8-2016

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Keywords
Food safety modernization act, Preventive controls, Small food facilities, Quality management, Challenges

Comments
This is the accepted manuscript of an article published in *Food Control* 66 (2016): 241–249. The final version can be found at http://dx.doi.org/10.1016/j.foodcont.2016.02.001.

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Abstract: The Food Safety Modernization Act (FSMA) was signed into law in the United States in 2011, shifting the existing food safety focus from a reactive to a preventive approach. According to literature, legislative requirements of FSMA can be challenging for small food facilities affected by the regulations immediately or in near future. Thus, the purpose of this research was to utilize quality management tools to identify and prioritize major challenges faced by small food facilities in adopting the preventive controls' component of the FSMA legislation. Data was collected using semi-structured interviews of food industry representatives and academic professionals from the Midwest region of the United States. An affinity diagram was used to identify the set of challenges that emerged from the interviews, following which a weighted multi-voting survey was used to prioritize the identified challenges. Major identified challenges included: understanding of the FSMA law, cost of implementation, timeline for implementation, employee preparedness, absence of quality culture, and employee willingness. Furthermore, a difference was observed in how industry representatives and academic professionals rank ordered the above-listed challenges.

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1. Introduction

Food safety continues to be a major issue in the food system of the United States. Food safety related illnesses and deaths account for a $77 billion burden on the United States every

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year (Scharff, 2012). Although the small food and grain handling/processing facilities traditionally have not focused on food safety and quality management systems, the adulteration of the food products in such facilities have played significant role in recent food safety incidents, leading to a higher level of concerns (Thakur & Hurburgh, 2009). Additionally the existing food safety tools, such as Hazard Analysis and Critical Control Point (HACCP), are less capable of addressing the need for identification, quantification, control, and management of these food safety risks, especially in the grain handling and processing facilities (Sperber, 2005). This highlights that the prevalent food safety management system in United States is not well organized and is less prepared to manage food safety hazards (Congressional Research Service, 2007). Hence, the Food Safety Modernization Act (FSMA) was enacted as a Public Law 111-353 on January 4, 2011, amending Title 21 of the United States Code, U.S.C.: Food and Drugs (FDA, 2015).

The FSMA legislation was aimed at overhauling the existing approach to food safety by enabling stakeholders to concentrate on preventive controls rather than simply reacting to food safety events. The law provides the Food and Drug Administration (FDA) with increased authority to inspect food products and authorize mandatory recalls for contaminated products. The proposed FSMA rules are divided into four titles: (1) improving the capacity to prevent food safety problems, (2) improving the capacity to detect and respond to food safety problems, (3) improving the safety of imported food, and (4) miscellaneous provisions (e.g., employee protection and budget details). Section 103 under Title 1 includes the requirements of Hazard Analysis and Risk Based Preventive Controls (HARPC) (Kheradia & Warriner, 2013), which necessitates a preventive food safety system for facilities handling/ processing food or food ingredients (FDA, 2011). The food safety plan under HARPC requires a qualified person in each

facility to evaluate the potential food safety hazards, identify and implement potential preventive controls, validate the performance of these controls, and maintain records to minimize the occurrence of evaluated hazards using a scientific methodology (FDA, 2011). HARPC is a shift from the existing food safety management system (FSMS), because it mandates a logical pre-assessment of food safety hazards. According to FDA, there are different preventive control requirements for facilities engaged with food for human consumption (bakery, beverages, cheese etc.) and animal consumption[2] (feed or pet food).

Furthermore, for the purpose of the HARPC requirements for human food, the FDA (2015) has classified businesses into three categories based on the number of employees and total annual sales: (1) small business facilities, (2) very small business facilities, and (3) other facilities (see Table 1). In this manuscript, the term "small business" or "small facilities" refers to both small and very small businesses. Some of the small food facilities are exempt[3] from HARPC requirements of FSMA (FDA, 2015). Despite of several exemptions the small food facilities might have to adopt the regulations due to competitive nature of the market, future business requirements, or supplier verification requirements of their business associates. Moreover, the FDA might also have to revisit the exemption limits of HARPC to increase the coverage of the law for developing a holistic food safety system in the Unites States (Center for

[2] Grain handling and processing facilities can be classified under raw agricultural commodities for use as food - such as facilities processing vegetable oils, grain flour, food sweeteners, or other whole grain products (Shaw & Snyder, 2012). But most of the grain facilities in Mid-west region of United States process feed and other food for animal consumption. In some operations, animal feed is a byproduct of human food processing. Since food and feed facilities have different set of regulations, they can have different set of challenges.

[3] The following small & very small business facilities are partially or fully exempt from the HARPC requirements:

a.) Involved with low risk manufacturing, packaging or storage activities for specific foods products on farm (e.g. jams, jellies, honey & maple syrup).
b.) Facilities who are only involved in manufacturing of juice, seafood, alcohol, or low-acid canned foods
c.) Facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

Progressive Reform, 2013); thus, the exempted small food facilities might also have to comply with HARPC regulations of FSMA in the near future. This study is applicable to potentially non-exempt or voluntary small food facilities[4] who will comply with either partial or full requirements of preventive control regulations for human food immediately or in near future.

Table 1
Classification of food facilities as per the Food and Drug Administration (2015)

Industry classification	Characteristics
Very small	Averaging less than $1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale
Small	A business with fewer than 500 full-time equivalent employees
Other	a business that is not small or very small

Historically, small businesses have not had extensive experience with prevalent food safety management systems (FSMS) and standards such as ISO 22000: 2005, HACCP, SQF code[5], or GFSI[6] guidelines (FDA Federal Register, 2014), which form the basis for HARPC implementation in food businesses. On the contrary, most large food facilities already have extensive experience with the prevalent FSMS for satisfying the safety requirements of the buyers. Therefore, the most considerable benefits of HARPC rules will be derived from small business adopting preventive controls (Center for Progressive Reform, 2013).

In addition, Layton (2009) predicted that FSMA's impact and success would be highly dependent on the integrated participation of all stakeholders. Small food facilities are important stakeholders in the value chain, and participation of these facilities is an important component of inclusive food safety of United States' food system

[4] Small food facilities involved with food processing/manufacturing i.e. making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.
[5] SQF - Safe Quality Food Institute's SQF Code
[6] GFSI - Global Food Safety Initiative

Furthermore, although HACCP is a globally accepted quality management system in which food safety is addressed through the critical analysis of potential hazards during production, procurement, handling, manufacturing, distribution, and consumption of the finished products (FDA, 2011), it does not adequately address the needs of a process-based system in a small food and grain handling/processing facility because of non-inclusion of non-critical control points during risk assessments (Thakur & Hurburgh, 2009). HARPC requirements augment the HACCP system by addressing its shortcomings and in turn HACCP forms a base for HARPC implementation (Levin & Newslow, 2013).

