coding	70%	2%	28%
Business Management	15%	53%	32%

Table 2.11: Pearson's chi-squared test results for traceability infrastructure

Infrastructure	**Manufacturing Type (DF=1)**	**Company Size (DF=1)**	**Years in Business (DF=1)**
Operation Control	3.35 (0.0670)	12.32 (0.0004)	0.69 (0.4073)
Accounting Program	0.89 (0.3451)	1.47 (0.2257)	5.40 (0.0201)
Inventory Records	2.26 (0.1325)	12.61 (0.0004)	1.02 (0.3137)
Lot Coding	0.21 (0.6489)	9.14 (0.0025)	0.12 (0.7301)
Business Management	1.35 (0.2453)	5.53 (0.0187)	3.82 (0.0507)

Note: p-values are reported in parentheses, α=0.05, DF=degrees of freedom

Accounting Programs

Survey participants were asked to answer a question that asked if their company utilized a software program for accounting purposes. 57 of the 57 participants responded to the question. Table 2.10 shows the response percentages for traceability infrastructure. Responses were compared against manufacturing type, company size, and years in business. See Table 2.11 for Pearson's chi squared test results. Significant differences in responses were affirmed for years in business (Table 2.11). Companies with more than 10 years in business, 92% utilized an accounting program, compared to only 67% for companies in business less than 10 years.

Inventory Records

Participants were asked how the company keeps track of inventory in relation to electronic tracking. 56 of the 57 participants responded to the question. Table 2.10 shows the response percentages for traceability infrastructure. Responses were compared against manufacturing type, company size, and years in business. See Table 2.11 for Pearson's chi squared test results. Significant differences in responses were affirmed for the size of the company (Table 2.11). Companies that had 25-499 employees, 63% used a combination of paper-based and computer based tracking versus 45% for companies with 0-24 employees. Companies that had 25-499 employees, 33% used only computers to electronically track inventory versus 10% for companies with 0-24 employees. Companies that had 25-499 employees, 4% keeps track of inventory only on paper versus 28% for companies with 0-24 employees.

Lot Coding

Participants were asked if their company documents and stores lot code information for raw ingredient use. 56 of the 57 participants responded to the question. Table 2.10 shows the response percentages for traceability infrastructure. Responses were compared against manufacturing type, company size, and years in business. See Table 2.11 for Pearson's chi squared test results. Significant differences in responses were affirmed for the size of the company (Table 2.11). Companies that had 25-499 employees, 89% documents and stores lot code information for raw ingredient use vs. 52% for companies with 0-24 employees.

Business Management Software

Participants were asked what type of business management software program the company uses. 55 of the 57 participants responded to the question. Table 2.10 shows the response percentages for traceability infrastructure. Responses were compared against manufacturing type, company size, and years in business. See Table 2.11 for Pearson's chi squared test results. Significant differences in responses were affirmed for the size of the company (Table 2.11). Companies that had 25-499, 26% utilized a business management system compared to 4% for companies with 0-24 employees.

Challenges

Participants were asked identify the most challenging aspect of the Food Safety Modernization Act. 55 of the 57 participants responded to the question. Responses were compared against manufacturing type, company size, and years in business. Significant differences in responses were affirmed for the size of the company (Chi square test results: 20.67, p-value: 0.0009). 65% of companies with 0-24 employees identified understanding the

FSMA law as the biggest challenge compared to only 30% for companies with 25-499 employees. Figure 3 shows the percentage response rate for each challenge category compared to company size.

