FOOD SAFETY CULTURE: AN UNDERLYING CAUSE FOR SUCCESS AND FAILURES

OF FOOD SAFETY MANAGEMENT SYSTEMS

A Paper
Submitted to the Graduate Faculty
of the
North Dakota State University
of Agriculture and Applied Science

By

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In Partial Fulfillment of the Requirements
for the Degree of
MASTER OF SCIENCE

Major Program:
Food Safety

April 2018

Fargo, North Dakota

North Dakota State University
Graduate School

Title

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MASTER OF SCIENCE

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ABSTRACT

Food Safety Culture (FSC) is an emerging behavior-based food-safety management concept. FSC has been linked as an underlying cause for food-safety management-system failures during foodborne outbreaks and recall investigations. This paper reviews the available literature on FSC for the origin, definitions, factors, barriers, and dimensions that influence the FSC's performance and measurements. Data were obtained from peer-reviewed journals as well as publicly available information on the World Health Organization (WHO), Food and Drug Administration (FDA), and Center for Disease Control and Prevention (CDC) websites. The roles of organizational leadership and communication, food-handler behaviors, risk perception, regulatory authorities, and technological advancements are evaluated for FSC development and enhancement. It can be concluded that there is a need for a strong FSC within food manufacturing and service organizations because it enhances the food-safety management systems' performance and may also reduce the global burden of foodborne illnesses and diseases.

ACKNOWLEDGEMENTS

First and foremost, I would like to thank my graduate adviser, Dr. Charlene Wolf-Hall, for providing invaluable support and direction throughout my studies. Without her patience and belief, it would not have been possible to complete my degree. I would also like to thank Dr. Paul Schwarz for providing the opportunity to share the academic and professional knowledge which I attained at NDSU and in the food-manufacturing industry. Many thanks to Dr. John McEvoy for serving on my committee and providing valuable feedback on my work. Last, I would like to acknowledge the encouragement from my parents, Surendra Kumar and Kusum Lata, and my wife, Arushi Kaushik, for keeping me motivated to complete my degree requirements.

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LIST OF ABBREVIATIONS

CDC ....Center for Disease Control and Prevention.

DALY ....Disability Adjusted Life Year.

HACCP ....Hazard Analysis and Critical Control Points.

FSC ....Food Safety Culture.

FSMS ....Food Safety Management System.

FDA..Food and Drug Administration.

FSMA...Food Safety Modernization Act.

USDA...United States Department of Agriculture.

WHO..World Health Organization.

1. INTRODUCTION

Foodborne illnesses are a significant cause of morbidity and mortality as well as an impediment to socioeconomic development worldwide (*89*, *90*). In 2007, the World Health Organization (WHO) launched a collaborative project with the European Centre for Disease Prevention and Control (ECDC) to estimate the global burden of foodborne diseases (*90*). The report suggested that almost 1 in 10 people fell ill from eating contaminated food during 2010 (*90*). The report recognized 31 global foodborne hazards which caused 600 million foodborne illnesses; 420,000 deaths; and 33 million Disability-Adjusted Life Years (DALYs), illustrating the global burden of foodborne diseases (*90*). The foodborne diarrheal-disease agents' impact included 550 million illnesses; 230,000 deaths; and 18 million DALYs (*90*). Children accounted for one-third of the deaths from foodborne diseases (*90*). Diarrheal foodborne diseases caused about 220 million illnesses in children (<5 years old), leading to 96,000 deaths (*90*). Both developed and developing countries are affected by this widespread and growing health problem (*90*, *94*).

In the United States, recent estimates by the Center for Disease Control and Prevention (CDC)/Scallan et al. showed that, each year, 1 in 6 American (48 million) get sick due to foodborne hazards, leading to about 3,000 deaths and 128,000 hospitalizations (*13*, *65*, *66*). In 2013, the CDC published surveillance data for foodborne disease outbreaks in the United States during the 1998-2008 period; the CDC received reports of about 13,405 foodborne disease outbreaks, resulting in 273,120 illnesses; 9,109 hospitalizations; and 200 deaths (*28*). The problem not only affects the health of consumers, but also the economic growth and development of countries (*67*, *68*, *94*). Scharff et al. researched the economic effect of the foodborne-illness burden estimates provided by the CDC (*67*, *68*). Scharff et al.'s models estimated that the average cost per foodborne-illness case was $1,626 (90% credible interval [CI], $607 to $3,073) for the enhanced cost-of-illness model and $1,068 (90% CI, $683 to $1,646) for the basic model (*67*). The resulting aggregated annual illness cost was $77.7 billion (90% CI, $28.6 to $144.6 billion) and $51.0 billion (90% CI, $31.2 to $76.1 billion) for the enhanced and basic models, respectively (*67*).

The Grocery Manufacturing Association (GMA) suggests that a food company's recall has about $10 million in direct costs (*34*). The direct costs typically include notifying the affected parties (regulatory bodies, supply chain, and consumers), product retrieval, storage, destruction, unsalable product and labor costs involved with remediation, and investigation processes during the recall (*34*). These direct costs do not include other significant costs, including litigation costs, fines and post-recall mandated regulatory oversight, lost sales, the effect on the company's market value (stocks) and brand reputation, and the economic impact to the industry (*34, 78*). When analyzed over time, these burden estimates may show some improvement but not to the desired magnitude. In recent years, there has been a lot of focus on the lack of food-safety management systems, such as Hazard Analysis and Critical Control Points (HACCP), inspections, auditing, training, etc., but this focus has not shown a significant influence to reduce the burden.

This paper reviews key findings about some of the major foodborne outbreaks caused by the major pathogens *(Salmonella, Listeria, and E. coli)* in the last decade. The outbreak case studies include includes post-recall investigation outputs and comments from the stakeholders, such as owners, regulators, inspectors, and employees, regarding the incidents' root causes. The recurring food-handling issues during these catastrophic outbreaks may have more elements that contribute to the failure of food-safety systems. It is important to understand the underlying cause of recurring non-conformities and failures for food safety systems because these failures result in significant events, such as outbreaks and recalls (*81*). The Food Safety Culture (FSC) is believed to be an underlying cause for the failure of food-safety management systems, thus influencing the foodborne illness and disease burden across the globe (*31*, *93*, *94*).

The FSC concept has evolved from the safety and organizational culture studies and the practices within industries such as aviation, nuclear power, space, information technology, and health. Researchers, including Chris Griffith, Frank Yiannas, K. M. Livesey, and D. A. Clayton, introduced the concept of food safety culture during 2009-2010. FSC is an integration of three separate disciplines: organizational culture, food science, and social cognitive science (*31*, *62*, *94*). Griffith et al. suggest that the factors which influence the FSC are very similar to ones identified in other disciplines that use organizational culture to improve performance, e.g., safety culture. Griffith et al. consider food safety culture an “emerging risk factor” because it has recently been recognized as a contributory factor in outbreaks, but it is one which could be highly significant (*31*).