However, the literature illustrates several challenges of small food facilities, across the globe, with the implementation of HACCP. For example, Dzwolak (2014) identified several challenges for Polish small food businesses in the adoption of HACCP. He recognized that the lack of understanding of various guidelines, the lack of qualified and experienced staff, limitations related to finances, and restricted technical know-how are some of the significant challenges for small businesses. Bas, Yüksel, and Çavusoglu (2007) examined HACCP-related challenges for Turkish food businesses. They established lack of prerequisite programs (essential for risk analysis), inadequate equipment, limited employee training, and lack of employee motivation as potential roadblocks for successful implementation of HACCP. Because the literature cited various concerns for small food facilities across the globe in HACCP adoption, there is a greater probability that these facilities will also face challenges in the implementation of HARPC requirements.

Particularly relevant to the setting of this study, SGS (2014) listed the following as the possible hurdles for FSMA (HARPC) adoption in the United States: understanding of requirements of the law, complexity of integrating FSMA requirements with prevalent food

safety management systems (FSMS), and absence of quality culture. Even the FDA has recognized that small food facilities will likely face financial concerns in the implementation of the preventive control requirements of FSMA because they lack experience with HACCP-based models (FDA Federal Register, 2014).

Hence, it is imperative to address the challenges faced by small food facilities in implementation of legislative requirements of HARPC for inclusive food safety of United States food system. But, despite potential concerns, less has been discussed about it in the literature. Accordingly, this study is aimed to utilize a quality management approach to identify the major challenges of small food facilities with HARPC requirements of FSMA and prioritize them for small food industries.

2. Methodology

The participants of this study were selected representatives from industry and academia specializing in the field of food safety, quality assurance, and FSMA from the Midwest region of the United States. In all, 13 participants, both from industry and academics, were subjected to similar semi-structured interview. As shown in Fig. 1, the data collected from these interviews were analyzed and 34 challenges faced by small food facilities in the adoption of HARPC requirements of FSMA were identified. These 34 challenges were grouped into six broad themes using an affinity diagram. The same 13 participants were given a survey in which they were asked to rank order the six identified themes of challenges using weighted multi-voting. This methodology, as shown in Fig. 1, resulted in six prioritized themes of challenges, which can be useful for policymakers, industrialists, and researchers alike.

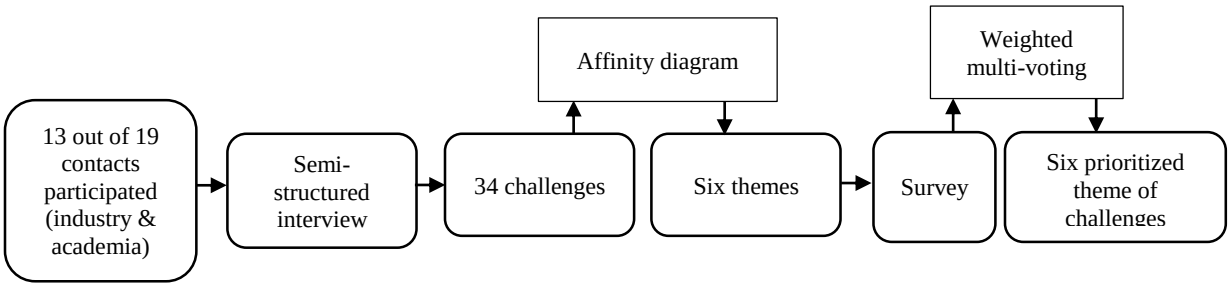

Fig. 1. Methodological flow of the research study (Affinity diagram and Weighted multi-voting are quality management tools used to analyze the interviews and survey)

2.1. Quality Management

A quality management system is a methodological approach to improve processes, products, and services for delivering customer value (Houston, 2008) and to drive continuous improvement to deliver high-quality products. The quality management approach is dependent on several systemic tools such as (1) management and planning tools, (2) process analysis tools, (3) decision-making tools, (4) data collection tools, and (5) root cause analysis tools (Tague, 2005). In this study, management and decision making tools were used to analyze data from semi-structured interviews. In earlier studies, Shafer, Smith, and Linder (2005) used an affinity diagram to categorize business models and Kumar, Antony, Singh, Tiwari, and Perry (2006) used multi-voting for project prioritization. In this research authors use these tools to identify and prioritize various challenges encountered by small food facilities in adoption of HARPC requirements of FSMA. Affinity diagram and multi-voting survey were used because of the nature of the data and the objective of study. The existing literature too has validated the reliability of these tools.

2.1.1. Affinity diagram

An affinity diagram is used to organize ideas into categories based on underlying similarity of data generated during interviews, brainstorming, and group discussions (Pyzdek & Keller, 2014; Shafer, Smith, & Linder, 2005). In the current study, an affinity diagram was used

as a tool for compiling and sorting data collected during face to face and telephonic interviews. Identified challenges were grouped into their respective categories under suitable thematic headings. Thirty-four challenges were grouped into six themes, which were later rank ordered by participants using weighted multi-voting.

2.1.2. Weighted multi-voting

Multi-voting, or nominal prioritization, is generally used with an affinity diagram to narrow a large list of options to a smaller list of priorities (Kumar, Antony, Singh, Tiwari, & Perry, 2006; Quality Glossary ASQ, 2013). In this study, multi-voting was used to rank order each category of challenges generated from the interviews. To assign a ranking to the challenges, participants were presented with the six challenges identified by the affinity diagram. Participants were asked to compare the identified challenges and, based on their perception, distribute a set number of points (six) to the six theme of challenges, with the most pressing challenges assigned a greater number of points as compared to less pressing challenges, which were assigned fewer or no points. The flexibility to apply all the points to any one critical challenge or distribute the points more equally was at each participant's discretion.

2.2. Participants

Participants of this study were representatives from the food industry and academics. The classification of these individuals as an industry representative or an academician was made on the basis of their fulltime professional engagements. There were three categories of participants (1) individuals who had been engaged in industry throughout their career, (2) individuals who had been engaged in academic work throughout their career, (3) individuals who had overlapping experience in industry and academics. Individuals identified as being in categories one and two were classified as industry representatives or academic professionals, respectively. Those

identified as being in category three were classified according to their current professional engagements. Furthermore, individuals with industrial or academic experience could have had prior experience with food safety, quality assurance, or FSMA but might not currently be working in those areas directly.

