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Adoption of Food Safety Modernization Act: A Six Sigma Approach to Risk Based Preventive Controls for Small Food Facilities

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Abstract
According to the Center for Disease Control (CDC, 2010), 17% of Americans are at risk from food borne illnesses leading to 325,000 hospitalizations and about 3000 deaths every year. There have been several occasions in past during which these outbreaks have posed serious health concerns such as E. coli 0157:H7 in spinach - 2006, Salmonella Saintpaul in pepper - 2008, Salmonella Typhimurium in peanut butter - 2008, and Salmonella Enteritidis in eggs - 2010 (Haglund, 2011; Pouliot, 2012). As a result food businesses have lost billions of dollars in recall of contaminated food such as 500,000 bushels of soybean had to be destroyed in a Nebraska elevator after contamination from 500 bushels of soybean already affected by engineering corn. Similarly Starlink corn, not approved for human consumption, entered the food supply chain triggering a recall of more than 300 food products affecting food supply chain seriously (Laux, Hurburgh & Mosher, 2008). These incidents suggest that the American food safety1 system at that time was unorganized and ill equipped to counter potential food hazards (Becker & Porter, 2007).

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Introduction

According to the Center for Disease Control (CDC, 2010), 17% of Americans are at risk from food borne illnesses leading to 325,000 hospitalizations and about 3000 deaths every year. There have been several occasions in past during which these outbreaks have posed serious health concerns such as E. coli 0157:H7 in spinach - 2006, Salmonella Saintpaul in pepper - 2008, Salmonella Typhimurium in peanut butter - 2008, and Salmonella Enteritidis in eggs - 2010 (Haglund, 2011; Pouliot, 2012). As a result food businesses have lost billions of dollars in recall of contaminated food such as 500,000 bushels of soybean had to be destroyed in a Nebraska elevator after contamination from 500 bushels of soybean already affected by engineering corn. Similarly Starlink corn, not approved for human consumption, entered the food supply chain triggering a recall of more than 300 food products affecting food supply chain seriously (Laux, Hurburgh & Mosher, 2008). These incidents suggest that the American food safety[1] system at that time was unorganized and ill equipped to counter potential food hazards (Becker & Porter, 2007).

As a result, Food Safety Modernization Act (FSMA) was enacted as a public law on January 4th, 2011, amending Title 21 of United Sates Code on Food and Drugs. As per the Food and Drug Administration (FDA), FSMA was introduced to ensure holistic safety of U.S. food supply chain by shifting existing food safety focus from a reactive approach to a preventive controls emphasis.

FSMA is an attempt to strengthen the existing food safety net by providing FDA with increased authority to inspect food products and authorize mandatory recalls for contaminated goods. FSMA (Public Law 111-353) rules are divided into four Titles: (1) Improving capacity to prevent food safety problems, (2) Improving 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 (Improving capacity to prevent food safety problems) illustrates requirements of Hazard Analysis and Risk Based Preventive Controls (HARPC) (Kheradia & Warriner, 2013), which introduces a framework requiring all food facilities to implement a preventive food safety system (FDA, 2011). The food safety plan under HARPC requires the stakeholders in charge of a food facility to evaluate the potential hazards, identify solutions, implement preventive controls, monitor performance of these controls, and maintain records to minimize the occurrence of evaluated hazards using a scientific methodology (FDA, 2015). HARPC is a shift from the existing food safety management system, because it mandates a logical pre-assessment of safety hazards which was previously less prevalent.

1 As per WHO, 2011 Food Safety is defined as a commitment by stakeholders of food value chain to consumers that food will be devoid of physical, chemical, and biological hazards.

On the other hand, legislative requirements of new regulations can be challenging, especially for small food facilities[2] (Levin & Newslow, 2013). Historically, these facilities lack resources to build capacity for new requirements. Literature recognizes these challenges as lack of understanding of guidelines, lack of qualified and experienced staff, limitations related to finances, restricted technical know-how, and lack of infrastructure (Bas, Yüksel & Çavusoglu, 2007; Dzwolak, 2014; Sansawat & Cook 2014). Table 1 enlists challenges highlighted by literature while adopting different quality management systems in food industry across the world. According to Layton (2009), FSMA is going to impact everyone in the food production chain, and hence effective implementation of FSMA depends on integrated participation by all stakeholders, especially the small food facilities. And since almost all large facilities already have extensive experience with other quality management systems 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 (Heinzerling et. al., 2013).