This paper highlights some common factors, dimensions and definitions of food safety culture which could instrumental in measurement and evaluation of FSC in food manufacturing and service organizations. Measuring the FSC is a crucial requirement to achieve the desired food-safety goals and FSC performance The FSC measurement allows senior business leaders to invest appropriate resources in order to enhance FSC performance and to achieve the ultimate food-safety goal of reducing foodborne illnesses and mortalities at a global level (*42*). This paper highlights the published literature and methodologies for measuring and developing the FSC. Finally, the paper also discusses the role of regulatory bodies and technological advancements that could help food businesses to enhance the FSC in their organizations.

2. OBJECTIVE

The purpose of this review is to document the available literature about the Food Safety Culture (FSC) concept and its significance as an emerging risk factor. The paper addresses the following questions:

1. What is FSC? How did it evolve?
2. How does FSC affect foodborne illnesses and outbreaks? Why do we need it?
3. What are the gaps and barriers in the current food-safety assessment tools and management systems?
4. How can FSC be measured? What research studies have been conducted on FSC measurement in food-manufacturing and food-service organizations?
5. How is good FSC created at a food-manufacturing plant?
6. How do regulatory initiatives and emerging technology influence FSC?

3. METHODOLOGY

The information provided in this paper is based on peer-reviewed journal articles which are available online when using search engines, including PubMed, the NDSU library, Google Scholar, and ScienceDirect. All the relevant articles that filtered for food safety culture were analyzed for this literature review. Foodborne-illness burden estimates, outbreak and recall data, and reports were pulled from regulatory and public-health agencies such as the Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), and the World Health Organization (WHO). Other information sources included online articles, reports, websites, magazines, and books published about food safety culture.

4. LITERATURE REVIEW

4.1. The Burden of Foodborne Illnesses and Outbreaks

Foodborne diseases are a significant cause of morbidity and mortality as well as an impediment to socioeconomic development worldwide (*90*). Foodborne disease (FBD) is commonly transmitted through the ingestion of food which is contaminated by microbiological bacteria and viruses, parasites, and chemicals and biotoxins (*90*). The risk of food-product contamination exists throughout the supply chain, i.e., farm to fork. Because the food-supply chain is increasingly complicated with global trade and sourcing perspectives, there is a higher risk to consumers worldwide. The failure to produce a food ingredient to a required standard due to accidental or deliberate contamination could lead to multiple manufacturers and counties within the supply chain being affected (*46*).

The effectiveness of food-traceability systems may vary from manufacturer to manufacturer, often creating extended delays during outbreak investigations and leading to more consumers being affected by contamination incidents (*90*). The consumers who are affected by products that are contaminated with foodborne hazards, specifically biological and chemical hazards, face lethal consequences which result in severe diseases, hospitalization, and deaths (*13*, *90*). Biological hazards such as norovirus and high risk pathogens foodborne pathogens like *Salmonella*, *Listeria*, *E.coli* O157:H7, *Shigella, Clostridium perfringens, and Staphylococcus aureus* have caused serious illnesses and deaths upon consumption of contaminated foods (*90*). Chemical hazards like aflatoxin, dioxin, melamine, mercury, cadmium, arsenic, and allergens have also been associated with significant recalls in past (*90*) These illnesses and outbreaks constitute a burden and can have a significant influence on a country's economic development and food-supply systems (*90*). Estimates for the overall burden of foodborne illnesses are helpful to allocate resources and to prioritize much-needed control and interventions to reduce the occurrence (*65*, *66*, *67*, *68*).

4.1.1. Global Burden

In 2007, WHO launched a collaborative project with the European Centre for Disease Prevention and Control (ECDC) to estimate the global burden of foodborne diseases (*90*). The Foodborne Disease Burden Epidemiology Reference Group (FERG) established by WHO, led this initiative. The objectives of this study included the estimation of global foodborne disease burden and strengthened capacity to conduct cost-effective country-specific assessments of prevention, intervention and control measures to improve national food safety systems and standards (*90*). These estimates cover a defined list of causative agents of microbial, parasitic and chemical origin (*90*). The study included 18 foodborne diseases in nearly 30 countries (*46*). The researchers identified the need for such a survey as these foodborne hazards were causing deaths (diarrheal diseases 2.2 million deaths) and most substantial share of the disease burden in developing countries, and hence jeopardizing the international development efforts (*46*, *90*). The lack of this disease burden information causes hurdles for policy makers and others in areas of resource allocation, food safety standard development, cost assessment & effectiveness and risk management strategy development (*46*, *67*, *90*).

A final report was published in 2015 by the WHO/FERG to provide the first estimates of global foodborne disease incidence, mortality, and disease burden in the form of Disability Adjusted Life Years (DALYs) (*90*). The DALY is the sum of the number of years of life lost to mortality (YLL) and the number of years lived with disability due to morbidity (YLD) (*90*). The report estimates of the global burden of foodborne diseases suggest almost 1 in 10 people fall ill every year from eating contaminated food (*90*). The report outlines 31 identified global foodborne hazards causing 600 million (95% uncertainty interval [UI] 420-960 million) foodborne illnesses, 420,000 (95% uncertainty interval [UI] 310,000-600,000) deaths and 33 million (95% uncertainty interval [UI] 25-30 million) DALYs of global burden of foodborne disease in 2010 (WHO 2015). The foodborne diarrheal disease agents were the leading cause for the burden and included 550 million illnesses, 230,000 (95% UI 160,000-320,000) deaths and 18 (95% UI 12-25) million DALYs in 2010 (*90*). Additional facts identified in the report included: Children account for ⅓ of the deaths from foodborne diseases diarrheal foodborne diseases caused 220 million illnesses in children (<5 years old) causing 96000 deaths (*90*). Both developed and developing countries are affected by this widespread and growing health problem. The highest burden per population was identified in Africa, followed by South-East Asia and the eastern Mediterranean sub regions (*90*).

4.1.2. US. Burden

In the U.S., CDC leads the initiatives to identify the burden of foodborne illnesses and outbreaks on a periodic basis. The CDC has a Foodborne Disease Outbreak surveillance system that collects data on the occurrence of two or more cases of a similar illness resulting from ingestion of a common food (*28*). CDC surveillance systems serve the purpose of identifying food vehicles, new and emerging pathogens, handling practices, the point of contamination and trends in food disease outbreaks (*28*). The state, local and territorial health department identify and investigate foodborne disease outbreak and submit their findings and reports. The reporting systems evolved from paper-based reports (1971-1997) to web-based systems like electronic Foodborne Outbreaks Reporting System (eFORS) (1998-2008); and National Outbreak Reporting System (NORD) (*28*). In 2011, CDC reported US foodborne illness burden estimates based on a study done by Scallan et al. The report included the estimates of annual number of domestically acquired, foodborne illnesses, hospitalizations, and deaths due to 31 pathogens and the unspecified agents transmitted through food in United States. A total of 47.8 million (90% CI 28.7-71.1 million) illnesses, 127,839 (90% CI 62,529–215,562) hospitalizations, and 3,037 (90% CI 1,492–4,983) deaths annually (*13*, *66*).