Thus, for this research, industry representatives were defined as individuals who were currently working with the industry and had current or prior industrial experience with food safety, quality assurance, or FSMA in a small food industry, and academic representatives were defined as individuals who were currently working with research, education or extension and had current or prior academic experience with food safety, quality assurance, or FSMA. The participants were classified as either academic professional or an industrial representative using the available demographic data which was later confirmed during the interviews. In all, eleven industry representatives and eight academic professionals were identified via online profiles and telephonic inquiries. They were contacted via telephone and emails; six out of eleven industry and seven out of eight academic representatives agreed to participate in the study.

2.3. Interviews

2.3.1. Design of interview questions

Semi-structured interviews were used for the study because of the qualitative nature of the research. It helped the participants to be explicit about their views around a specific theme (Creswell, 2014). Open-ended questions in semi-structured interviews facilitate an informal way to better understand the topic at hand and provide a reliable data for analysis (Bernard, 2011).

Interview questions were drawn from the FSMA guide for food industry published by the American Institute of Baking (AIB, 2014) and minutes of the 2011 FDA public meeting on

preventative controls[7]. Several demographic and contextual questions were posed to the participants such as those related to (1) prior and current industry or research experience with food safety, quality assurance, and FSMA; (2) current responsibilities or industry association; (3) general perceptions about HARPC requirements of FSMA; and (4) major challenges of HARPC implementation by small food facilities as perceived by participants based on their overall experience of food safety in academics or industry.

2.3.2. Pretesting

Prior to conducting interviews, the questions were pretested with academicians who had previously worked with food safety, quality assurance, or FSMA. Their feedback was used to refine the questions. Some of these improvements included language reform, change in sequence of questions, and the addition of technical definitions.

2.3.3. Interview procedure

Semi-structured interviews were conducted from February to April, 2015. A telephonic or a face-to-face interview, lasting for about 45 to 90 minutes, was conducted with each participant. Hand-written notes were used to record the interviews. Minutes of these meetings were transcribed and shared with the respective participants for member check or informant feedback. This helped to validate the responses and to ensure that interviewee comments were interpreted correctly by the interviewers (Creswell & Miller, 2000).

2.3.4. Content analysis

All hand-written notes, minutes of meetings, and telephonic conversations were collectively organized into a Microsoft Word® document. Authors coded the interview data and the emergent codes were grouped into common themes using an affinity diagram. This affinity

[7] Public meeting on "Food Safety Modernization Act: focus on preventive controls for facilities" held on April 20th, 2011 at U.S. Food and Drug Administration White Oak Campus, Maryland

diagram was used to classify the challenges accordingly (Denzin & Lincoln, 2011). These themes were subsequently used in the multi-voting survey to rank order the category of challenges.

2.4. Survey

2.4.1. Design of survey

An online survey was designed so that participants could perform multi-voting ordering of the identified challenges. The survey questions were divided into two categories: (1) individual demographic questions (current or prior experience in academics or industry with food safety, quality assurance or FSMA, education status, age group, and formal training received) and (2) contextual questions (rank order or prioritize the identified challenges). The participants were given an option to skip any question by selecting the "choose not to answer" option. They were encouraged to input text responses at the end of the survey to provide feedback regarding the survey design or the study (Flaherty, Honeycutt, & Powers, 1998).

2.4.2. Survey dissemination

The survey was disseminated using Qualtrics®, an online survey dissemination and analysis software. An online survey was chosen because it provided access to all participants and was efficient in terms of both time and cost (Wright, 2006). Survey data collection took place from April to May, 2015. The survey contained a cover letter and a consent document explaining the details of the research study and participant rights. All research participants had access to high-speed Internet and computers to participate in the study.

An FDA three-minute video primer on HARPC requirements of FSMA was embedded in the survey for the participants' reference. Graphic images were used to explain the survey questions to effectively engage the participants (Short & Reeves, 2009). The images represented

the intended meaning of different options to help participants better understand the questions and be objective in their responses.

2.4.3. Survey responses and content analysis

The survey responses were randomly coded as IR (referring to industry representatives) and AP (referring to academic professionals) based on the classification of participants as per sub section 2.2. All survey responses were designed to be kept anonymous. The survey data were analyzed using Qualtrics® Online Survey Software.

3. Results

3.1. Participant profiles

Demographic information of all the participants, collected using the anonymous online survey described in sub-section 2.4.1., is listed in Table 2. Approximately 54% of the participants were from academics, and 46% were from industry, as classified during the interviews. Four out of seven academic professionals had earned a Ph.D., and three had earned a master's degree in food safety or quality-assurance-related disciplines. The majority of industry representatives had earned a bachelor's degree in a relevant field. Using the viewpoints of both industry representatives and academicians helped researchers to understand the challenges of small food facilities from a broader perspective.

Table 2
Profiles of the participants

Participant code[a]	Age range (in years)	Education qualification	Food safety or quality assurance experience (range in years)	Trainings attended in QMS[b] or food safety
AP – 1	Over 60	Master's	11–15	Company training, others
AP – 2	31–35	Ph.D.	0–5	HACCP
AP – 3	36–40	Ph.D.	0–5	Company training
AP – 4	41–45	Ph.D.	11–15	ISO 9001, six sigma, certified technology manager, company training

AP – 5	26–30	Ph.D.	0–5	No certification
AP – 6	36–40	Master's	0–5	No certification
AP – 7	51–55	Master's	6–10	Certified quality manager, company training
IR – 1	26–30	Bachelor's	6–10	HACCP, company training, ISO 9001
IR – 2	Choose not to answer	Master's	0–5	Company training
IR – 3	Over 60	Bachelor's	6–10	No certification
IR – 4	51–55	Bachelor's	Over 30	HACCP, company training
IR – 5	56–60	Bachelor's	26–30	HACCP, ISO 9001, certified quality manager, company training
IR – 6	Over 60	Master's	Over 30	HACCP, others

[a] AP, academic professional; IR, industry representative
[b] QMS, quality management systems

3.2. Findings of the semi-structured interviews

The input provided by the participants during the interviews was fundamental in identifying different challenges. Results from some of these interviews are summarized in the following paragraphs.