To our knowledge there is no known research which analyzes different adoption challenges for HARPC requirements of FSMA specific to the small food facilities. Purpose of this research is to apply tools of six sigma to identify and prioritize major challenges faced by small facilities in United States and recommend potential guidelines while adopting selected components of the law. Some of the small food facilities are exempt[3] from HARPC requirements of FSMA (FDA, 2015). This study is applicable to potentially non-exempt small food facilities who will have to comply with either partial or full requirements of preventive control regulations.

Table 1

Challenges faced by food facilities while adoption of different quality management systems as cited in literature

Challenges	Quality System	Facility size	Country	Source
Understanding of requirements	FSMA	Small, Large	United States	AIB[a] (2015)
Lack of Prerequisite programs, Lack of Infrastructure, Time, Employee motivation	HACCP[b]	Small, Large	Turkey	Bas, Yüksel & Çavusoglu (2007)
Understanding of guidelines, Employee engagement, Lack of Finance, Infrastructure	HACCP	Small	Poland	Dzwolak (2014)
Understanding expectations, Lack of trainings, No guidelines	HARPC	Small, Large	United States	FDA (2011)

2 As per FDA small and very small facilities are defined as organizations employing fewer than 500 persons and having less than $1 million in total annual sales respectively; for the purpose of this research small facilities refer to both small and very small facilities.

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 food 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.

Lack of Prerequisite programs, Lack of Infrastructure, Time, Employee motivation	HACCP	Small, Large	Turkey	Bas, Yüksel & Çavusoglu (2007)
Understanding of guidelines, Employee engagement, Lack of Finance, Infrastructure	HACCP	Small	Poland	Dzwolak (2014)
Understanding expectations, Lack of trainings, No guidelines	HARPC	Small, Large	United States	FDA (2011)
Lack of qualified managers, Third party consultants	Quality systems	Small	Greece	Karipidis et. al. (2009)
Lack of system experts, Employee engagement, Lack of quality culture	Quality systems	Small, Large	United States	Kheradia & Warriner (2013)
Understanding of requirements, Employee training	HACCP	Small, Large	United States	Levin & Newslow (2013)
Lack of Infrastructure, Supplier partners, Lack of clear regulations	FSMA	Small, Large	United States	Sansawat & Cook (2014)

[a] American Institute of Baking, [b] Hazard Analysis and Critical Control Point

Six Sigma and Food Industry

Six sigma is a methodological approach to improve processes, products, and services for delivering customer value (Houston, 2008). It is a systematic method to drive continuous improvement and deliver high quality products. It is based on previously developed quality control tools and techniques (Quality Glossary ASQ, 2013).

There are several six sigma methodologies available, one of them being DMAIC (define - measure – analyze – improve – control). It has been used in past for manufacturing processes in food industry to improve product & process quality (Hung & Sung, 2011). Hung and Sung (2011) have successfully demonstrated application of DMAIC for improvement of process in a food company in Taiwan by decreasing shrinkage defects in small custards. Peariso (2006) emphasized a much deeper relationship of food safety, six sigma, HACCP and plant profitability by suggesting a more integrated approach to these tools. Six sigma tools have been suggested to augment HACCP system by including the non-critical control points, reducing variation, and driving process improvement. Cutler (2007) highlights different challenges with food industry when it comes to six sigma adoption such as competition, variability, perishable raw material, and complex regulatory guidelines.

Thus literature highlights a need for addressing adoption concerns of HARPC in small food facilities using a more systematic approach such as DMAIC. Even though six sigma is data driven approach authors have demonstrated use of a qualitative framework to delineate project objectives, identify challenges, assess baseline, find root cause, and suggest possible solutions. (Crow 2002; George, 2002; Hung & Sung, 2011; Zhen, 2011).

4. HACCP is a widely accepted 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).
5. The FDA is still working to finalize guidelines for preventive control of FSMA and final rules will be issued in August 2015

Methodology

This research study is based on a verifiable premise that small food facilities might face challenges to adopt HARPC requirements of FSMA. The literature and participants of this study have reaffirmed the premise. The application of various stages of six sigma (DMAIC) for this project are demonstrated in Figure 1.