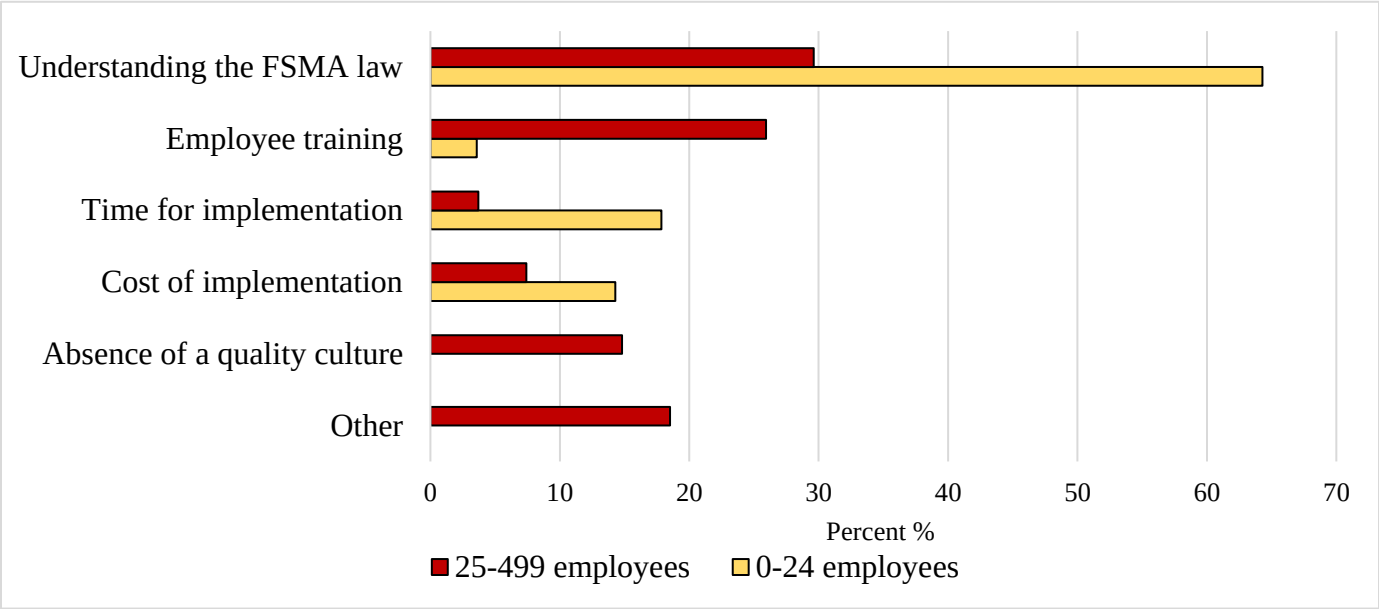

Figure 2.3: Challenge rankings in response percentage based on company size

Discussion

A significant variable, affecting the different compliance requirements and traceability infrastructure, was the company size within the small business category. Pearson's chi-squared tests showed the most significant results (lowest p-values) when a division was made between companies at the 25 employee mark. 10 of 14 factors showed dependency for company size, 5 of 14 factors showed dependency for years in business, and 3 of 14 factors showed dependency for manufacturing type. The results of the significance difference in responses based on firm size is on par with previous literature (Rouvière, 2016). Rouvière, 2016 stated that a firm's size is an important contributing factor in how FSMA requirements should be determined, however determining the cutoff sizes for compliance requirements could not be determined based on size alone and food safety considerations

need to be accounted for. The FDA recognizes that technical guidance and training on preventive controls is needed at the small business level for the success of FSMA (Sebelius, 2013).

Years in business was a significant factor for verification, SOPs, training records, recall plan, and accounting program integration. Companies with more than 10 years in operation were more confident with verification, utilizing SOPs, establishing training records, and as a group developed more recall plans than companies with less than 10 years in operation. Companies with less than 10 years of operation proved to be more willing to adopt new technology as 30% had integrated an ERP or MRP system versus 9% for businesses with more than 10 years in operation. Prior findings suggests in the similar lines of this research, that legacy small manufacturing companies may have a hard time finding software programs to fit into their already established processes (Raymond & Uwizeyemungu, 2007). These findings advocate that new food businesses may need more help than already established businesses, in learning to integrate verification, SOPs, training records, and a recall plan into their facilities.

The food manufacturing facility type (human versus animal) proved to be significant in the factors for food allergen controls, training records, and having a PCQI. Only 36% of animal food companies had food allergen controls in place compared to 77% for human food companies. One of the biggest differences in FSMA between human and animal food manufacturing is the requirement for food allergen controls; required in human food facilities, not in animal food facilities. So, these results are expected as the law would be the driver to have the allergen controls in place. In 2012 a study found that 70% of human food facilities had food allergen controls in place for storage practices (Gendel, Khan, & Yajnik,

2013). Animal food facilities showed more confidence in having training records (92%) and a PCQI (92%) compared to human food facilities (60% training records, 61% PCQI). These findings are surprising given the fact that animal food facility compliance dates are one year after human food facility compliance dates. Even with the small sample size of animal food facilities, one would wonder if the state of Iowa has had a more impactful outreach program to animal facilities on FSMA compared to human food facilities.

One of the greatest changes to operations for the small business category is the requirement of the PCQI and their involvement in the development of the food safety plan (U.S. Food and Drug Administration, 2018b). Only 68% of companies surveyed stated they had a PCQI working with their facility. This is a major concern as the grace periods for compliance requirements have started to pass. Without the PCQI, a facility cannot develop a food safety plan that will be in compliance with the law. Companies with 0-24 employees showed a considerable need for a PCQI with only 52% having one, compared to 85% of companies with 24-499 employees. The PCQI is a critical component for the success of FSMA because of the level of understanding centered on preventive controls needed to develop an effective food safety plan.

The technical capabilities for traceability infrastructure varied significantly for the size of the company. As reported by Bhatt et al., 2013, small businesses have different ways of capturing data: manually on paper, writing on paper and entering information into a computer system, and using electronic technologies. Companies that had 25 or more employees: 93% used some type of MES system, 96% used computers in some form for inventory tracking, 89% documented and stored lot code information, and 22% utilized an ERP system. Companies that had 24 or less employees: 50% used some type of MES system,

55% used computers in some form for inventory tracking, 52% documented and stored lot code information, and 4% utilized an ERP system. Because of the cost savings and food borne illness decline realized from a reduction in traceback times, integrating technology into small food supply chains is critical (Bhatt et al., 2013). However, based on literature review there has not be a clear theoretical framework for the insertion of a food traceability as it has advanced in different scientific fields for distinctive purposes (Karlsen, Dreyer, Olsen, & Elvevoll, 2013). Because of the different technologies available and information that is being captured by each one, it is important to establish a common technology utilized by food manufacturing. This research appeals to the IFT reported recommendations to the FDA in which the top priority was the establishment of homogeneous recordkeeping requirements across the whole food supply chain system without exemptions based on class (Bhatt et al., 2013). From this research, a focus on technology adoption for companies with less than 25 employees is showing a need because of the significantly less utilization compared to the larger company counterparts.

The analysis of challenges directly correlated with the findings of (Grover et al., 2016). Understanding of the FSMA law ranked the greatest challenge to overcome (Figure 2.3; Grover et al., 2016). Even though understanding the FSMA law was the highest ranked category, larger small businesses (25-499 employees) had a significant difference in rank order of the challenges compared to businesses with 24 or less employees (Figure 2.3). With a greater understanding of the law, a company has the ability to assess where the resources are needed to become in compliance. The second highest ranked challenge for companies with 25-499 employees was employee training (Figure 2.3). Since companies with 0-24 employees identified understanding the law overwhelmingly as the greatest challenge (65%),

it would be hard for them to determine the gaps in time, cost, and training requirements for successful implementation. As compliance deadlines have started to pass and understanding of the law is still the greatest urgency, there is a need for small companies to rapidly become educated to allow for assessment of other factors, especially companies with 24 or less employees.