One of the first interviews was conducted with an academic professional who had more than 10 years of experience with food safety and quality assurance both as an academic and industry professional. Based on the classification criteria in sub section 2.2, he was classified as an academic professional. As part of his university assignment, he was currently working with the FDA to develop FSMA-related training modules for food inspectors. He believed that HARPC requirements of FSMA was an important step towards the modernization of food safety laws in United States. When asked about the challenges of implementing the HARPC requirements of FSMA in small food facilities, he argued that the challenges were twofold. The first challenge was the lack of clarity of guidelines; the FDA is required to provide clear guidelines regarding its expectations from small food facilities regarding the implementation of HARPC requirements. The second challenge was the lack of quality culture in small food facilities; small organizations will be required to create a quality culture, which previously was less prevalent. To successfully implement a food safety plan, it will be important for these

facilities to define and mitigate risks through continuous improvement efforts. He suggested that management focus will play a key role in aligning the organization's goal with FSMA requirements. He believed that, due to the lack of clarity of the HARPC guidelines, small food facilities believe that HARPC is HACCP, as he noted, "with the HARPC requirements, facilities think that by developing HACCP they will be okay; however the HARPC food safety plan also contains good manufacturing practices, prerequisite programs, and food defense plans".

One of the other interviews was conducted with two quality managers of a grain handling and processing facility in Iowa. One of them had over 30 years and the other had over 10 years of experience with food safety and quality assurance systems in small food facilities in the Midwest. Currently, they were working as quality professionals and had the responsibility of implementing food safety plans and FSMA regulations for a grain handling and processing facility that had 280 permanent employees and $800 million in annual sales. For this study, these participants were classified as industry representatives based on the criteria mentioned in sub section 2.2. They had played a key role in implementing various food safety management systems (FSMS) and standards such as ISO 22000: 2005, HACCP in their facility and getting the facility ISO 9001 certified. After their recent experience with HACCP and ISO certifications, the managers were not very apprehensive about the HARPC requirements of FSMA. They believed that building a quality culture within a facility is the most important requirement for implementing any quality system as it requires more discipline among employees. According to them, the biggest challenge in implementing HARPC would be communicating FSMA rules to employees and encouraging their participation. The managers recollected their experiences while implementing HACCP in their present facility and drew a parallel with the HARPC requirements of FSMA: "If we had not implemented ISO 9000 guidelines, assimilation of the quality

management system would have been difficult in our [present] facility. The sudden transition to a different quality system such as HACCP might have expected a huge budget investment. Moreover, internal culture and employee acceptability would have been a challenge. With ISO guidelines and HACCP in place, we are not worried about the implementation of FSMA requirements".

Another interview was conducted with an academic professional who had approximately five years of experience with food safety and human nutrition. He had extensive experience with food microbiology, animal meat safety, and HACCP-related food safety programs. He was currently working as an extension specialist with one of the land-grant universities in the Midwest. In his current role, he was working with small food and grain industries around the Midwest to help resolve various challenges of FSMA adoption by conducting training for employees of these companies. He believed that FSMA is a much-needed set of regulations. He suggested that it is very important for the small food industries to understand that food safety is closely linked to food quality. Higher quality will translate into higher profitability. This academic professional believed that cost of implementing HARPC requirements will be a challenge, as a higher number of trained employees, infrastructure for recordkeeping, and new equipment will be required for facilities, but that eventually the resulting efficiency will increase profitability. He noted that building a food safety culture among employees in small food facilities is a challenge, and management focus and monitoring would be essential in overcoming that challenge: "Motivation and building food safety culture will be the key to effectively engaging employees for FSMA implementation. The culture must come from management to employees [top-down], hence rewards and recognitions are important"

One of the last interviewees was a manager from an agricultural insurance company for small food and grain facilities. He had more than 15 years of experience with food and feed safety, quality assurance, HACCP, risk assessment, and food defense. He had worked for several small food facilities in the Midwest for more than 10 years before being hired in his current position as a subject matter expert for food safety and quality systems in the insurance company. As a part of his current responsibilities, he was accountable for working with several small food industries (clients of his company) to help them establish food safety and quality assurance systems to meet FSMA regulations, which are mandatory for insurance purposes. He was classified as an industry representative based on the criteria mentioned in sub section 2.2. The manager had great insights into challenges faced by small food facilities in implementing HARPC requirements of FSMA. However, he believed that the implementation of HARPC might not be a concern for small food facilities, as most of them supply raw materials to larger food manufacturing facilities. Rather, the larger facilities will be required to verify the compliance of their suppliers to meet the FSMA requirements under the supplier verification program of FSMA regulations, which will be mutually beneficial.

3.3. Identified challenges and the affinity diagram

The data from all the transcribed interviews were analyzed, and the emergent challenges were coded accordingly. As a quality management tool, the affinity diagram was used to consolidate the ideas and help organize the 34 identified challenges into six potential themes for further analysis. All themes and identified challenges are shown in Fig. 2. The challenges such as interpretation of HARPC requirements, lack of knowledge of process mapping, and lack of clarity of guidelines were classified under the theme of “lack of understanding of the FSMA law”. The theme of “cost of implementation of law” had the following challenges listed i.e. cost

of quality, budget planning, infrastructural investments, and cost of employee training and cost of third party consultants. The challenges such as restricted time for implementation and long-term investments were categorized under "Timeline of implementation". The responses such as lack of employee training, lack of qualified quality managers, and lack of qualified employees were classified as "employee preparedness". Lack of HACCP or food safety systems, no