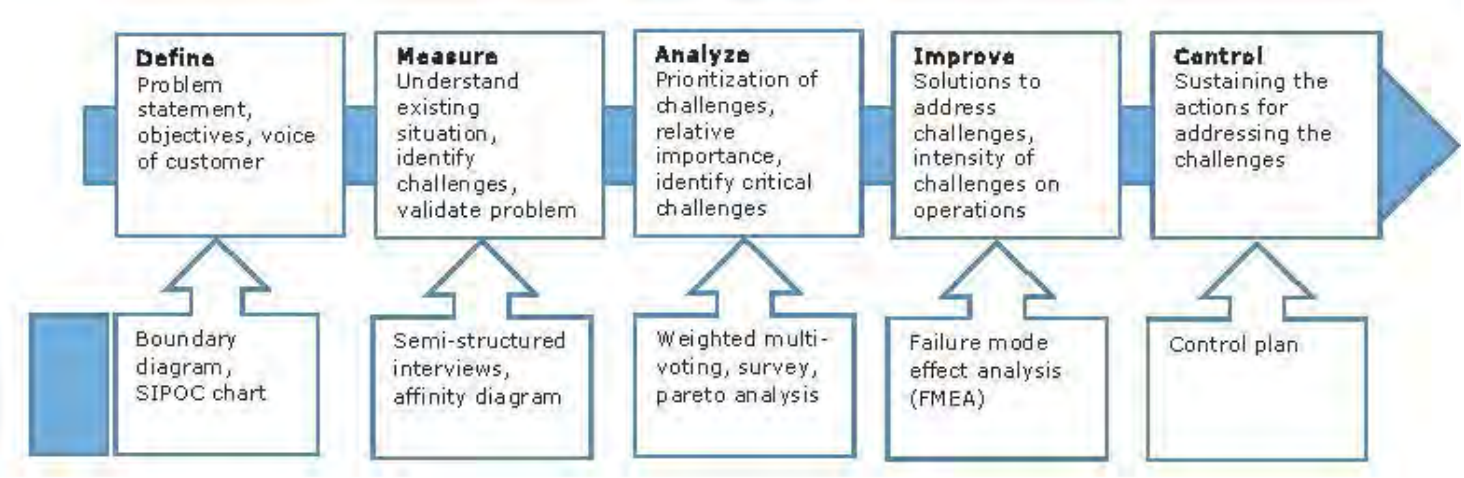

Figure 1. Project flowchart for DMAIC

Define

In define phase the problem statement, stakeholders, objectives and scope of the study were clearly outlined (Prasad, Subbaiah, & Padmavathi, 2012). SIPOC chart (supplier, input, processes, output and customer) was used to map the process. In our study, FDA was considered as customer or end beneficiary of implementation of HARPC in small food facilities. FDA has enlisted all requirements of HARPC in Public Law 111-353, which acts as Voice of Customer (VoC). Specific measurable targets for goal statement were identified. Based on the literature review, the authors aimed at identifying 6~8 challenges and prioritizing them into 2~3 challenges.

Measure

Measure phase was used to understand the intensity of problem statement and explore potential factors affecting adoption of HARPC requirements by small facilities. Challenges were identified using semi-structured interviews of representatives from food industry and academia. For semi-structured interviews, contextual questions were designed by referring published FSMA guide of American Institute of Baking (AIB, 2015) and by transcribing the minutes of FDA public meetings (FDA, 2011). Interview queries included contextual questions such as general perception of individuals about HARPC requirements of FSMA, and major challenges of small facilities while

6. Authors wanted to utilize both perspectives of industry representatives and academicians, because the FDA worked closely with them to phrase and mend requirements of the law (FDA, 2011).

implementation of HARPC as perceived by the participants. Affinity diagram was used to identify challenges by observing common themes in interview data. It was used for organizing ideas into categories based on underlying similarity of data generated during interviews (Pyzdek, 2003; Shafer, Smith, & Linder, 2005). Thirty four seemingly different challenges were grouped into six themes which were later used for multi-voting or prioritization. Table 1, which enlists all the challenges from literature, was used to validate and refine the problem statement.