Limitations and future work

This research study in only focused on small businesses in one Midwest state to understand the current challenges of FSMA implementation. Other states throughout the U.S. may exhibit different behavior towards FSMA compliance based on type of food processing and the state's food safety laws that are established in accordance with federal laws. Because FSMA compliance date for small businesses was in September of 2017, the survey took place after the initial compliance date has passed. Even though the survey is anonymous, there is a threat to the accuracy of information the survey participant may be willing to provide if the resulting answer may show a lack in FSMA compliance. To help avoid inaccurate responses, the survey participation was completely voluntary and participants could skip any questions that they do not wish to answer. However, an absence in FSMA confidence may have deterred potential research participants, thus skewing the data to more positive results for preventive control compliance requirements. This study was only focused on number of employees for business classification. The FDA utilizes financial metrics to further classify the different business categories. Thus, very small businesses/small businesses would all be group into the small business category for this study. The study was conducted for human and animal food manufacturing facilities, even though the law is similar for both groups, differences in regulations exists and a specific questionnaire for each

type of manufacturing may be more beneficial in determining the current state of compliance requirements.

Continued research will aid in the progression of food supply chain safety in the U.S. There is a need to understand a basic model that will aid in forming a parallel traceability infrastructure throughout small businesses. There is a need to understand the effectiveness of PCQI training for the development of food safety plans, and if the different training platforms (in-person/online/hybrid) prove to be more effective. This research study casted a wide net over preventive controls and traceability infrastructure from the manufacturing facility point of view. Quality audit data at food facilities will be an important factor to compare perception of preventive controls and traceability structure versus actual implementation.

Conclusion

Despite the limitations of the research, an insight into the current state of preventive control and traceability infrastructure of small food facilities was revealed. A quantitative understanding of small business operations is valuable to discern where necessary resources need to be deployed. This study revealed that the size of the company within the small business category proves to be a major variable for FSMA implementation. As understanding the law is of high priority, this research helps provide an insight into what preventive control categories are better understood by small businesses, and what ones need more attention. Success of FSMA is dependent upon the success of the food industry's abilities to make changes to their supply chain systems, with the end goal leading to the abatement of food borne illnesses.

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CHAPTER 3. FOOD SAFETY MODERNIZATION ACT: A LEAN SIX SIGMA APPROACH TO TRACEABILITY IN SMALL AND MEDIUM SIZED ENTERPRISES

A paper accepted into the Seventh International Conference on Lean Six Sigma

Quin Schultz, Shweta Chopra

Abstract

Purpose: Consumers want accessible quality, safe, and traceable food products to ensure protection from food borne illnesses. In 2011, the U.S. government implemented the Food Safety Modernization Act (FSMA). The law requires the food industry to move from a system that responds to food contamination to a system that prevents food contamination. Lean Six Sigma (LSS) methodologies can improve an organization's product traceability time and information accuracy. The LSS tools allow for an organization to be structured in the areas of record keeping, process control, and employee training.

Design/Approach: This research focuses on improving Small to Medium Sized Enterprises (SMEs) compliance with the FSMA by addressing the need for traceability within their supply chains. A review of literature showed LSS methodologies can aid SMEs in FSMA compliance by addressing traceability needs.

Findings: Outcomes of the research show the current challenges SMEs face for successful implementation of the FSMA, and methods for improvement plans. Traceability needs to be a key component in FSMA adaptation plans.

Social Implications: The Center for Disease Prevention and Control reports that, in the U.S., food borne illness is contracted by 48 million people and results in 3,000 deaths

annually. Food borne illnesses can be diminished by successful implementation of the FSMA throughout SMEs.

Originality and Value: There is a need to understand the current state of the FSMA and how food supply chains are adapting to the new requirements. SMEs need a cost effective solution to improve traceability of food products within their systems for progress in reducing food borne illnesses.

Introduction

The need to know more information about the food that we are consuming has become less of a luxury and more of a requirement. Consumers want accessible quality, safe, and traceable food products. In 2011, the U.S. government implemented the Food Safety Modernization Act (FSMA). The law requires the food industry to move from a system that responds to food contamination to a system that prevents food contamination (U.S. Food and Drug Administration, 2017). Small food manufacturing facilities face a challenge with upgrading their current manufacturing practices to be in compliance with FSMA. Contamination of food products can happen during production, processing, distribution, and preparation throughout the food supply chain (Center for Disease Control and Prevention, 2017). The Center for Disease Prevention and Control reports that in the U.S. food borne illness is contracted by 48 million people per year and results in 3,000 deaths annually (Scallan et al., 2011).

The FDA classifies a small business as one that has fewer than 500 employees (U.S. Food and Drug Administration, 2017). Many small to medium sized (SMEs) manufacturing facilities still use a paper based tracking method for lot traceability. Inventory traceability is the key to ensure product visibility and safety throughout the supply chain. During high

priority product tracking needs, a system must be in place to quickly access batch records and raw ingredient lot information. The paper based tracking system can be languid when time is a critical component for tracking purposes.

A mock study was done by the Institute of Food Technologists (IFT) and Deloitte Consulting where the number of illnesses from 8 outbreak investigations were converted to costs. The focus of the study was to see how traceability times affect the outbreak in terms of cost. By reducing the product tracking time by 25%, 50%, and 75% in the study, the cost savings resulted between 18 thousand to 14 million dollars depending on the case (Bhatt et al., 2013). Moving from a paper based tracking system to an electronic based tracking system can improve on tracking times for products. The use of Lean Six Sigma (LSS) methodologies combined with electronic tracking methods can improve traceability, quality, and product safety throughout a food supply chain.