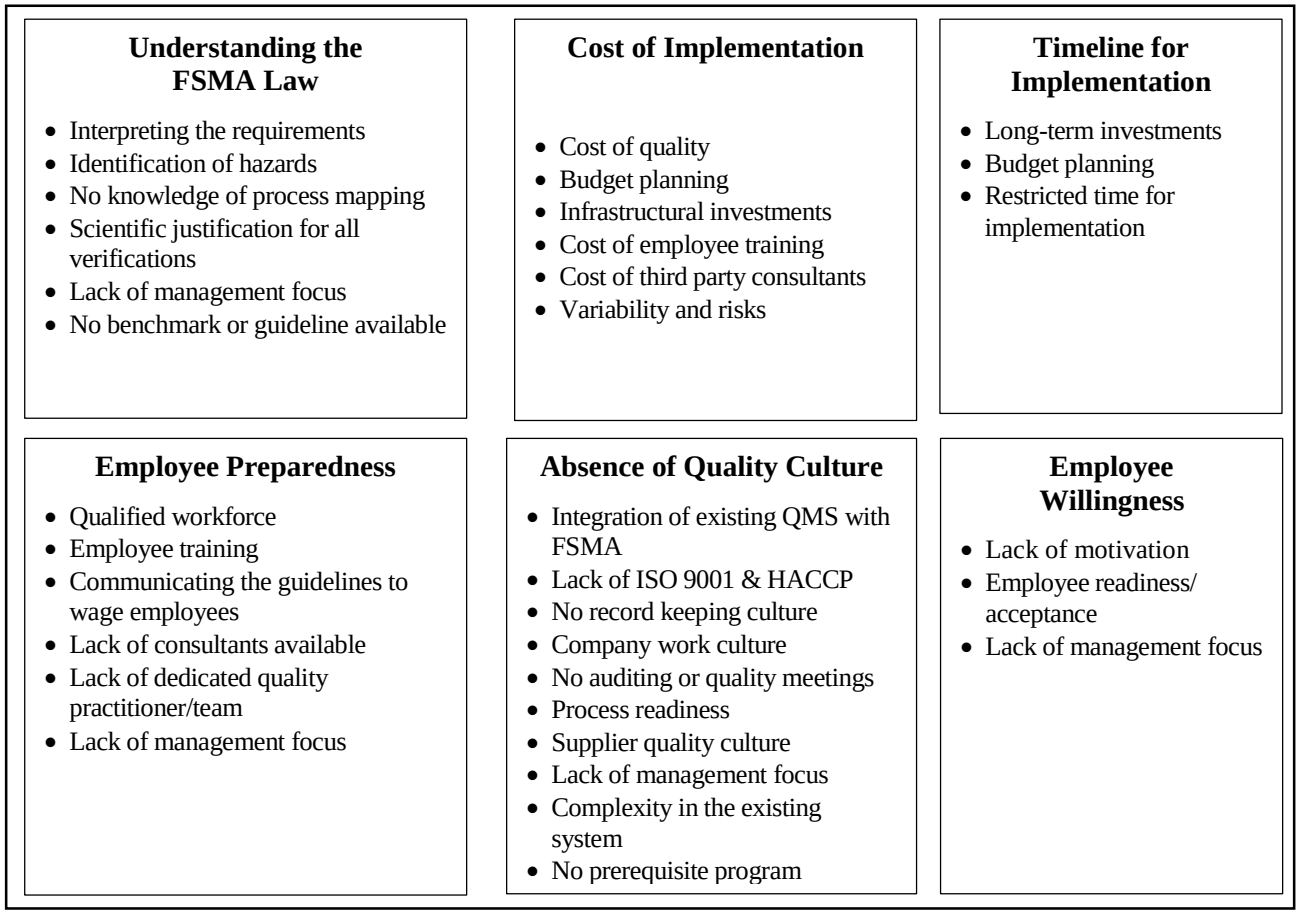

Fig. 2. Affinity diagram; the bold headings at the top of the blocks represent the six identified themes

prerequisite programs, and lack of employee discipline were classified under "absence of quality culture" and lack of motivation or lack of readiness of employees to change was categorized under "employee willingness."

3.4. Findings of the multi-voting survey with prioritized challenges

A multi-voting survey was designed using the six identified theme of challenges. The participants prioritized these six challenges by distributing more points to the most important challenge and fewer or no points to the least significant challenge(s). Each participant rated the challenges in order of perceived significance. The sum total of the distributed points by all the participants were used to rank the challenges in order from the most significant to the least, as follows: (1) understanding of the FSMA law, (2) cost of implementation, (3) timeline for implementation, (4) employee preparedness, (5) absence of quality culture, and (6) employee willingness (see Fig. 3).

As a part of the survey, participants were also allowed to provide their opinion in a separate text box option, as described in sub section 2.4.1. Some of the responses were: “I find lack of skill, lack of availability of legal counsel, constraints on time and money as the biggest road blocks to smaller companies implementing food safety systems. In some cases it holds them back from growing sales” (IR – 4) and “Clear communication of requirements and expectations will be essential for effective HARPC implementation” (IR – 6).

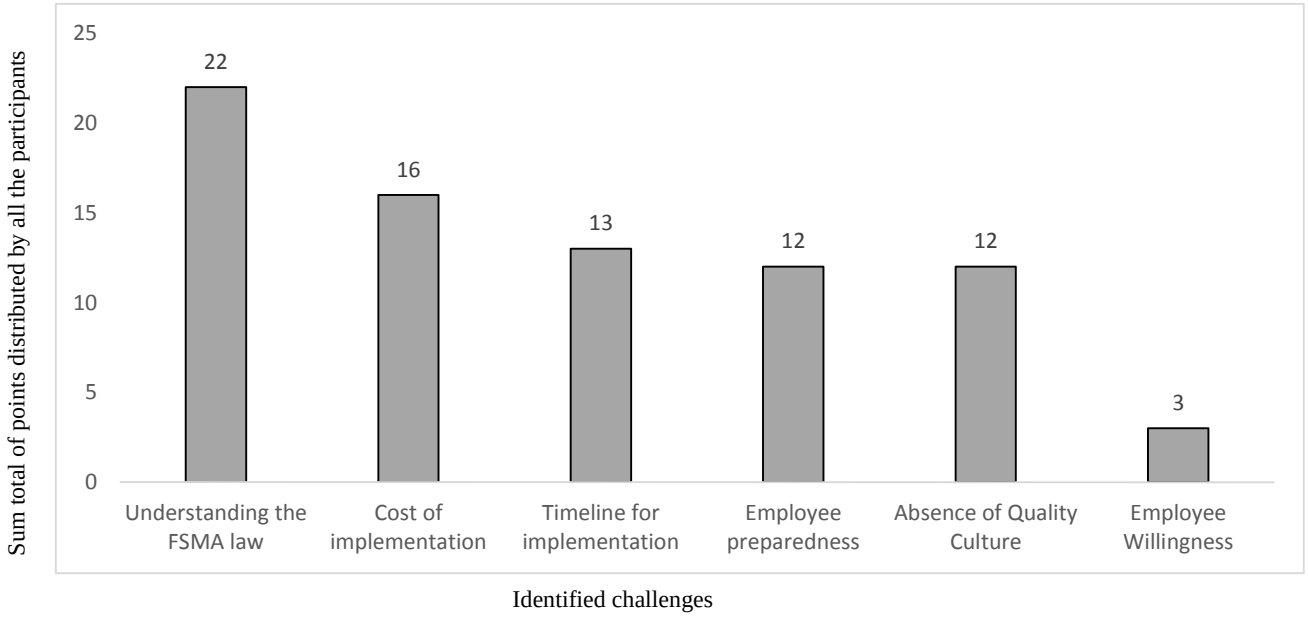

Fig. 3. Results of the weighted multi-voting. The numbers at the top of each bar represent the sum total of the points distributed by all the participants (industry and academics) to that challenge.