The estimates also show 31 known foodborne pathogens cause about 9.4 million (90% CI6.6–12.7 million) illnesses, 55,961 (90% CI 39,534–75,741), and 1,351 (90% CI 712–2,268) deaths annually. Norovirus and nontyphoidal *Salmonella* were the top two pathogens contributors for domestically acquired foodborne illness resulting in hospitalizations and deaths. Prior to Scallan et al., Mead et al. (1999) reported estimates of the overall burden of foodborne illnesses, hospitalizations and deaths caused by known and unknown agents (*53*, *66*, *67*). Mead et al. annual estimates includes that approximately 76 million foodborne illnesses, 325,000 hospitalizations, and 5,000 deaths occur each year in United States (*53*). The study reported that the 28 known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths (*53*). In 2013, CDC also published surveillance data for foodborne disease outbreaks in the United States during 1998-2008 period which outlines that CDC received reports of 13,405 foodborne disease outbreaks, resulting in 273,120 illnesses, 9,109 hospitalizations, and 200 deaths (*28*).

4.1.3. Economic Burden Estimates

In 2012, Dr. Robert L. Scharff, a former Food and Drug Administration (FDA) economist and a current Ohio State University assistant professor in the Department of Consumer Sciences estimated the cost of foodborne illness. The study reflects the new CDC/Scallan et al. foodborne illness estimates that replaced CDC/Mead et al. estimates (*53*, *66*, *67*). The economic update included significant improvements like inclusion of uncertainty, the disaggregation of underdiagnoses and under-reporting factors, and the exclusion of travel-related illnesses (*67*). Scharff's models estimated the average cost per case of foodborne illness was $1,626 (90%

credible interval [CI], $607 to $3,073) for the enhanced cost-of-illness model and $1,068 (90% CI, $683 to $1,646) for the basic model. The resulting aggregated annual cost of illness was $77.7 billion (90% CI, $28.6 to $144.6 billion) and $51.0 billion (90% CI, $31.2 to $76.1 billion) for the enhanced and basic models, respectively (*67*).

The federal agencies like the Economic Research Service of the U.S. Department of Agriculture (USDA) and the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration (FDA) uses two cost-of-foodborne illness models (basic and enhanced) that account for health-related economic costs associated with foodborne illness (*67*). In 2015, a study published by Economic Research Service/USDA estimates the economic burden of 15 leading pathogens to be a total mean of $15.5 billion, with a range of $4.8 billion to $36.6 billion (*37*). These 15 pathogens studied account for 95%t or more of the foodborne illnesses, hospitalizations, and deaths in the United States for which a specific pathogen cause can be identified (*37*). About 84% of economic burden from these 15 pathogens is due to deaths (*37*). This study also ranks these 15 pathogens based on their total economic burden where *Salmonella* is ranked 1 with an estimated $3.7 billion in economic burden per year (*37*).

4.1.4. Cost to the Food Industry

An uncontrolled food contamination event within a manufacturing setting may lead to recalls and outbreaks. According to FSIS, "A recall is a firm's action to remove their products from commerce (e.g., by manufacturers, distributors or importers) to protect the public from consuming adulterated or misbranded products (*84*)." The number of food recalls in the U.S. have increased over time due to increased global and complex food supply chain; tighter regulatory requirements and their oversight; improved pathogen detection methods and dramatic impact of large-scale recalls and their media coverage. e.g., PCA 2009 (*33*, *34*, *78*). Besides the public health impact of food recalls, other economic issues arise from these significant events within the food industry (*34*).

According to GMA, the average cost of a recall to a food company is about $10M in direct costs (*34*). The direct costs typically include notification to affected parties (regulatory bodies, supply chain, consumers), product retrieval, storage, destruction, unsalable product and labor costs involved in remediation and investigation processes during the recall (*34*). However, these direct costs do not include other significant costs including litigation costs; the cost of fines and post-recall mandated regulatory oversight; lost sales; impact on company's market value (stocks), brand reputation, and industry impact (*33*, *34*, *78*). The estimated cost for American peanut butter containing product manufacturers due to the 2009 recall for *Salmonella* was about $1 billion (*33*). In today's world of extensive media coverage and social networking, it does not take much time for the food recall news to spread and negatively influence the brand. A GMA study found that "the day after a recall announcement, the stock price of the affected company underperforms the sector index by an average of 2.3 percent (*34*)." A poor recall execution can lead up to a 22% decline in two weeks after recall announcement (*34*). A recent example of such a brand impact include Chipotle Mexican Grill (Figure 4.1) significant stock market drop after 2015 *E. coli* recall.

Figure 4.1. 3-year history of Chipotle Mexican Grill stock price and the impact of Oct 2015 recall (*51*).

In 2010, Moises Resende-Filho and Brian Burr proposed a model to calculate direct costs for food recalls; (Price of Recall product (Pr) X Quantity of Recalled Product) + Notification Costs 4% + Transportation Costs 10% = Direct Cost of Recall (*63*). This model could provide estimates of recall impacts for food companies to make informed decisions.

$$C(QR) = PrQR + 0.04PrQR + 0.10PrQR = 1.14PrQR$$

In 2011, Grocery Manufacturers Association (GMA) shared financial aspects to quantify recall losses accurately. The report was based on a survey and interviews of 36 GMA members in the food, beverage and consumer packaged goods industry in the United States which generates sales of $2.1 trillion annually, employs 14 million workers and contributes $1 trillion in added value to the economy per year (*33*). 91% of respondents were from the food and beverage industry and approximately 58% of respondents had a recall experience in the last five years (*33*). The survey reported (Figure 4.2) 77% of respondents estimated the financial impact to be up to $30M.

23% of respondents reported even higher costs and 81% of respondents considered a recall as either "significant" or "catastrophic" concerning financial consequences due to interrupted business or profit loss, recall execution costs, liability risk and reputation damage or loss of brand equity (*33*).

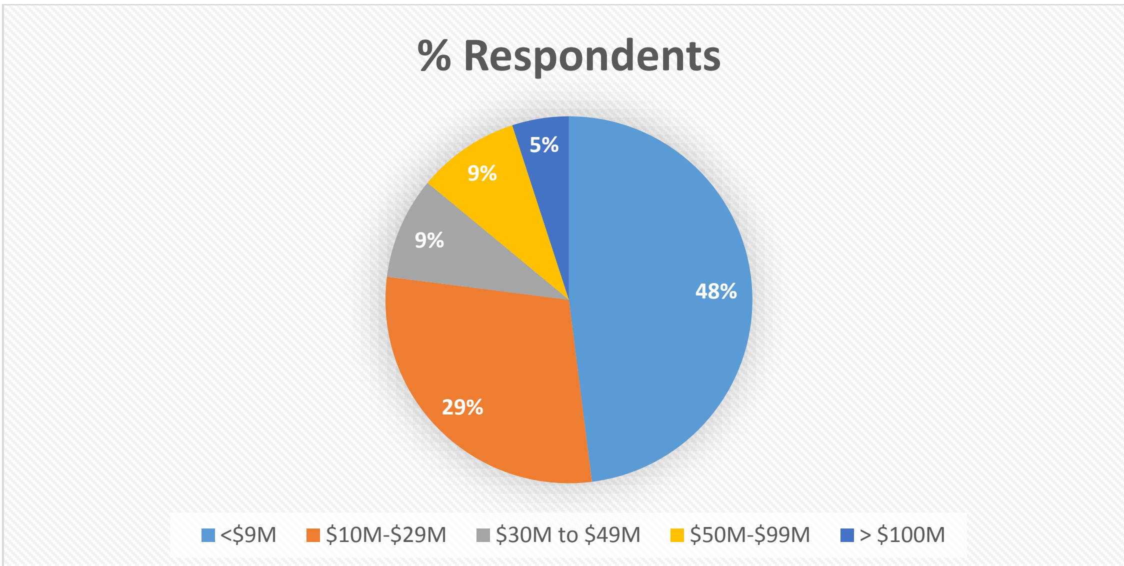

Figure 4.2. The financial impact in sales losses and direct impact incurred by GMA survey participants during food recalls (*33*).