Analyze

Analyze phase was used to establish significance of the six identified themes. This phase facilitated identification of those challenges which had greatest impact on implementation of HARPC requirements for small food facilities. These six themes were prioritized using weighted multi-voting which was disseminated using Qualtrics® survey software. Survey questions were divided into two categories i.e. (1) demographic information and (2) contextual questions regarding prioritizing the set of challenges. Participants had to compare all the listed challenges and then based on their perception, distribute six points among these challenges. They had the flexibility to assign all points to any one challenge, which they felt was the most critical challenge, or distribute these points among relevant choices accordingly. The sum total of all the points assigned to each theme by the participants helped in rank ordering of these six themes. Results of multi-voting was analyzed using Pareto diagram which helped authors identify challenges that deserve immediate attention.

Improve

Improve phase was used to identify possible solutions to eliminate or reduce the intensity of potential challenges. Failure mode and effect analysis (FMEA) was used to evaluate possible consequence of these challenges on operational status of small food facilities. It helped in identifying actions to eliminate chance of potential failure. The FMEA tabular form included parameters such as prioritized challenges, potential failure mode, potential effects of failure, SEV – severity, potential causes of failure, OCC – occurrence, DET – detection, RPN – risk priority number, and recommended action for small facilities (Prasad, Subbaiah, & Padmavathi, 2012). Possible solutions were also discussed with the participants during semi-structured interviews.

Control

Control phase was used for sustaining actions for addressing these challenges. Recommendations were made for counteractions through control plans for sustaining the recommended solutions.

Results and Discussion

A six sigma team was formed comprising of authors and other stakeholders. Experts were continuously involved to overlook the project details. Project selection was done based on literature review and previously available data. Considering the time constraint scope of the study was narrowed down. The boundary diagram in Figure 2 shows the project outline. Authors focused on Title I, section 103 of FSMA applicable for food industries which had already implemented HACCP or other quality management systems. Measurable goal and primary index of the project was identification of 6~7 challenges, prioritization of these challenges into 2~3 issues, and suggesting potential solutions. SIPOC chart in Figure 3 shows that final output of process is HARPC regularized business units, FDA being the direct customer. A baseline analysis demonstrated key requirements of the customer. Table 2 enlists the HARPC requirements taken from Public Law 111-353 as an input for Voice of Customer.