A difference between the opinions of industry representatives and those of academic professionals was revealed, as illustrated in Fig. 4 which represents the percentage of total points distributed by the respective category. Industry representatives participating in the survey believed that understanding of FSMA law was a significant concern. On the other hand, academic professionals believed that the cost of implementation was the primary concern, followed by timeline of implementation and understanding of FSMA law. Responses from both industry representatives and academic professionals suggest that employee willingness was not an immediate concern for small food facilities. It was also observed that participants with more experience with food safety, quality assurance, and FSMA believed strongly that understanding of the FSMA law and timeline for implementation were more significant challenges, whereas participants with less experience believed employee preparedness to be a more significant challenge.

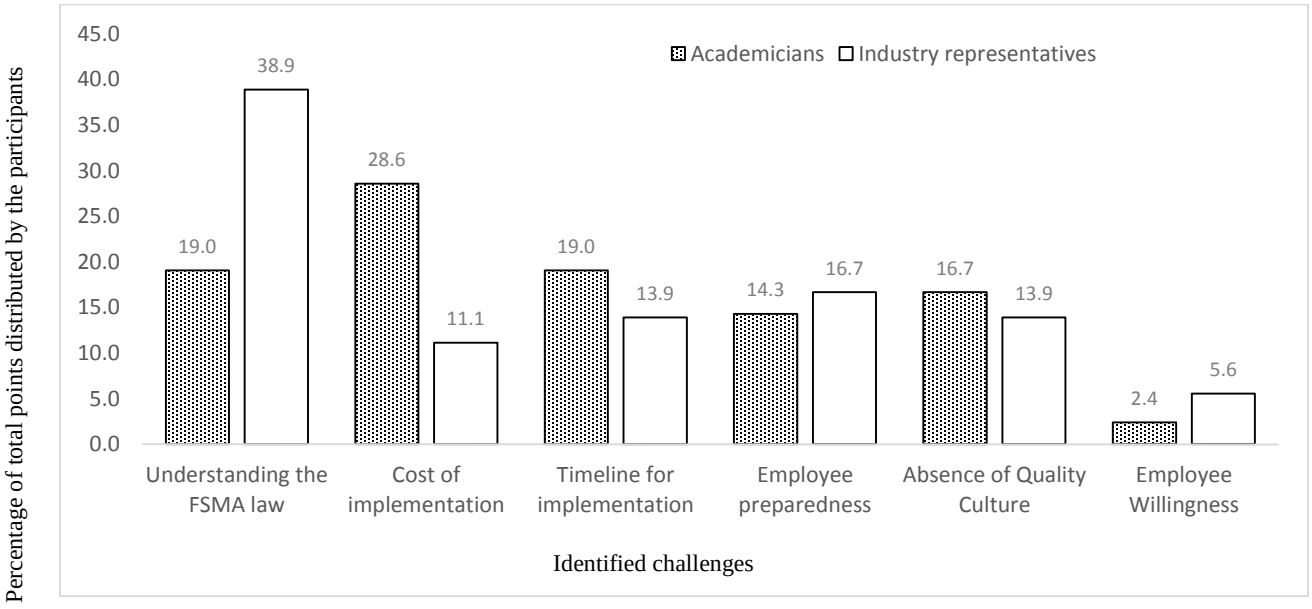

Fig. 4. Normalized results of the weighted multi-voting by participant category: academicians vs. industry representatives. The numbers at the top of each bar represent the percentage of the points distributed to a particular

challenge to the total points available to the respective category of participants (industry and academics). [e.g. since there were seven academicians the total points available to them were 42 out of which they distributed eight points to the first challenge which is 19%]

4. Discussion

This study used recognized quality management tools of an affinity diagram and multi-voting to analyze data from semi-structured interviews and surveys of industry representatives and academic professionals. Based on the quality of the results, these tools were found to be effective in terms of organizing and prioritizing the data generated from the interviews. A quality management approach helped the researchers to systematically organize the information gathered from diverse stakeholders. The resulting information can be used to inform future continuous improvement and management changes among small food facilities. These tools exhibited a significant potential for future use in policy adoption studies in these facilities.

The challenges identified in this study were consistent with the findings of Bas, Yüksel, and Çavusoglu (2007); Dzwolak (2014); and SGS (2014), who found that lack of prerequisite programs, understanding of guidelines, lack of infrastructure, and employee motivation were among the few significant challenges. The findings of this study were not noticeably different from that of the existing literature on HACCP. This could be because of the respondents' previous experience with prevalent food safety management systems (FSMS) and standards such as ISO 22000: 2005, HACCP, SQF code, or GFSI guidelines. Most of the participants drew an inherent parallel between the HARPC requirements and other prevalent food safety management systems (FSMS). However, it remains to be seen how challenges will change over the course of HARPC implementation.

Despite the adoption challenges, participants of this study recognized the importance of the preventive control aspect of FSMA law. Academic and industry participants agreed that

FSMA is a much-needed set of regulations and that FSMA provides contemporary food safety tools which previously were missing (Knutson & Ribera 2011). Kheradia and Warriner (2013), Knutson and Ribera (2011) and Levin and Newslow (2013) have also emphasized the significance of the law by concluding that FSMA requirements are more structured and have a scientific approach to improving the food safety system of United States.

The resulting sequence of challenges suggest that understanding of FSMA law is a significant hurdle for implementation of HARPC requirements of FSMA among small food facilities. Several industry representatives highlighted that "language of law" and "lack of clarity of guidelines" are major barriers in understanding the expectations of HARPC requirements for small industries. This could be because small facilities often lack necessary resources such as a dedicated quality management team or a third party consultant to interpret the expectations of the law (Levin & Newslow, 2013). The American Institute of Baking (2014), Dzwolak (2014), Levin and Newslow (2013), and SGS (2014) have also reported that understanding of the requirements has been a significant barrier in the implementation of similar food safety management systems (FSMS) and standards.

In this study, the cost of implementation was identified as the second most significant challenge facing the implementation of HARPC requirements of FSMA among small facilities. According to the participants of the study, FSMA calls for increased investment in upgrading infrastructure, preparing employees, hiring third party consultants, developing a quality culture, and motivating employees. Bas, Yüksel, and Çavusoglu (2007) and Dzwolak (2014) recognized that implementation of a food safety system such as HACCP also calls for an upgrade in processes, products, and/or administrative infrastructure and that every upgrade is associated with an increase in expenditure, thus making it a challenge for implementation. Based on the

findings of this study, it may be assumed that the same would be true for the successful implementation of HARPC requirements of FSMA for small facilities with limited financial capabilities.