4.2. Barriers in current food safety management systems

In 2006, the World Health Organization (WHO) identified five key contributors to foodborne illness which includes temperature abuse during storage, improper cooking temperature, cross contamination between raw and fresh ready-to-eat foods, lack of hygiene and sanitation by food handlers, and acquiring food from unsafe sources (*61*, *62*, *89*). A Food Safety Management System (FSMS) which provides a systematic approach to control these food safety hazards during processing and handling within food businesses have been used extensively to enhance efforts for safe food production (*31*, *50*). FSMS contains all the documented procedures, practices and operating procedures based on pre-requisite programs and Hazards Analysis and Critical Control Points (HACCP) that influences food safety (*31*). Recent research suggests an

FSMS is certainly an integral part of the strategy to reduce food safety disease burden but may not be the only driver to achieve an organization's food safety goals (*31*, *94*). The repeated recalls and outbreaks in food manufacturing organizations with successfully audited and verified FSMSs show that there are more underlying factors contributing to food safety practice and performance failures.

Food safety inspections and audits are integral part of FSMS and have been an industry norm set by customers and regulatory authorities to meet food safety and quality management related expectations for food supply chains. According to Australia New Zealand Food Authority (ANZFA), an 'audit' involves "systematic and independent examination to determine whether quality/safety activities and related results comply with planned arrangements (*3*)." The audits also analyzes if arrangements are implemented effectively and are suitable to achieve objectives whereas an 'inspection' evaluates "conformity by measuring, observing, testing or gauging the relevant characteristics (*3*, *61*)." These audits can be of three different types; internal audits, second party audit and third-party audits (*61*). The internal audits include system reviews by the quality assurance & food safety management teams of the food establishment (*3*, *61*). The second party audits are performed by customers/buyers of the food supplier; third party audits are performed by an outside firm to provide an independent verification to examine compliance with laws and codes of practice (*61*).

The Global Food Safety Initiative (GFSI) is a non-profit organization that provides a benchmarking system for audit food safety schemes where "all recognized schemes have a common foundation of requirements which should provide consistent results, in regard to common requirements applied during the audit, but the benchmarked schemes cannot be considered equal (*27*, *47*)." Some common third-party food safety management audit system standards benchmarked under GFSI scheme include Safe Quality Food (SQF), British Retail Consortium (BRC), International Featured Standard (IFS) and Food Safety System Certification (FSSC) 22000 (*47*).

Powell et al. argues that the role of third-party audits to reduce the risk of contaminated food products reaching marketplace is not clear as there are no empirical evaluations that consider the correlation between audit scores and foodborne illness outbreaks (*61*). The Peanut Corporation of America (PCA) outbreak in 2009 is a clear example of the inadequacy of successful third-party audits as a means to demonstrate good food safety performance at food establishments (*55*, *62*). A third-party auditing body, American Institute of Bakery (AIB) International, was responsible for the safety verification of products manufactured at PCA facilities. In the final report of AIB audit conducted at PCA in 2008, the AIB auditor concluded: "The overall food safety level of this facility was considered to be superior (*55*)." This outbreak was also a result of ineffective inspections by state inspectors as they only identified minor issues with PCA manufacturing and food safety practices (*55*). Powell et al. researched limitations of these food safety inspection and audit systems as they do not provide complete picture and could be mis-leading when used as sole indicator of FSMS performance

In 2014, Jespersen conducted a study to evaluate the viability of performance standards, such as audit reports, performance monitoring, and audit records, to measure the food safety culture (*41*, *43*). The data collected during these audits are useful to assess food safety at a certain point, i.e., a snapshot in time, but do not reveal the complete picture in terms of an organization's food safety culture and its performance (*41*, *43*, *61*). The audits are only as effective as the standards which are audited (*61*). These audit standards may lack specificity to address commodity-/product-specific risks and practices (*61*). It is also noted that food companies often select audit-service providers with the lowest price quotes, limiting the audit's scope because a lower-cost provider may not cover all operations, locations, and products (*61*). A conflict-of-interest issue can arise because the food producers and retailers require their suppliers to pay for their own audits, and a supplier may not hire an auditor that provides low audit scores (*61*). Auditors incompetence to conduct adequate risk assessments and their non-legal obligations for follow-up expectations are also viewed as limitations for these programs (*61*).

Implementing the FSMS is not as simple as it may seem. A study done by Macheka et al. identified barriers with such implementations. The lack of financial resources was reported as the major barrier for implementing the FSMS (*50*). Other barriers included a lack of commitment from top management, a lack of expertise and/or technical support, employee resistance to change, inadequate infrastructure and facilities, thinking that small organizations do not need the FSMS, and a lack of enforcement for the food-safety policy (*50*). Ball et al. reported that small businesses with limited resources see implementing an HACCP as an economic burden (*6*). There is a lack of knowledge, expertise, and resources, leading to a lack of effective FSMS at small businesses (*5*, *6*).

In 2009, Ball et al. used a qualitative approach to identify in-plant factors that influence the implementation of FSMSs (*6*). The data reveal three main themes: production systems, operational characteristics, and employee characteristics (*6*). Other themes included food-safety behaviors and external factors. Wilcock et al. described factors that motivate owners/senior managers to implement HACCP at small- and medium-sized food companies (*6*, *87*). The research also identified the challenges faced and factors which are essential to successfully implement HACCP for small businesses (*6*, *87*). One challenge faced by owners/senior managers was problems recruiting a food-safety champion who could lead the program (*87*). It is not easy to find an individual who has strong technical knowledge and previous experience in production processes with the compensation ranges for small and medium business settings (*87*).

Time constraints was another challenge faced by the food-safety managers and coordinators (*87*). With a day-to-day operation to manage, it is often difficult to understand and to develop program with the necessary inputs. The lack of process details could lead to the HACCP program and food-safety systems being merely a document system for auditing and record purposes rather than being used as a risk-assessment tool. The food-safety managers/coordinators pointed out the challenges with breaking the staff's old habits and creating new ones (*87*). The food-safety managers also reported a difficulty in getting support, especially when implementation required additional financial expenditures (*87*). Companies often tailor their FSMS standards to the organization's specific content and production circumstances, leaving room for self-regulation (*59*). If not adequately resourced and checked, such self-regulation may result in failures to evolve within the FSMS.