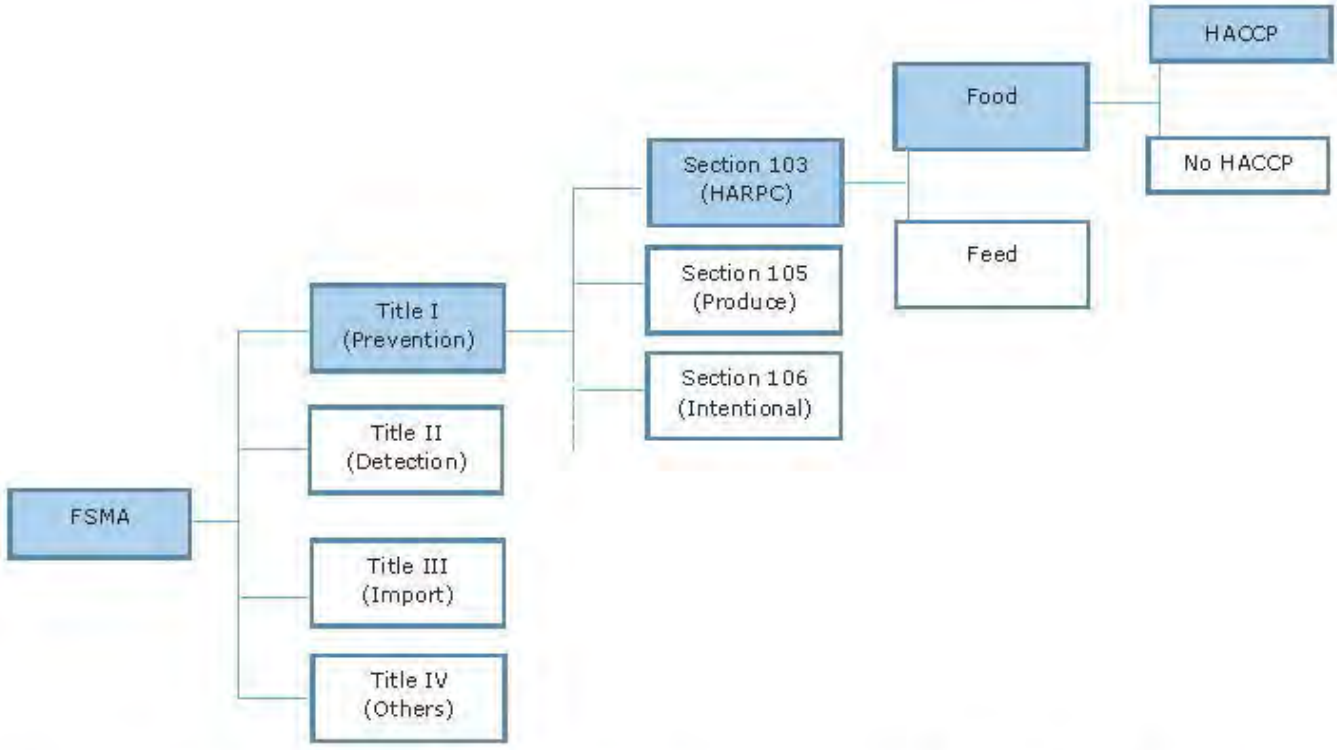

Figure 2. Project boundary diagram (Highlighted blocks represent the schematic flow of the project)

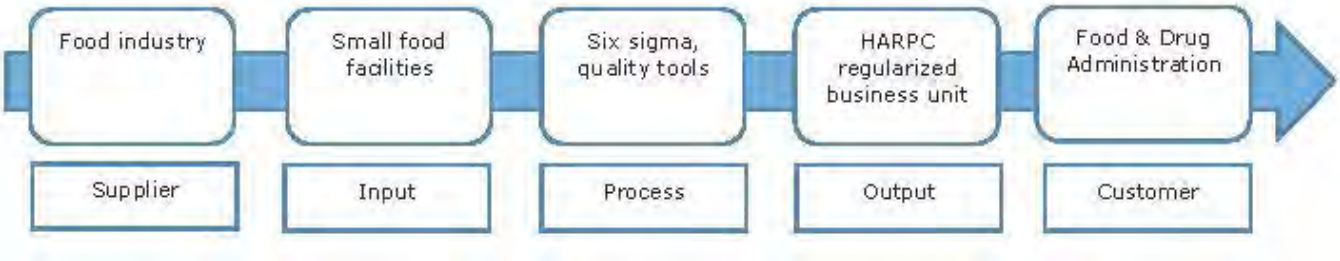

Figure 3. SIPOC diagram

Table 2
Baseline comparison of existing system and new requirements

Existing system	HARPC requirements

1. Unstructured, nonintegrated, reactive food safety approach	1. Structured, integrated preventive food safety approach
2. HACCP , food Safety plan voluntary	2. HARPC, food safety plan mandatory
3. Focus only on CCP[a] and critical limits	3. Comprehensive focus on CCP[a], PRP[b], GMP[c]
4. Hazards include physical, chemical, and biological	4. Hazards include physical, chemical, biological, allergens, and radiological
5. HACCP team– no justification required	5. HARPC team - qualified individuals, justification mandatory
6. Focus on CCP[a] effectiveness and verification	6. Focus on effectiveness, record keeping, proactive approach
7. Focus only on unintentional hazards	7. Focus on intentional hazards as well
8. Onus limited to quality team	8. Onus on all motivated employees

[a] Critical control point, [b] Prerequisite program, [c] Good manufacturing practices

Semi-structured interviews were useful to measure existing challenges of small food facilities while adoption of HARPC requirements of FSMA. In all 13 out of 19 industry and academic representatives participated in the study. The participant profiles for semi-structured interviews are listed in Table 3. Out of all the participants 53.8% were from academia and 46.2% were from the industry. Most of the participants had an extensive exposure to quality management and food safety systems with small food industry. The participants were classified as industry or academic representative based on their present engagement only. The participants were mostly from the Midwest region of United States as this region is known to have high concentration of small food facilities. These participants were interviewed to identify potential challenges.

So 34 identified challenges were combined into six themes. Figure 4 shows different broad themes and all the identified challenges. This study enumerated the following six challenges for small food facilities in adoption of HARPC requirements of FSMA as "employee preparedness", "absence of quality culture", "timeline for implementation", and "employee willingness", "cost of implementation" , "understanding the FSMA requirements". The list is not exhaustive and is based on all the input from interviews and archival research.