Food Safety Modernization Act

In 2011, the Food Safety Modernization Act (FSMA) was signed into law in the U.S. For small businesses, compliance with FSMA started on September 18th, 2017 (U.S. Food and Drug Administration, 2017). FSMA was the driving force to update food regulations in the United States. FSMA allows the Food and Drug Administration (FDA) to have stricter controls on the supply chain by enforcing the new law through audits and determining audit frequency based on risk. Some of the general requirements for most food manufacturers and distributors are: have registered with the FDA, created a food safety plan that focuses on prevention through hazard analysis, and created a food defense plan that has strategies to reduce the severity of exposure (Kennedy et al., 2014). The generalized guidelines follow the basic premise for Hazard Risk Analysis by reducing probability (prevention) and reducing

severity (exposure). FSMA is focused on the concept of maintaining a safe food supply chain. One of the biggest concerns with FSMA is the ability to control food coming into the U.S. from other countries. Having an established food traceability network that can be tracked for compliance is key to food import safety (Drew and Clydesdale, 2015).

Drew and Clydesdale (2015) argue that one of the biggest challenges with the implementation of FSMA is controlling the additional 50 rules, reports, and documents signed into the law. This could be unachievable with the already overtasked FDA culture. To ensure success of the new law, resources must be available to track compliance and provide guidance to supply chain nodes. Food safety improvements can only be realized if the FDA is prepared for compliance. If resources are not available to ensure compliance and track progress, the success of FSMA may be at risk. According to (U.S. Food and Drug Administration, 2016) FSMA had a funding gap of nearly $300M. The overarching goal of FSMA is to improve food safety in the United States. The Center for Disease Control and Prevention reports that in the U.S. food borne illness is contracted by 48 million people per year and results in 3,000 deaths annually (Scallan et al., 2011). If FSMA fails to show improvements to food borne illnesses and deaths, the law will be a penniless step for food safety. Table 3.1 shows the major changes for human food facilities from the Bioterrorism Act of 2002 to the implementation of the Food Safety Modernization Act of 2011 (FSMA). Small to Medium Sized Enterprises (SMEs) face major challenges with upgrading their current manufacturing practices to be in compliance with FSMA.

Table 3.1: Bioterrorism Act of 2002 vs. the Food Safety Modernization Act of 2011.

	Bioterrorism Act of 2002	**Food Safety Modernization Act of 2011**
Prevention Controls Requirements	None	Education and personnel training requirements Prevention Control Qualified Individual (PCQI) Food safety plan with hazard analysis
Facility Registration	One Time	Biennial
Record Keeping	Establishment and maintenance of records for up to 2 years One back (source) and one forward (recipients) identifiable	Establishment and maintenance of records for up to 2 years One back (source) and one forward (recipients) identifiable
Administrative Detention of Food Products	Product can cause serious adverse health consequence or death	Product believed to be adulterated or misbranded
Food Defense Plan against Intentional Adulteration	None	Written plan with employee training and includes records
Mandatory Recall	None	FDA has authority

Table is not inclusive of all new FSMA requirements. Information summarized from the (U.S. Food and Drug Administration, 2018).

A recent study on adoption of FSMA has cited six challenges that SMEs face: (i) comprehending the law, (ii) cost of complying, (iii) time to implement changes, (iv)

employee preparedness, (v) lack of quality culture in the company, and (vi) employee attitude towards changes (Grover et al., 2016). Lean six sigma methodologies can mitigate five of the six challenges. The basis of Lean Six Sigma is a methodized timeline to reduce cost, while improving quality and process controls within an organization (challenges (ii), (iii), and (v)). Employee engagement is embedded in a Lean Six Sigma culture which helps better prepare employees for changes to processes (challenges (iv) and (vi)).

Traceability

Traceability in a food supply chain allows for the forward and backward tracking of products as they move from a source to a consumer. When there is a food crisis, traceability is a critical component for minimizing exposure and preventing illness throughout a population. Throughout the science community there are many definitions of product traceability. A review of literature found that there are more informative definitions that apply to food supply chains. Product tracking is how something is identified during the forward movement through a supply chain. Product tracing is how something is identified through backward movement in a supply chain. In order for a comprehensive traceability system to be in place, a product must be able to be tracked, traced, and historic information about the product must be accessible (Bosona and Gebresenbet, 2013).

Bosona and Gebresenbet (2013) stated five distinct categories that have led to the development of traceability: (i) food safety and quality concerns, (ii) regulatory concerns, (iii) social concerns, (iv) economic concerns, and (v) technology advancement concerns. The continuous introduction of new laws and regulations drives the need for traceability. For example, FSMA has required supply chains to move from responsive to preventative food systems. The new regulation has required food supply chains to review current practices and

implement changes to improve on preventative food safety measures (U.S. Food and Drug Administration, 2017). There are many benefits that result from product traceability. According to Pizzuti and Mirabelli (2015), a summary of the benefits can be outlined in 6 ideas from literature review:

Table 3.2 Benefits of Traceability

Benefits	Control Measures
Increased Efficiency and Control	Ability to locate, identify, and retrieve raw materials
Reduction of Costs	Reduced product exposure times during recall
Distinct Job Duties	Total supply chain involvement
Increased Speed of Data Acquisition	Quick access to lot information
Reduced Risk and Protection	Limits exposure to impurities throughout supply chain
Company Brand Improvement	Provides customers with product makeup

Traceability can only be achieved if communication and standardization in an organization is obtained. Lean Six Sigma is based on the methodologies that are structured in employee engagement and involvement.

For a food supply chain to implement a robust traceability system or improve an existing one they must be able to overcome several obstacles. When a new traceability system is implemented the organizational structure will have to adjust. There will be a need for document control and maintenance. New standard operating procedures will have to be in place to ensure the uniformity of interactions from end to end of the supply chain. To go along with new technology and standard operating procedure adaptation, training will need to be performed to ensure proper actions for complete system success. For small enterprises, cost to implement new technology in the short term may be one of the biggest challenges. However, improvements in speed and efficiency can reduce long term cost in the event of an outbreak or crisis (Pizzuti and Mirabelli, 2015). A mock study was done by the Institute of Food Technologists (IFT) and Deloitte Consulting where the number of illnesses from 8 outbreak investigations were converted to costs. By reducing the product tracking time by

25%, 50%, and 75% in the study, the cost savings resulted between $18K to $14M depending on the case (Bhatt et al., 2013).