According to Powell et al., to prevent foodborne-hazard contamination incidents within an organization, one needs to go beyond the fundamentals of food-safety management systems (FSMS) that include regulatory compliance, standard operating procedures, policies, training and auditing systems (*62*). Yiannas shares similar thoughts regarding a traditional food-safety management system and recommends an approach beyond traditional training, testing, and inspections that needs to be followed in order to manage risks and to achieve FSC success in at a retail establishment and in the food-supply chain (*94*). This approach requires a better understanding of organizational culture and the human dimensions of food safety in order to change the way people do things, i.e., to change their behavior. The behavior change can be achieved by integrating the best science, management, and communication systems (*62*). Yiannas suggests combining food science with behavioral science to create a behavior-based food-safety management system or food safety culture (*94*).

4.3. Underlying Causes for Foodborne Outbreaks and Recalls

The CDC and FDA have reported holding temperature, inadequate cooking, cross-contamination of equipment, and poor personal hygiene as some common, contributing factors for foodborne outbreaks (*80*, *94*). U.S. FDA investigations have revealed problems with food-handling behaviors in the food-service industry (retail and on site) as a critical risk factor for the outbreaks (*83*). These behaviors are risk factors which have been studied to understand their contribution to the increased likelihood of food poisoning. Griffith et al. proposed 'organizational food safety' culture as an 'emerging risk factor' as well as the need for FSC's in-depth study to assist with the prevention of outbreak incidents (*31*).

FSC is considered to be an emerging risk factor because it was recently recognized as significantly contributing to outbreaks. Griffith et al. breaks the food safety culture into its components in order to develop tools to improve compliance with food-safety practices (*31*). FSC is a common denominator for some foodborne illness outbreaks and recalls that have occurred in the past decade. These outbreaks and recalls often occur due to cost-cutting initiatives which lead to compromised food handling and processing for food products (*62*). These recalls affect associated companies immensely, influencing the company's brand identity; financial losses; and, at times, bankruptcy (*31*, *62*). Griffith et al. suggest that, when an outbreak occurs, it is important to consider the business's FSC in addition to traditional risk factors. The following sections are some examples where poor FSC was a root cause that led to tragic and damaging consequences for consumers and other stakeholders (*31*).

4.3.1. Maple Leaf Foods' Listeria Outbreak

In August of 2008, a deadly Listeriosis outbreak occurred in Canada due to contaminated meat products which were manufactured by Maple Leaf Foods. The outbreak led to serious illnesses for 57 individuals and the tragic loss of 23 Canadian lives. Following this tragic event, in January 2009, Prime Minister Stephen Harper appointed Sheila Weatherill as an investigator to conduct a comprehensive and independent investigation about the outbreak. She provided a report which included 57 recommendations to strengthen Canadian food-safety systems (*85*). These 57 recommendations were estimated to cost about $75 million to implement, and the Canadian government agreed to fulfill all of them (*48*).

During the investigation, the contamination source was identified as an accumulated bacteria niche deep within the slicing machines on lines 8 and 9 (*43*, *85*). Besides sanitation in-effectiveness to clean these hard-to-reach areas, other environmental factors, such as the building's age and location, condensation, airflow, and drain back-up, also contributed to the level of contamination (*43*, *85*). Prior to the recall, Maple Leaf Foods was perceived to be a company with a strong commitment to food safety; the company complied with the regulatory requirements under the Federal Meat Inspection Act, had satisfactory ratings during government inspection, had comprehensive HACCP plans, had a 40-step food-safety program/system, and conducted third-party audits (*43*, *85*). The contamination and environmental issues evolved, reflecting the lack of management and gaps for good manufacturing practices (GMPs) compliance (*43*, *85*).

Organizationally, the root cause was believed to be a combination of technical and behavioral deficiencies as well as assumptions about food safety. The failures were apparent in the stakeholders' statements during the investigations (*43*, *85*). Dr. Brian Evans, Executive Vice President of the Canadian Food Inspection Agency (CFIA) said, "In hindsight, it was determined that the company was doing environmental testing. There was information being kept at the plant that was not provided at that time to the inspector. We must achieve a collective commitment and culture that supports the timely and transparent sharing of all information, even in the absence of regulatory obligation, to maximize food safety outcomes" (*85*). Dr. Randy Huffman, the Chief Food Safety Officer of Maple Leaf Foods, said, "The idea of a 'food safety culture' is that every person in the organization should understand their role in producing safe food and the challenge is in the communication of that message" (*85*). These statements from stakeholders reveal how food safety culture is recognized as a cause at a deeper level post-crisis. This identification and hindsight is consistent with catastrophic safety accidents like the one occurred at Chernobyl nuclear plant (*39*).

The Maple Leaf Food's president and CEO, Michael McCain, committed to never let such an event happen again on his watch; he changed the company's strategy to focus equally on people and systems along with a clearly communicated vision to "always produce safe, great tasting food manufactured in a safe environment" (*43*). Lone Jespersen, who is currently a principal at Cultivate LLC and is a former director of food safety and operations learning at Maple Leaf Foods, said, "People, and more specifically their behaviors, are the common denominator that defined success and failure in our journey to eradicate foodborne illness" (*43*).

4.3.2. Wales *E. coli* O157 Outbreak

In September 2005, an outbreak of *E. coli* O157 occurred in South Wales (England), affecting more than 150 people (mostly children) (*31*). It was the largest incidence of *E. coli* O157 in Wales and the second-largest one in the United Kingdom. The public inquiry, led by Professor Hugh Pennington, identified serious breaches of the food-safety regulations and practices at John Tudor & Sons (a business) that led to the outbreak (*60*). The key focus of this investigation was to conduct in-depth reviews of the food-safety management practices and the cross-contamination potential for the manufacturing systems. The root cause of the outbreak was identified as a cross-contamination occurrence at a packaging machine which was used for both raw and cooked meats. William Tudor, the owner of John Tudor & Sons, had a significant disregard for food safety and consumer health. William Tudor failed to follow critical procedures regarding cleaning and sanitation as well as cross-contamination prevention (*62*). Tudor also falsified food-safety records and lied to regulatory Environmental Health Officers (EHOs) (*62*). Some factors that lead to the outbreak included poorly trained staff, poor maintenance and damaged construction in the cooked-meat area, a very poor and inadequate HACCP plan, spoiled meat products comingled with spices to mask off-odors, and a lack of hand-washing facilities for employees (*32*, *60*).

In addition to these technical factors, Pennington and Griffith explained, "the food safety culture for a business serving high-risk food was completely inadequate and would not have controlled the risk of cross-contamination" (*60*). Even though Tudor had an advanced food-hygiene qualification, the company's culture was one with little regard for the importance of food safety but a high priority for saving money (*60*). The business failed to follow critical procedures, such as personal-hygiene practices, effective cleaning, and adequate separation of raw and cooked meats (*60*). The food-business operators were paid very low wages and were often understaffed for the increased production-output needs. Pennington report concluded, "The Outbreak need not have happened. The root cause of it, and thus the responsibility for it, falls squarely on the shoulders of William Tudor" (*60*).