Table 3
Profile of participants

Participant code	Age (range in years)	Education qualifications	Experience with food safety in industry (range in years)	Kind of training in QMS[a]
AN[b] – 1	More than 60	Masters	11 – 15	Company training, others
AN[b] – 2	31 – 35	PhD	0 – 5	HACCP
AN[b] – 3	36 – 40	PhD	0 – 5	Company training
AN[b] – 4	41 – 45	PhD	11 – 15	ISO 9001, six sigma, certified technology manager, company training
AN[b] – 5	26 – 30	PhD	0 – 5	No certification
AN[b] – 6	36 – 40	Masters	0 – 5	No certification
AN[b] – 7	51 – 55	Masters	6 – 10	Certified quality manager, company training
IR[c] – 1	26 – 30	Bachelors	6 – 10	HACCP, company training, ISO 9001
IR[c] – 2	Choose not to answer	Masters	0 – 5	Company training
IR[c] – 3	More than 60	Bachelors	6 – 10	No certification
IR[c] – 4	51 – 55	Bachelors	More than 30	HACCP, company training
IR[c] – 5	56 – 60	Bachelors	26 – 30	HACCP, ISO 9001, certified quality manager, company training
IR[c] – 6	More than 60	Masters	More than 30	HACCP, others

[a] QMS (Quality Management Systems), [b] AN (Academician), [c] IR (Industry Representative)