Advancements in technology allows for different traceability systems to be in place. Using lean tools combined with technology can improve a traceability system effectiveness. For example, the lean tool Failure Mode Effect and Criticality Analysis (FMECA) was used to perform an assessment on a pasta production process. The FMECA process was able to identify several operations that resulted in undesirable traceability outcomes. The study showed that there were several failure modes that needed to be changed in order to maintain accurate traceability records for production (Bertolini et al., 2006). Food borne illnesses are related to healthcare associated infections, in that in both instances a lack or breakdown in a process results in a potentially fatal transmission of an organism. During a recent study of 20,000 patients who underwent a surgical procedure, Lean Six Sigma methodology showed to reduce healthcare acquired infections by 20% (Montella et al., 2017). Using lean tools to understand potential gaps in processes can help move a food organization from a contamination responsive approach to a prevention approach.

Lean Six Sigma Approach to Traceability

Under the current law of FSMA there has been no upgrades to traceability standards since the Bioterrorism Act of 2002. The FDA recognizes that there are major voids in the one step back, one step forward policy. In response to food borne illness outbreak product tracing needs, the FDA has stated that the current regulations limit the ability of the agency to quickly access the necessary data. The FDA has identified four challenges for product traceability in the current law (i) absence of requirements for all supply chain nodes, (ii) absence of uniform data and record keeping regulations, (iii) absence of connecting receiving

and shipping of materials from supply chain nodes, and (iv) lack of developed infrastructure traceability technology (Califf, 2016).

The problem SMEs face is that they are expected to be in compliance with the new FSMA requirements as of September 18, 2017. If SMEs have performed major changes to organizational operations without traceability considerations, the success of the new law could be in jeopardy. Traceability is the building block for the drastic changes required by FSMA. Traceability allows for record keeping which in turn allows organizations to implement preventative controls and identify hazards. A comprehensive food safety plan cannot be developed without traceability as a structured requirement. Lean Six Sigma tools can allow for a food facility to improve traceability with a focus on improving cost, quality, and implementation time. Table 3.3 describes how lean tools can improve traceability throughout a supply chain.

Traceability is the building block for the drastic changes required by FSMA. Traceability allows for recording keeping which in turn allows organizations to implement preventative controls and identify hazards. A comprehensive food safety plan cannot be developed without traceability as a structured requirement. Lean Six Sigma tools can allow for a food facility to improve traceability with a focus on improving cost, quality, and implementation time (Ben-Tovim et al., 2008; Bertolini et al., 2006; De Steur, Wesana, Dora, Pearce, & Gellynck, 2016; Gupta & Jain, 2015).

Table 3.3: Use of Lean Six Sigma Tools for Traceability Improvements

LSS Tool	Use in Traceability Improvement
1. Value Stream Mapping	Identifies and quantifies waste throughout a supply chain. Allows an organization to see the movement and flow of all information and key traceability points (Chen, 2017; De Steur et al., 2016).
2. 5S	Requires the involvement of production workers to sort, set-in-order, shine, standardize, and sustain a process. Key for organization to achieve sustainable traceability. Allows a facility to recognize when a condition is aberrant (George et al., 2005; Gupta and Jain, 2015).
3. Poka-Yoke	"Mistake Proofing" can help reduce loss of information. Failure of documentation could prove detrimental for traceability in a system. If a stakeholder forgets to record information that is needed for traceability, poka-yoke can help signal and eliminate loss of information as material moves up the supply chain (Antonelli and Stadnicka, 2016).
4. Standard Work	Standard work is a continuous process improvement tool that aids in; the documentation of current processes for all shifts, the reduction in variability, and easier training. Documentation is key for traceability, and standardized work plays a significant role in training employees to document each and every process and process variability (Ben-Tovim et al., 2008) .
5. FMEA (Failure Mode and Effects Analysis)	Use to identify how people, supplies, machinery, operations, and environment cause process problems. Can expose disruptions that reveal vulnerable information record retention points and prioritize behavior to reduce risk (Bertolini et al., 2006; Dora Manoj and Gellynck Xavier, 2015).

Conclusion

By utilizing Lean Six Sigma Tools to enhance traceability in food supply chains, SMEs can quickly address five of the six major challenges for FSMA adaptation. The basis of Lean Six Sigma methodology allows an organization to reduce cost while improving quality on a defined timeline. Employee engagement is embedded in the LSS culture which helps better prepare employees for changes to processes and training requirements. LSS tools provide SMEs with a cost effective solution to integrate FSMA requirements for successful food safety supply chain augmentation.

Future Work

Future research that will aid in the progression food supply chain safety in the United States will consist of: Measuring quantitative data on contamination response systems before and after LSS implementation during mock recalls at the factory level. Measuring the limitations for SMEs to move from responsive control systems to prevention control systems by survey distribution. Statistical data on traceability prevention control responses will help develop a comprehensive food safety plan for FSMA requirements.

Research Limitations

The number of SMEs that currently need to comply with FSMA and their current traceability methods are unknown. FSMA compliance rates for SMEs are not published. Because the law is very new to the food chain network, the ability of FSMA to show food safety improvements is undocumented.

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CHAPTER 4. SUMMARY AND CONCLUSION

Despite the limitations of the research, an insight into the current state of preventive control and traceability infrastructure of small food facilities was revealed. A quantitative understanding of small business operations is valuable to discern where necessary resources need to be deployed. This study revealed that the size of the company within the small business category proves to be a major variable for FSMA implementation. As understanding the law is of high priority, this research helps provide an insight into what preventive control categories are better understood by small businesses, and what ones need more attention. Success of FSMA is dependent upon the success of the food industry's abilities to make changes to their supply chain systems, with the end goal leading to the abatement of food borne illnesses.