4.3.3. XL Foods, Inc.'s *E. coli* Outbreak

XL Foods' recall was the largest meat recall in Canadian history; the recall occurred at XL Foods, Inc.'s beef-processing plant in Brooks, Alberta, between September and October 2012. This outbreak led to 18 confirmed cases of *E. coli* O157:H7, and the scope included a recall of about 1,800 products (4,000 metric tons) from Canadian, U.S., and other international markets (*49*). Fortunately, there were no fatalities during the recall, but from a business standpoint, there were financial losses between $16 million and $27 million, which eventually led to JBS Foods taking the ownership of XL Foods (*49*). At one point, XL Foods was the second-largest beef processor in Canada and was responsible for 40% of the Canadian slaughter (*49*). An independent review of this recall was conducted by a panel appointed by the governor in council; the panel submitted a report to the minister of agriculture and agri-food outlining the root causes and recommendations for this incident.

During the investigation, it appeared that plant personnel and the CFIA's on-site official did not always meet their responsibilities for food-safety programs (*49*). Some notable gaps included high-line speeds to maximize production and profits, leading to missed inspection and sanitation activities; labor shortages (30% turnover at the Brooks plant); no trend analysis of high-event periods (HEPs); *E. coli* exceeding a predetermined threshold; a lack of adequate sampling programs; a lack of periodic sanitation programs; and non-implementation of the bracketing policy (*49*). In their executive summary, the investigators summed up the relevance of FSC as a contributing factor: "In short, we found a weak food safety culture at the Brooks plant, shared by both plant management and CFIA staff." (*49*).

4.3.4. Blue Bell Creameries' Listeria Outbreak

On April 20, 2015, Blue Bell Creameries voluntarily recalled all of its products (ice cream, frozen yogurt, sherbet, and frozen snacks) made at all of its facilities (*14*). The recall was a result of a series of investigations led by South Carolina, Kansas, and Texas' state health departments. During the inquiry, the PulseNet system, based on Deoxyribonucleic Acid (DNA) fingerprinting techniques such as Pulse Field Gel Electrophoresis (PFGE) and Whole Genome Sequencing (WGS), was the tool to confirm the linkage between 10 infected people and the isolates collected from Blue Bell's ice-cream and manufacturing environment (*14*). All 10 people were hospitalized, resulting in 3 reported deaths in Kansas (*14*). According to the CDC, 5 cases (0 deaths) were linked to the Broken Arrow, Oklahoma, facility, and other 5 cases (3 deaths) were linked to the Brenham, Texas, facility (*14*). No cases were linked to the Sylacauga, Alabama, facility.

On May 7, 2015, the FDA released its findings from inspections conducted at Blue Bell's production facilities in Brenham, Texas; Broken Arrow, Oklahoma; and Sylacauga, Alabama (*14*). The FDA observations reported in these inspections highlights the lack of infrastructure and risk awareness by management of the company. These observations point towards a lack of commitment from the senior management to address a critical pathogen-contamination issues and GMP gaps at the plant. The summary of root-cause assessments provided by Blue Bell Creameries did not mention negligence to facility infrastructure needs by the leadership team i.e. lacking a good FSC culture. After the recall, outside experts were involved with the root-cause analysis and helped to enhance the company's microbiological monitoring programs. The firm should have reacted to the available non-conforming environmental data to understand the ineffectiveness of its pathogen-monitoring program and should have proactively utilized the appropriate resources to mitigate the risks.

4.3.5. Peanut Corporation of America's Salmonella Outbreak

The 2008-09 processed-peanut *Salmonella* outbreak was one of the largest ones in U.S. history with the recall scope being 3,900 products from over 200 companies (*16*, *88*). This *Salmonella* outbreak led to a total of 714 illnesses and 9 deaths across 46 U.S. states and Canada that were linked to *Salmonella Typhirium* (*88*). Following the recall, Stewart Parnell, the Peanut

Corporation of America's (PCA) president, filed for bankruptcy and was the target of a federal criminal investigation with accusations of intentionally sending *Salmonella*-contaminated peanut products into commerce (*88*).

On January 9, 2009, the Minnesota State Department of Agriculture isolated the outbreak strain from an unopened container of King Nut peanut butter (*16*, *62*). The King Nut peanut butter was manufactured at PCA's Blakely, Georgia, facility where some former workers and experts reported their observations and insights to *Chicago Tribune* after the recall.

The FDA report on the PCA outbreak outlines that the firm retested the product until negative results were achieved, and at times, the product was shipped despite being positive for *Salmonella* (*16*, *62*). The facilities had inadequate controls and resources to prevent contamination and to provide sufficient cleaning, sanitation, and pest-control activities. The manufacturing equipment was adjusted to maximize the production throughput by undermining the necessary quality and food-safety control, e.g., roasting temperatures and belt speeds (*62*). PCA's negligent leadership and mismanagement of serious foodborne hazards reflect the poor culture that prevailed at the organization. The auditing bodies' negligence also points towards the lack of standards and culture within the auditing bodies. In September 2015, Stewart Parnell was sentenced to 28 years in prison, and his brother, Michael Parnell, a PCA peanut broker, was sentenced to 20 years in a federal prison. The Quality Assurance (QA) manager, Mary Wilkerson, was also sentenced to a 5-year prison term (*19*).

4.3.6. Jensen Farms' Cantaloupe *Listeria* Outbreak

The 2011 multi-state outbreak of *Listeria monocytogenes* linked to cantaloupes distributed by Jensen Farms resulted in the hospitalization of 147 people and 33 deaths across 28 states. A collaborative investigation led by local, state, and federal public-health and regulatory agencies revealed the factors contributing to the contamination of cantaloupes manufactured at Jensen Farms' production field in Granada, Colorado: an unsanitary environment and product handling; a lack of appropriate facility and equipment design; and an inadequate cooling infrastructure (no pre-cooling) (*4*, *15*, *79*). Bob Whitaker, chief science and technology officer at the Produce Marketing Association, said, "The best science in the world won't stop consumers from being sickened and could result in our businesses being ruined until we create a culture within our operations that serves as a guidepost to everyday decisions" (*4*).

4.4. Food Safety Culture: Evolution and Definitions

The concept of food safety culture has evolved from the two related and previously known concepts of organizational and safety culture. In any major safety-related catastrophic accident, faulty design, operator error, and training gaps are often reported at the surface level, but the underlying causes for such incidents are organizational and safety culture (*31*, *39*). A popular example of such an incident is the 1986 Chernobyl accident which resulted in the death of 30 operators and firemen due to steam explosions, fires, and radioactive material releases into the atmosphere at a nuclear plant located in the Ukraine (*39*, *54*). The accident was the result of a flawed Soviet reactor design and serious errors made by the plant's operators (*39*, *54*).

The Chernobyl disaster highlighted human and organizational factors as the underlying cause(s) which was evident in statements made by academician and International Atomic Energy Agency's (IAEA) nuclear-safety reviews (*54*). Dr. Valeri A. Legasov, the head of former Soviet delegation to the post-accident IAEA review meeting said, "The Chernobyl accident illustrated the critical contribution of the human factor in nuclear safety" (*54*). The IAEA's safety reviews and summary reports concluded that the underlying root cause of the Chernobyl accident was 'so-called human factor' (*54*). This event led to major changes in the nuclear industry's safety culture to overcome deficiencies in nuclear-plant operations not only in the Ukraine, but also around the world (*39*).

The concept of organizational safety culture has evolved within occupational health and safety by, first, focusing on equipment, the workplace, and procedures, followed by a focus on the management and safety culture (*30*). In-depth research on safety culture and safety climate has been conducted within the field of health and safety (*31*, *94*). In 1993, the Health and Safety Commission stated, "The safety culture of an organization is the product of the individual and group values, attitudes, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety programs. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures" (*91*).