The timeline for implementation was voted as the third significant challenge. FDA (2015) has defined specific compliance dates for all eligible food facilities with respect to preventive controls for human food. Small businesses, as defined in section 1, will have two years to comply, very small businesses must comply within three years, and other businesses would have to comply within one year after publication of the final rules. Participants of the study suggested that the timeline might be a challenge for the small food facilities, as the evolution of employee capabilities and skills would take time beyond the defined deadlines (Bas, Yüksel, & Çavusoglu, 2007; Karipidis, Athanassiadis, Aggelopoulos, & Giompliakis, 2009). Similar concerns have been reported by others (Mortlock, Peters, & Griffith, 1999; Panisello, Quantick, & Knowles, 1999; Ward, 2001). Participants expressed concerns regarding the timeline and cost because these factors govern other identified challenges. It will take both time and money to understand the expectations of law, develop employee skills, and nurture a quality culture.

Employee preparedness and absence of quality culture were equally ranked at the fourth position. Employee preparedness refers to readiness of employees to comply with new requirements in terms of knowledge, and hands-on experience (Alavosius, Houmanfar, & Rodriquez, 2005). Participants who had less experience with food safety (i.e., zero to ten years) were greatly concerned about the challenge of employee readiness, whereas participants with more than 20 years of experience with food safety were less concerned about this challenge. Youn and Sneed (2002) identified lack of employee training as the biggest barrier toward effective implementation of quality systems, but in this study, contrary to the published

literature, employee preparedness was ranked low as compared to other challenges. This finding is significant but cannot be generalized beyond this study.

In contrast to other challenges, absence of quality culture was also ranked low. Absence of quality culture refers to lack of systematic practices within the organization which facilitates continuous improvement. According to Levin and Newslow (2013), ISO 9001, ISO 22000, HACCP, prerequisite programs, and good manufacturing practices help establish a favorable work culture, which in turn facilitates the integration of new requirements with existing processes. As per the participants of the study, the absence of a quality culture increases pressure on the cost and timeline of implementation. But it might have been ranked low because of the comparable priorities; participants believed that cost plays a critical role in establishing a quality culture.

According to Patricia, Stanley, Hubert, and William (1997), employee willingness is defined as resistance of employees to changing circumstances. Employee willingness was voted as the least significant challenge, receiving just four percent of the total point share. Contrary to these results, Lam, Cho, and Qu (2007) suggested that employee reluctance is a significant challenge for adoption of new systems. In the present study, this contrast was observed because many participants believed that the responsibilities of the employees are defined by the organization and any resistance to change can be overcome by other motivations such as trainings, rewards, and recognition. The authors believe that the perception of this challenge can be organization specific. For most of the small food facilities struggling with basic resources such as man, machine and money, factors such as employee willingness are of less priority.

The findings of this study also highlight a difference in the perspectives of academic professionals and industry representatives with regard to the ranking of perceived challenges for

small food facilities. The industry respondents convincingly expressed their belief that understanding the expectations of FSMA law is a concern. They gave almost 40% of their point share to that challenge, leaving the remaining 60% of the points to be distributed among the other five challenges. In contrast, the academic professionals voted for the cost of implementation as the largest challenge by giving it 28% of the total share. Several past studies have also shown a distinct gap in the perceptions of industry representatives and academic professionals (Nicholson & Cushman, 2000; Siegel, Waldman, Atwater, & Link, 2004). The observed difference might be because of the potential gap between the practical and theoretical exposure of the participants in the two groups. Historically, academia is believed to be less appreciative of the pragmatic challenges and industry is believed to be less aware of the nuances and complexities of policy making (Finke, Ward, & Smith, 1996).

4.1 Study limitations and future work

Several limitations of the study prevent the generalizability of the findings of the study. This research focused on only the HARPC requirements of FSMA for small food facilities. FSMA has several sections, along with HARPC, that might concern small and large facilities alike. Moreover, the results of this study were taken from a small representative sample from academic and industry based in the Midwest region of the United States; therefore, the results are not representative of the perspectives of all food safety professionals in United States. However, the findings of this study will be important for future research work. Furthermore, the industry representatives in this study were quality professionals who were well versed with food safety and quality management practices.

This study utilized qualitative methods to analyze the data, whereas a quantitative (statistical) approach would have lent a significant accountability to these observations. Finally, the discussion reported here was based on the rules of FSMA as of April 2015. The final rules for FSMA were still under review as of this writing, and the perceptions of academic and industry professionals could change as a result of changes reflected in the final rules. Additionally the preventive control requirements for human and animal food facilities are different so these facilities might have different set of challenges while adopting the requirements. The current study analyzes the impact of only human food regulations on small food and grain handling/ processing facilities; however they might be engaged in animal feed production as well.

The researchers of this study have identified different constraints faced by small food industries in the adoption of HARPC and look forward to addressing them individually in future research. Future work could also help to better understand the root cause of the differences in the opinions of academic professionals and industry representatives and look for ways to bridge the gap between them.

5. Conclusion

This research was an attempt to identify and prioritize different challenges that small food facilities might face during adoption of HARPC requirements of FSMA by evaluating the perception of academic professionals and industry representatives. Although there was disagreement among the academic professionals and industry representatives on the prioritization of challenges, in general the participants believed that FSMA is a much-needed set of regulations. The research efforts in this study is just the beginning of the exploration of the

successful implementation of FSMA regulations among small food facilities and will be a strong stepping stone for future research.

Acknowledgments

The authors would like to thank the academic professionals and industry representatives who participated in the study.

References

Alavosius, P. M., Houmanfar, R., & Rodriquez, N. J. (2005). Unity of purpose/unity of effort: Private-sector preparedness in times of terror. *Disaster Prevention and Management: An International Journal, 14*(5), 666–680.

American Institute of Baking. (2014). *What you need to know about FSMA.* Manhattan, KS.

Bas, M., Yüksel, M., & Çavusoglu, T. (2007). Difficulties and barriers for the implementing of HACCP and food safety systems in food businesses in Turkey. *Food Control, 18*(2), 124-130.

Bernard, H. R. (2011). *Research methods in anthropology: Qualitative and quantitative approaches* (5th ed.). Lanham, MD: AltaMira Press.