Fourteen different factors were analyzed from the questionnaire data: (i) food allergen controls, (ii) verification activities, (iii) current good manufacturing practices, (iv) food safety plan, (v) training records (vi) standard operating procedures, (vii) hazard analysis, (viii) recall plan, (ix) preventive controlled qualified individual, (x) operational control, (xi) accounting programs, (xii) inventory records, (xiii) lot coding, (xiv) business management software. Results were compared against the type of manufacturing, the size of the company, and how many years the company has been in business. A significant factor affecting the adoption of FSMA within the small business category proved to be company size. Chi-square analysis revealed significant results in preventive control practices and traceability infrastructure at divisions of 0-24 employees, and 25-499 employees. Companies that had 25-499 employees showed better preparation in implementing preventive controls for distinct FSMA compliance requirements. Also, companies that had 25-499 employees showed a

leading advancement in technology adoption for establishment of traceability infrastructure versus companies that had 0-24 employees. The small business category spans a large range of employee sizes (499 or less). The results indicate that a special focus may be needed on businesses with less than 25 employees for FSMA preventive control requirements to be successful in small businesses. This research revealed that specific FSMA training modules may need to be targeted towards companies with less than 25 employees.

By utilizing Lean Six Sigma Tools to enhance traceability in food supply chains, small businesses can quickly address five of the six major challenges for FSMA adaptation. The basis of Lean Six Sigma methodology allows an organization to reduce cost while improving quality on a defined timeline. Employee engagement is embedded in the LSS culture which helps better prepare employees for changes to processes and training requirements. LSS tools provide small businesses with a cost effective solution to integrate FSMA requirements for successful food safety supply chain augmentation.

Continued research will aid in the progression of food supply chain safety in the U.S. There is a need to understand a basic model that will aid in forming a parallel traceability infrastructure throughout small businesses. There is a need to understand the effectiveness of PCQI training for the development of food safety plans, and if the different training platforms (in-person/online/hybrid) prove to be more effective. This research study casted a wide net over preventive controls and traceability infrastructure from the manufacturing facility point of view. Quality audit data at food facilities will be an important factor to compare perception of preventive controls and traceability structure versus actual implementation.

APPENDIX A. INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
2420 Lincoln Way, Suite 202
Ames, Iowa 50014
515 294-4566

Date: 1/25/2018

To: Shweta Chopra
4344 Elings Hall

CC: Quin Schultz
4324-H Elings

From: Office for Responsible Research

Title: Utilizing Quality Management Systems to Enhance Traceability of Food Products in Small and Medium Enterprises for Food Safety Modernization Act Compliance

IRB ID: 18-013

Study Review Date: 1/25/2018

The project referenced above has been declared exempt from the requirements of the human subject protections regulations as described in 45 CFR 46.101(b) because it meets the following federal requirements for exemption:

- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures with adults or observation of public behavior where
  - Information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects; or
  - Any disclosure of the human subjects' responses outside the research could not reasonably place the subject at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

The determination of exemption means that:

- **You do not need to submit an application for annual continuing review.**
- **You must carry out the research as described in the IRB application.** Review by IRB staff is required prior to implementing modifications that may change the exempt status of the research. In general, review is required for any modifications to the research procedures (e.g., method of data collection, nature or scope of information to be collected, changes in confidentiality measures, etc.), modifications that result in the inclusion of participants from vulnerable populations, and/or any change that may increase the risk or discomfort to participants. Changes to key personnel must also be approved. The purpose of review is to determine if the project still meets the federal criteria for exemption.

  Non-exempt research is subject to many regulatory requirements that must be addressed prior to implementation of the study. Conducting non-exempt research without IRB review and approval may constitute non-compliance with federal regulations and/or academic misconduct according to ISU policy.

  Detailed information about requirements for submission of modifications can be found on the Exempt Study Modification Form. A Personnel Change Form may be submitted when the only modification involves changes in study staff. If it is determined that exemption is no longer warranted, then an Application for Approval of Research Involving Humans Form will need to be submitted and approved before proceeding with data collection.

Please note that you must submit all research involving human participants for review. **Only the IRB or designees may make the determination of exemption**, even if you conduct a study in the future that is exactly like this study.

Please be aware that **approval from other entities may also be needed.** For example, access to data from private records (e.g. student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **An IRB determination of exemption in no way implies or guarantees that permission from these other entities will be granted.**

APPENDIX B. QUESTIONNARIE

INFORMED CONSENT DOCUMENT
Title of Study: Assessing preparedness of small and medium enterprises for Food Safety Modernization Act utilizing Quality Management System to enhance traceability

Investigators: Quin Schultz, Shweta Chopra

INTRODUCTION
My name is Quin Schultz, I am a master's student in the Department of Agricultural and Biosystems Engineering. My Co-PI (Dr. Shweta Chopra) and I are working on a research study focused on challenges related to adoption of FSMA among small food facilities. You are being invited to participate in this study. The survey should not take more than 15 minutes.

DESCRIPTION OF PROCEDURES
If you agree to participate, you will be asked to complete a questionnaire.

RISKS
There are no foreseeable risks that you may incur.

BENEFITS
If you decide to participate in this study, there will be no direct benefit to you. It is hoped that the information gained in this study will benefit manufacturing from a better understanding of the challenges small food facilities face while adoption of the Food Safety Modernization Act.

COSTS AND COMPENSATION
You will not have any costs and compensation from participating in this study.

PARTICIPANT RIGHTS
Your participation in this study is completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled. You can skip any questions that you do not wish to answer.

CONFIDENTIALITY
This study is approved by Iowa State University - Institutional Review Board (#18-013) and will comply with IRB protocol on data management and analysis. Your survey responses will be anonymous.