In the management literature, organizational culture has been defined in multiple ways by Schein (1997), Deal and Kennedy (1982), Cooper (1998), and Dodsworth et al. (2007). The organizational culture essentially entails shared philosophies, traditions, norms, communication, and control systems within an organization (*31*). In simple terms, organizational culture is "the way of doing things" in an organization (*31*, *94*). Schein's contribution to organizational-culture research is a significant one. He published a book titled *Organizational Culture and Leadership* which includes three major sections related to culture: the definition of organizational culture and leadership, the dimensions of culture, and leadership's role to build and evolve the culture (*70*, *71*).

Schein views culture and leadership as two sides of the same coin. On one hand, "cultural norms" define how a given organization will define leadership, and on the other hand, the only thing of real importance that leaders do is to create and manage culture (*71*). Schein's research provides a theoretical framework to characterize an organization's food-safety culture. He defines organizational culture as "a pattern of shared basic assumptions that was learned by a group as it solved its problems of external adaptation and internal integration, that has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems" (*71*). Schein shares the three levels of culture: the central level represents the core assumptions and beliefs (the way we do things around here); the intermediate level is based on values that involve strategies, goals, and philosophies; and the third level includes artifacts (visible organizational structures and processes) (*70*, *71*).

C.J. Griffith, K.M. Livesey, and D.A. Clayton have conducted extensive reviews of the literature available on organizational and safety culture to formulate the FSC concept. FSC is a component of organizational culture that focuses on developing food-safety practices and behaviors at food establishments (*31*). Following the organizational hierarchy, FSC can be developed at three distinct levels. The central level is comprised of upper management laying down the core values and mission statements to influence the work ethics and to sustain acceptable standards for food-safety performance (*31*, *70*). The middle-level management is entrusted with the task of measuring perceptions about the safety culture as well as the attitudes and beliefs that may characterize specific food-safety behaviors (*30*, *31*). The third level manifests the cultural values and beliefs in the physical and social environment through employee behaviors and actions (*30*, *31*).

FSC can be thought of as how and what an organization's employees think about food safety on day-to-day basis (*30*, *31*, *94*). In 2001, Gilling et al. identified the importance of behavioral science to improve food-safety management systems (*26*, *75*). However, Griffith et al. and Yiannas were the first people to propose definitions for food-safety culture (*31*, *94*). According to Griffith et al., food-safety culture is “the aggregation of the prevailing, relatively constant, learned, shared attitudes, values and beliefs contributing to the hygiene behaviors used within a particular food handling environment” (*31*). Instead of visualizing food-safety risk factors with a non-technical or epidemiological classification, Yiannas suggests to imagine them as the behavior associated with the food handlers (*94*). His visualization of these risk factors led him to believe that “food safety equals behavior” (*94*).

The two primary methods, regulatory inspections and training, certainly improve food-safety systems, but they are not enough to achieve the needed food-safety success and performance (*94*). Yiannas emphasizes the importance of understanding organizational culture and the human dimensions of food safety (*93, 94*). In order to change the way people do things, it is important to change their behavior (*93*, *94*). This change could be achieved through a better integration of behavioral sciences and food sciences to develop a behavior-based food-safety management system or food-safety culture instead of only having food-safety program (*94*). Yiannas analyzed several definitions for safety culture and adapted them for the food-safety context. He liked simple definitions by the McKinsey Company, ‘‘Culture is the way we do things around here” and proposed food-safety culture as “how an organization or group does food safety” (*9, 94*). Yiannas also relates food-safety culture in an organization with the employee’s integrity: “In organizations with enlightened food safety cultures, employees do the right thing not because the manager or customer is watching, but because they know it’s right and they care” (*91, 94*).

Ball et al. define food-safety culture as “the patterns of beliefs, values and learned behavior that have developed during an organization's history which are manifested in daily activities that impact food safety” (*5, 87*). Taylor et al. propose an FSC definition: “assumptions, attitudes and values towards food safety that prevail within an organization and are taught to new employees, directly and indirectly, as the correct way to think and behave in relation to food safety" (*10*, *75*). According to Powell et al., "a culture of food safety is built on a set of shared values that the operators and their staff follow to produce and provide food in the safest manner" (*62*). It is important to identify the risks associated with business practices that affect food safety and to effectively manage them in order to maintain FSC within an organization (*62*, *91*). Baur et al. said, "Food safety culture means that controlling foodborne pathogens should permeate every aspect of an operator's mission and be at the forefront of every employee's mind" (*8*).

De Boeck et al. reviewed the available literature to distinguish food-safety culture from food-safety climate because the terms are often used interchangeably in the literature (*24*). De Boeck et al. define food-safety culture as "the interplay of the food safety climate as perceived by the employees and the managers of a company (so called human route) and the context in which company is operating, the current implemented FSMS, consisting of control and assurance activities (so called techno-managerial route) resulting in a certain (microbiological) output" (*23*, *24*). Food-safety climate is defined as "the relative priority in an organization or work unit as perceived by the employees" (*24*). The food-safety climate is an individual's or the collective perception of a situation by employees within an organization and a "snap shot" of the prevailing food-safety culture (*24*). Overall, food-safety culture can be considered a bigger framework where food-safety climate is a sub-component that works in conjunction with FSMSs. Food-safety culture and climate are multidimensional, i.e., not measured by one attribute (*31*).

In the regulatory world for food, several countries have identified food-safety culture as a key driver for the needed success of food-safety initiatives and improvements. In the United Kingdom, the Food Safety Authority (FSA) developed a diagnostic toolkit to measure the food-safety culture. The FSA toolkit was a result of extensive research conducted after a major *E. coli*

O157 outbreak that occurred due to inferior cultures and behaviors at businesses and by enforcement bodies (*91*). Another major outbreak in Canada due to *E. coli* contamination at XL Foods led the Canadian Food Inspection Agency (CFIA) to develop an action plan, requiring "a strong food safety culture to be developed within the processing plant and adopted by both plant and CFIA staff- at all levels" (*11*).

Food Standards Australia New Zealand (FSANZ) states, "Food safety culture in a business is how everyone (owners, managers, employees) thinks and acts in their daily job to make sure that the food they make or serve is safe. It's about having pride in producing safe food every time, recognizing that a good quality product must be safe to eat. Food safety is your top priority" (*25*). In the United States, the Food and Drug Administration (FDA) recognizes the need for culture changes within the U.S. food industry and its regulatory network. The Food Safety Modernization Act (FSMA) should influence the food-safety culture in coming years, but no specific initiatives or tools are being developed for measurements and guidance.

4.5. Factors and Dimensions that Influence the Food Safety Culture

The success of food safety at a food-manufacturing or service organization depends on clear identification and understanding about the factors that influence a food-safety culture. The FSC factors are derived from research and reviews of organizational and safety culture concepts in order to apply the ideas in food-manufacturing and service settings. Researchers, including Griffith et al., Yiannas, Taylor et al., Hinsz et al., Ball et al., Jespersen et al., and Wright et al., have identified culture factors and dimensions which became the basis of their FSC measurement tools and research. This section includes the factors and dimensions identified by their research and publications. Some common factors and dimensions include the commitment of leadership, management, and employees; knowledge; management systems; communication; accountability;

employees' confidence; training; environmental factors (infrastructure and tools); work habits; values and behaviors; and risk perception and awareness (*6*, *30*, *36*, *41*, *59*, *75*, *91*, *94*).