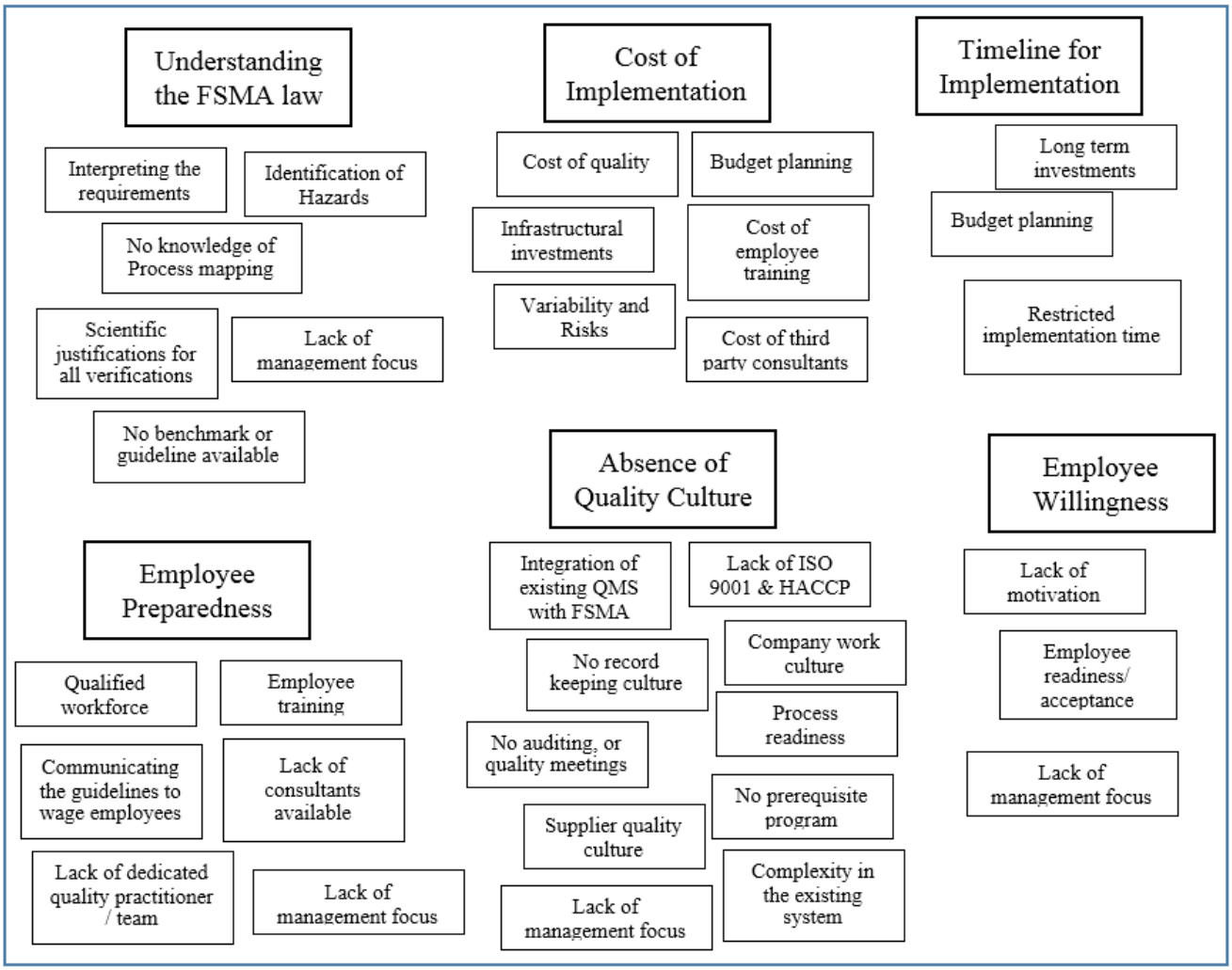

Figure 4. Affinity diagram

Participants listed in Table 3 also voted for multi-voting survey for prioritizing the identified challenges. The challenges were ranked in the following order of significance by the participants using the methodology as mentioned in "analyze" phase: Understanding of the FSMA guidelines, cost and timeline for implementation, employee preparedness, absence of quality culture, and employee willingness. As shown in Figure 5, "understanding of the FSMA law" received maximum vote share. Many industry representatives highlighted that "language of law" and "clarity of guidelines" is a major barrier in understanding the expectations of FSMA for small food industries. This might be because several of such small facilities lack necessary resources for a dedicated quality management team or a third party consultant to interpret expectations of the law (Levin & Newslow, 2013). In this study, cost of implementation was voted as the second most significant challenge facing the implementation of HARPC as these requirements will call for increased investment in upgrading infrastructure, preparing employees, hiring third party consultants, developing a quality culture and motivating employees (Bas, Yüksel & Çavusoglu, 2007; Dzwolak, 2014). Timeline for implementation was voted as the third significant challenge. Participants of the survey suggested that timeline might be a challenge for the small food facilities as evolution of employee capabilities and skills will take time beyond the expected deadlines[4] (Karipidis et. al., 2009; Bas, Yüksel & Çavusoglu, 2007).

Table 4 shows the failure mode effect analysis (FMEA) for three prioritized challenges. It also enlists recommended actions or solutions for counteracting these challenges. It is observed that a gradual investment of resources in building a strong quality culture in the organization, beginning with implementation of ISO 9000, ISO 22000 guidelines and then advancing to others, will help small food facilities overcome these challenges as it brings in more discipline among employees and steadily prepares them for new requirements. Out of all the semi-structured interviews in "measure" phase, one of them was conducted with a small food facility in Iowa; the quality managers of the facility recollected their experience while implementation of HACCP in their facility and drew a parallel with HARPC requirements of FSMA. They are quoted as:

> "If we had not implemented ISO 9000 and ISO 22000 guidelines, assimilation of quality management system would have been difficult in our facility. The sudden transition to a different quality system [HACCP] might have expected a huge budget investment. Moreover internal culture and employee acceptability would have been a challenge. With ISO 9001:2015 and HACCP in place we are not worried about the implementation of HARPC requirements of FSMA which might not be the case for other small food facilities."

Thus sudden transition to higher quality systems will expect huge budget investments (Levin & Newslow 2013). So a continuous nurturing of a quality culture in the organization is a sustainable solution.