QUESTIONS OR PROBLEMS
For further questions regarding this survey, feel free to contact me at qschultz@iastate.edu or Co-PI at schopra@iastate.edu. If you have any questions about the rights as a research subject, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Research Assurances, 1138 Pearson Hall, Iowa State University, Ames, Iowa 50011.

Thank you for your time and consideration!

Sincerely,

Quin Schultz,
Research Assistant,
Agricultural & Biosystems Engineering,
4324 F - Elings Hall,
Iowa State University
qschultz@iastate.edu

Questions:

1.) What type of food facility is your company?
   - Human Food
   - Animal Feed

2.) Please select the most relevant category you identify yourself with?
   - Operator
   - Technician
   - Manager/Supervisor
   - Owner
   - Other (Please Specify): _____

3.) How many years of experience in the Food Manufacturing Industry do you have?
   - 0-5
   - 6-10
   - 11-15
   - 16-20
   - Other (Please Specify): _____

4.) What is your formal education status?
   - PhD
   - Masters
   - Bachelors
   - Associates
   - High School Diploma
   - No Formal Education
   - Choose not to answer

5.) What age group do you belong to?
   - 18-25
   - 26-35
   - 36-45
   - 46-55
   - 56-65
   - 65+
   - Choose not to answer

6.) How many employees work at your company?
   - 0-9
   - 10-24
   - 25-99
   - 100-499
   - Other (Please Specify): _____

7.) How many years has your company been in business?
- Less than 1
- 1-2
- 2-5
- 6-10
- Other (Please Specify): _____

8.) Does your company utilize computers for operational processes?
- Yes
- No
- Unknown

9.) Does your company have a website?
- Yes
- No
- Unknown

10.) Does your company use email for business purposes?
- Yes
- No
- Unknown

11.) Does your company use a software program for accounting purposes?
- Yes
- No
- Unknown

12.) Have you heard of the Food Safety Modernization Act of 2011 (FSMA)?
- Yes
- No
- Unknown

13.) Has your company made changes to operations/company policies due to the Food Safety Modernization Act (FSMA)?
- Yes
- No
- Unknown

14.) Has your company ever performed a Hazard Analysis?
- Yes
- No
- Unknown

15.) Does your company have a recall plan in place in the event of product contamination?
- Yes
- No
- Unknown

16.) Does your company have a food safety team?
- Yes
- No
- Unknown

17.) Have you received training on Hazard Analysis Critical Control Points (HACCP)?
- Yes
- No
- Unknown

18.) Does your company have a HACCP certified individual?
- Yes
- No
- Unknown

19.) Does your company use any aspects of Lean Six Sigma?
- Yes
- No
- Unknown

20.) What aspects of Lean Six Sigma does your company use? (Check all that apply)
- 5S
- Kaizen Events
- DMAIC
- Total Productive Maintenance (TPM)
- Value Stream Mapping
- None of the above

21.) Does your company keep records of inventory?
- Yes
- No
- Unknown

22.) Does your company use handwritten notes for record keeping?
- Yes
- No
- Unknown

23.) Does your company document and store lot code information for raw ingredient use?
- Yes
- No
- Unknown

24.) How does your company keep track of inventory?
- Electronically using computers
- Manually using paper-based record keeping
- Combination of paper-based and computer based
- Unknown

25.) Does your company have a Preventive Controls Qualified Individual (PCQI)?
- Yes
- No
- Unknown

26.) Are you a Preventive Controls Qualified Individual (PCQI)? If so what type of class did you take?
- Online class
- Live class
- Hybrid/Blended
- I am a PCQI due to my past experience/background
- I am not a PCQI

27.) Has your company ever been inspected by the FDA?
- Yes
- No
- Unknown

28.) Has your company ever been inspected by the State of Iowa?
- Yes
- No
- Unknown

29.)What type of business management software program does your company use?
- Enterprise Resource Planning Software (ERP)
- Materials Requirement Planning Software (MRP)
- Do not use a business software program
- Unknown

30.) Does your company have a training program for employees that utilizes Standard Operating Procedures (SOPs)?
- Yes
- No
- Unknown

31.) I feel the Food and Drug Administration (FDA) has done an excellent job of communicating the new requirements for the Food Safety Modernization Act (FSMA)? (Select One)

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

32.) I feel the State of Iowa has done an excellent job of communicating the new requirements for the Food Safety Modernization Act (FSMA)? (Select One)

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

33.) I understand the new food safety requirements of the Food Safety Modernization Act (FMSA)? (Select One)

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

34.) My company has food allergen controls in place to prevent mishandling of allergenic ingredients? (Select One)

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

35.) My company validates process controls to make sure they are effective? (Select One)

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

36.) My company uses Current Good Manufacturing Practices (CGMPs) to keep the cleanliness of food-contact surfaces? (Select One)

Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

37.)I feel comfortable that my company is in compliance with FSMA? (Select One)

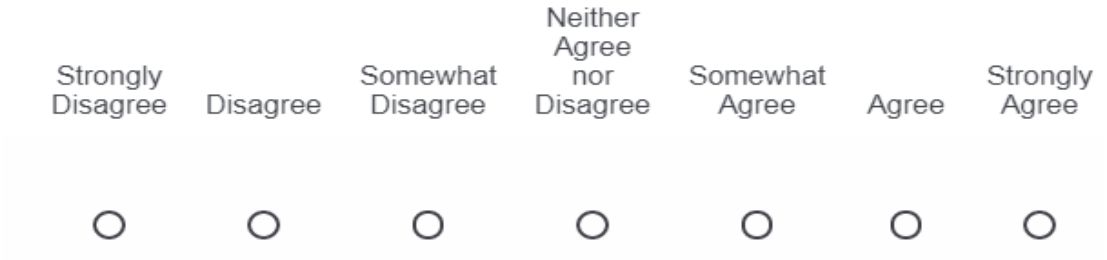
Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
○	○	○	○	○	○	○

38.)What formal training have you received in Quality Management Systems?