Center for Progressive Reform. (2013). *Current good manufacturing practice and hazard analysis and risk-based preventive controls for human food* (Docket ID No. FDA-2011-

N-0920). Washington, DC: Heinzerling, L., McGarity, T. O., Shapiro, S., Steinzor, R., & Patoka, M.

Congressional Research Service. (2007). *The federal food safety system: A primer, report for Congress*. Washington, DC: Becker, S. G., & Porter, D. V.

Creswell, J. W. (2014). *Research design* (4th ed.). Thousand Oaks, CA: SAGE Publications.

Creswell, J.W. & Miller, D.L. (2000). Determining validity in qualitative inquiry. *Theory into practice, 39*(3), 124 – 130.

Denzin, N. K. & Lincoln, Y. S. (2011). *The SAGE handbook of qualitative research* (4th ed.). Thousand Oaks, CA: Sage Publications.

Dzwolak, W. (2014). HACCP in small food businesses – The Polish experience. *Food Control, 36*(1), 132 – 137.

Federal Register. (2014). *Current good manufacturing practice and hazard analysis and risk-based preventive controls for human food* (Document no. 2014-22446). Pittsburgh, PA: U.S. Government Printing Office.

Finke, R. A., Ward, T.B., & Smith, S.M. (1996). Creative cognition: theory, research and applications. Bradford: MIT press.

Flaherty, T. B., Honeycutt, E. D., & Powers, D. (1998). The Academy of Marketing Science National Conference Proceedings' 98. Springer.

Food and Drug Administration. (2011). *Public meeting on the food safety modernization act: Focus on preventive controls for facilities*. Silver Spring, MD: U.S. Food and Drug Administration.

Food and Drug Administration. (2015, February 21). *FSMA proposed rule for preventive controls for human food.* Retrieved from http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm.

Houston, D. (2008). Rethinking quality and improvement in higher education. *Quality Assurance in Education, 16*(1), 61–79.

Karipidis, P., Athanassiadis, K., Aggelopoulos, S., & Giompliakis, E. (2009). Factors affecting the adoption of quality assurance systems in small food enterprises. *Food Control, 20*(2), 93–98.

Kheradia, A., & Warriner, K. (2013). Understanding the food safety modernization act and the role of quality practitioner in the management of food safety and quality systems. *The TQM Journal, 25*(4), 347–370.

Knutson, R., & Ribera, L. A. (2011). Center provisions and economic implications of FDAs food safety modernization act. *Agricultural and Food Policy Center Issue Paper, 11*(1), 1–13.

Kumar, M., Antony, J., Singh, R. K., Tiwari, M. K., & Perry, D. (2006). Implementing the lean sigma framework in an Indian SME: A case study. *Production Planning & Control: The Management of Operations, 17(*4), 407–423.

Lam, T., Cho, V., Qu, H. (2007). A study of hotel employee behavioral intentions towards adoption of information technology. *The International Journal of Hospitality Management, 26*(1), 49–65.

Layton, L. (2009, July 31). House approves food-safety bill; law would expand FDA's power. *The Washington Post*. Retrieved from http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073003271.html.

Levin, B., & Newslow, D. (2013, October 4). From HACCP to HARPC – what's best in class and how to get there. Retrieved from https://www.youtube.com/watch?v=v2VoBMgd0lU.

Mortlock, M. P., Peters, A. C., & Griffith, C. J. (1999). Food hygiene and hazard analysis critical control point in the United Kingdom food industry: Practices, perceptions, and attitudes. *J. Food Prot., 62*(7), 786–792.

Nicholson, A., & Cushman, L. (2000). Developing successful employees: Perceptions of industry leaders and academicians. *Education + Training, 42*(6), 366–371.

Panisello, P. J., Quantick, P. C., & Knowles, M. J. (1999). Towards the implementation of HACCP: Results of a UK regional survey. *Food Control, 10*(2), 87–98.

Patricia, C. B., Stanley, G. H., Hubert, S. F., & William, F. G. (1997). Who'll go? A review of factors associated with employee willingness to work overseas. *Human Resource Planning, 20*(3), 29-40.

Pyzdek, T., & Keller, P. (2014). *The six sigma handbook* (4th ed.). New York, NY: McGraw-Hill Education.

Multi-voting. (n. d.). *In Quality Glossary online.* Retrieved from http://asq.org/glossary/a.html

SGS. (2014). *Understanding the US Food Safety Modernization Act*. Switzerland, Geneva: Sansawat, S., & Cook, J.

Scharff, R. L. (2012). Economic burden from health losses due to foodborne illness in the United States. *Journal of Food Protection, 75*(1), 123–13.

Shafer, S. M., Smith, H. J., & Linder, J. C. (2005). The power of business models. *Business Horizons, 48*(3), 199–207.

Shaw, A. & Snyder, H. (2012). FDA food safety modernization act: registration for current and new facilities - U.S. bulk grains handlers and processing industries. *Iowa grain quality initiative*. Retrieved from http://www.extension.iastate.edu/NR/rdonlyres/454618E5-699C-44B4-987D-092D2E9ED131/172269/FSMAregistrationgrains.pdf.

Short, J. C., & Reeves, T. C. (2009). The graphic novel: A "cool" format for communicating to Generation Y. *Business and Professional Communication Quarterly, 72,* 414-430.

Siegel, D. J., Waldman, D. A., Atwater, L. E., & Link, A. N. (2004). Towards a model of the effective transfer of scientific knowledge from academicians to practitioners: Qualitative evidence from the commercialization of university technologies. *Journal of Engineering Technology Management, 21*(1), 115–142.

Sperber, W. (2005). HACCP does not work from farm to table. *Food Control, 16*(6), 511-514.

Tague, N. R. (2005). *The quality toolbox* (2nd ed.). Milwaukee, WI: American Society of Quality Press.

Thakur, M., & Hurburgh, C. R. (2009). Framework for implementing traceability system in the bulk grain supply chain. *Journal of Food Engineering*, *95*(4), 617-626.

United States Department of Agriculture. (2015). *Agriculture production and prices*. Retrieved from http://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-production-and-prices.aspx.

Ward, G. (2001). HACCP: Heaven or hell for the food industry. *Quality World (March),* 12–15.

Wright, K. B. (2006). Researching internet-based populations: Advantages and disadvantages of online survey research, online questionnaire authoring software packages, and web survey services. *Journal of Computer-Mediated Communication, 10*(3), 00.

Youn, S., & Sneed, J. (2002). Training and perceived barriers to implementing food safety practices in school foodservice. *The Journal of Child Nutrition & Management, 26*(2).