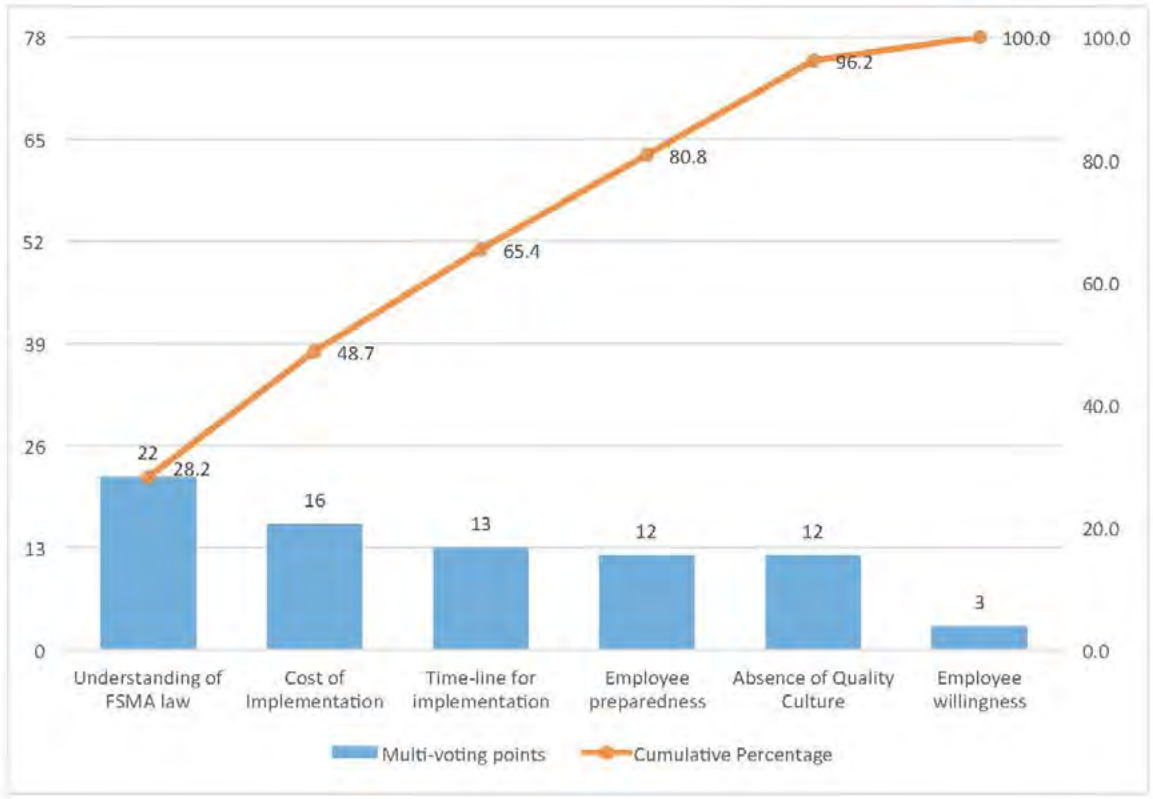

Figure 5. Pareto chart

7. Small businesses, as defined in introduction, 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.

Table 4
FMEA of the prioritized challenges and recommended action plan

Prioritized challenges	Potential failure modes	Potential effects of failure	SEV	Potential causes of failure	OCC	DET	RPN	Recommended action for small facilities
Understanding of FSMA law	Less/no clarity of guidelines/ expectations	Wrong investments, not meeting regulations	9	No quality management team, typical language of law, less trainings or communication by FDA	7	3	189	FDA needs to address this by imparting trainings. Small facilities should increase engagement through common forums GEAPS[a] , NGFA[b]
Cost of implementation	Diverting investments from business for training employees, upgrading infrastructure, developing quality culture	Less profitability, financial liabilities	7	Scale of business is small, financial know how is limited	7	3	147	Gradual implementation of quality management system will help facilities avoid a sudden burden on their treasuries.
Timeline for implementation	Timeline pressure, diverting resources	Not meeting compliance dates, wrong investments	7	Lack of resource, lack of quality management system	7	3	147	Developing a quality culture is imperative.

[a] Grain Elevator and Processing Society, [b] National Grain and Feed Association

Conclusion

Six sigma (DMAIC) approach helped the authors to systematically design project flow (Quality Glossary ASQ, 2013). It exhibits a significant potential for future use in policy adoption studies in food industry. The authors identified six set of thematic challenges and ranked them using multi-voting in the following order as "understanding the FSMA requirements" , "cost of implementation" , "timeline for implementation", "employee preparedness", "absence of quality culture" and "employee willingness". Based on the study authors conclude that a strong quality culture in the organization can help facilitate easy adoption of new requirements. Despite the adoption challenges, participants of this study have recognized the importance of preventive controls of FSMA law and feel that FSMA is a much needed set of regulations.

There are several limitations of the study that inherently restrict the outcome. One of them being that it is an observational study, owing to which the results cannot be generalized across all small food facilities in United States. With preliminary findings, this qualitative piece will be horizontally extended to several small food facilities across Midwest to gather quantitative data in future.

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