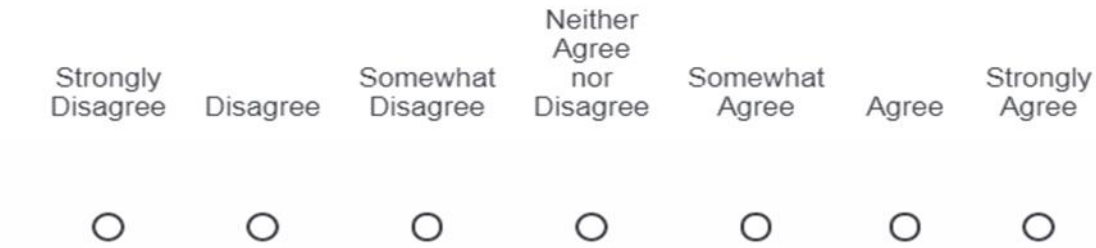
(Choose all that apply)

HACCP certification	ISO 9001	Six Sigma (Yellow, Green, Black or Master Black Belt)	Certified Technology Manager	Certified Quality Manager	Company Training	Others	No certification	Choose not to answer
☐	☐	☐	☐	☐	☐	☐	☐	☐

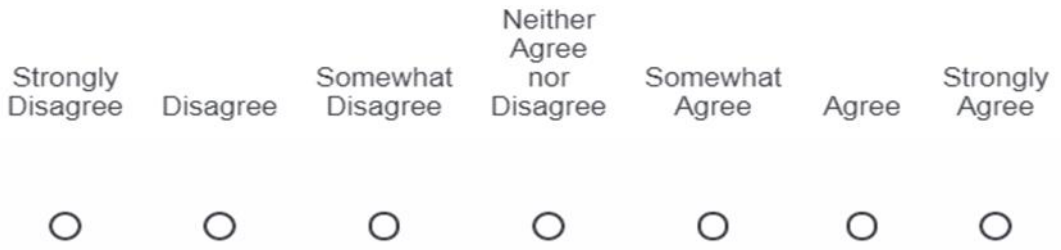
39.) I feel comfortable with implementing preventative control measures? (Select One)



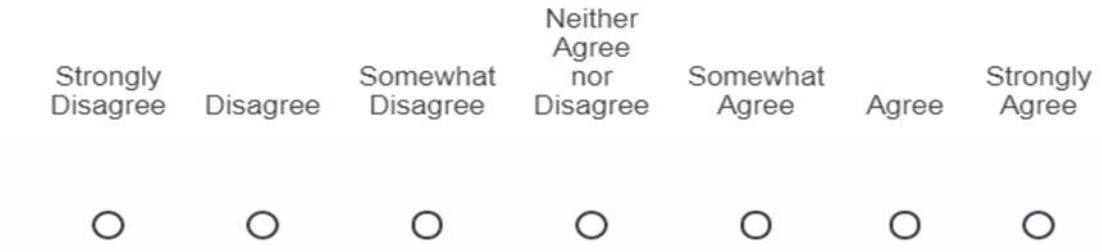
40.) I do not understand the preventative control measures required by the Food Safety Modernization Act? (Select One)



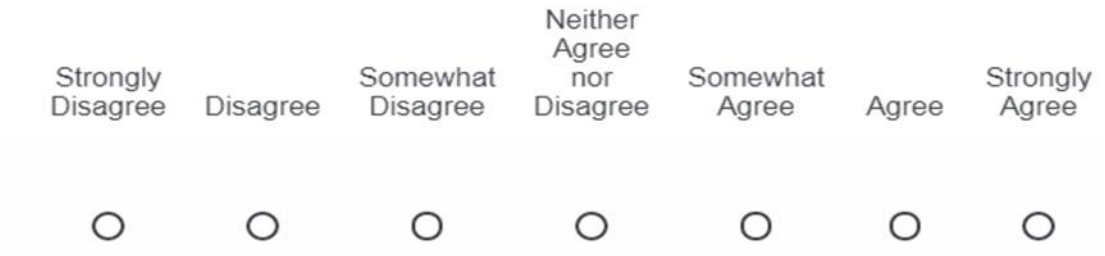
41.) I know where to find information about the Food Safety Modernization Act? (Select One)



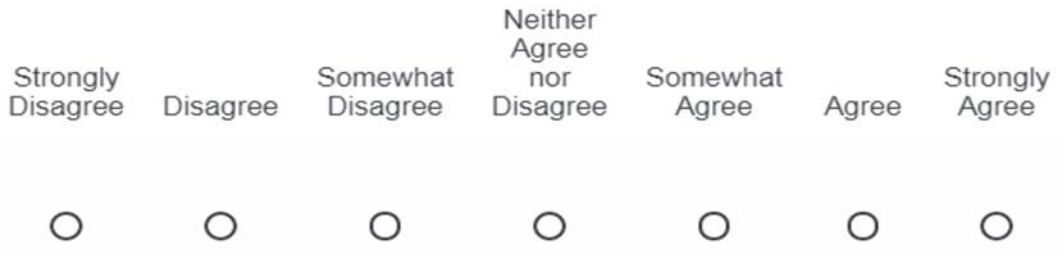
42.) My company has a food safety plan that contains a hazard evaluation? (Select One)



43.) My company keeps training records for all employees? (Select One)



44.) My company has documented Standard Operating Procedures (SOPs) for different work duties? (Select One)



45.) What is the most challenging aspect of the Food Safety Modernization Act? (Select One)

- Understanding of the FSMA law
- Absence of a Quality Culture in my Organization
- Employee Training
- Time to implement FSMA
- Cost to implement changes
- Other: (Please Explain in space below)