4.5.1. Food Safety Behavior Elements by Hinsz and Nickell

In 2007, two North Dakota State University professors, Verlin B. Hinsz and Ernest S. Park , collaborated with Gary S. Nickell, a professor at Minnesota State University, Moorhead, to investigate the role of work habits in the motivation for food-safety behavior and performance in a food-manufacturing environment (*36*). An integrated framework was developed based on the theory of reasoned action (Attitudes and subjective norms predict people's intentions to engage in specific behaviors.), the theory of planned behaviors (Perceived behavior control adds to the prediction of behavior.), and Triandi's model of intentional behavior (Habits play an important role in predicting behaviors.) (*36*). Four predictive elements of food-safety behavior emerged: attitude towards the behavior, subjective norms, perceived behavioral control, and work routines (*36*).

A subjective norm signifies "the social forces people perceive that might affect their intentions i.e. it indicates 'how individuals think people important to them think they should behave'"(*36*). Senior leaders, supervisors, and coworkers' expectations to engage in positive food-safety behaviors in order to prevent product contamination can be considered a subjective norm. A positive attitude and subjective norms about food safety predict an employee's intention to display positive food-safety behavior (*36*). Another key result of this study is the importance of work routines to predict a worker's food-safety behaviors (*36*).

4.5.2. FSC Core Elements by Frank Yiannas

Yiannas adopted five core elements from the corporate safety-culture research published by Whiting and Bennett that could influence the food-safety culture at food-manufacturing organizations (*86*, *94*).

1. Leadership at the top: Food-safety culture is a leadership function to create a vision, to set expectations, and to inspire employees to follow safe food practices (*94*). FSC starts at top and flows downward. In the food industry, food-safety management is often mentioned, but there is not enough attention on food-safety leadership (*94*). An organization with a strong food-safety culture not only has strong food-safety management systems, but also has strong leaders who are committed to influencing the workforce to adopt the correct food-safety behaviors (*94*). The leadership's role is to create a food-safety vision, to set expectations, and to inspire others to follow those ideals (*94*).
2. Confidence in the part of all employees: It is important for leaders to earn their employees' trust by food-safety-oriented actions, not words (*94*). The leaders need to visibly and routinely demonstrate ("walk the walk") that food safety is a key organizational value for the company (*94*).
3. Clearly illustrate the management's visibility and leadership: Strong leadership and vision at the top needs to be complemented with buy-in and support from the mid-level management in order to achieve a successful food-safety culture (*94*). Front-line employees closely observe the management, and managers who deviate from the prescribed food-safety standards which are as simple as hand washing will not demonstrate a "lead by example" mentality (*94*).
4. Accountability at all levels: Accountability means that there are checks and balances being measured to ensure that all employees understand and comply with the food-safety expectations as part of their job (*94*). In enlightened food-safety cultures, employees go beyond accountability for the food-safety expectations to a

high sense of ownership commitment where they tend to do the right things when no one is watching (*94*). An example would be an employee immediately reporting a roof leak that is in a food-processing environment to the supervisors.

5. Sharing knowledge and information: The regular sharing of knowledge and information holds the work units together and keeps them aligned on the food-safety objectives (*94*). This information sharing goes beyond simple food-safety training and should include regular communication using a variety of message tools and mediums (*94*). Yiannas mentions, "You can tell a lot about the food safety culture within an organization by their communication or lack of it" (*94*).

4.5.3. Food-Safety Performance Factors by Griffith et al.

Griffith et al. identified six culture factors that contribute to food-safety performance (Figure 4.3): a food-safety management system, style, and processes; leadership; communication; risk awareness, perception, and risk-taking behavior; management's commitment; and a food-safety oriented environment (*30*).

1. Food-safety management style and systems: Food-safety management is defined as "coordinated activities to direct or control food safety goals in an effective and efficient way through planning, staffing, organizing, directing and controlling organizational resources" (*30*). An example could be a routine sanitation-and-cleaning event that may occur prior to the start of a food-production run. The food-safety management systems are defined as "all the documented procedures, practices and operating procedures which influence food safety" (*30*). Within food-safety management systems, documentation includes three levels: food-safety policy and objectives; standard operating methods, instructions, and procedures;

and report forms and records. In the case of sanitation, these may include sanitation policy, sanitation standard operating procedures (SSOPs), pre-operation checklists, chemical concentration check records, etc. (*30*). Griffith et al. also emphasizes the management's involvement which is "the extent to which managers/supervisors get involved in the daily operations which can affect food safety and how much food handlers perceive them to be concerned about food safety" (*30*). This approach can be positively influenced by the manager's presence on the production floor during critical food-safety events to monitor and to audit compliance for food-handling practices with the required standards.

2. Food-safety leadership: According to Griffith et al., "food safety leadership can be defined as a measure of the extent the business's leader(s) are able to engage staff in hygiene/safety performance and compliance to meet the business's goals/vision/standards" (*30*). Griffith et al. also share some common leadership styles, such as transactional (motivate organizational goals over personal goals with a vision, values, and collective goods), transformational (motivate by clarifying roles, meeting needs, and having rewards),and laissez-faire (no vision assistance or guidance: likely to lead to a weak FSC) (*30*). An emphasis on the middle-management and senior-management role exists.

3. Food-safety communication: "Food safety communication is a measure of the quality of the transfer of food safety message and knowledge between management, supervisory staff and food handlers" (*30*). The communication can be done with regular meetings by sharing critical food-safety data with the employees in terms of sanitation success, environmental monitoring, and out-of-spec products along

with food-safety education about best practices. Other forms of communication may include letters, emails, and notices/posters. A positive culture needs to be cultivated, encouraging employees to discuss food-safety issues with their supervisors (*30*).

4. Food-safety commitment: "Food safety commitment is a measure of the extent to which food handlers and supervisors consider their own values and beliefs about food safety are aligned with those of the organization" (*30*). Leaders are encouraged to set food-safety goals and to provide regular feedback to the employees. Griffith et al. highlights three categories that influence an individual's organizational commitment: financial drive, pressure from others, and agreement with organizational practices (*30*, *91*).
5. Food-safety environment: "Environment describes the visible or discernable organizational structures and processes that characterize the internal dimension of business" (*30*). To enhance the food-safety culture, high perceived organizational support is needed; this support (financial, practical, psychological, and emotional) is measured by how employees believe that the organization is committed to food safety (*30*).
6. Risk perception, awareness, and risk-taking behavior: Risk perception is closely linked to the risk communication which is defined as an interactive process among an organization's employees to identify a risk and its potential effect, and to enact practices in order to eliminate or to minimize the identified risk (*30*). Perceived risks are evaluated for their effect on employee judgment, and decision making

related to food safety (*30*). "Risk awareness and risk taking behavior are highly relevant for food safety culture" (*30*).

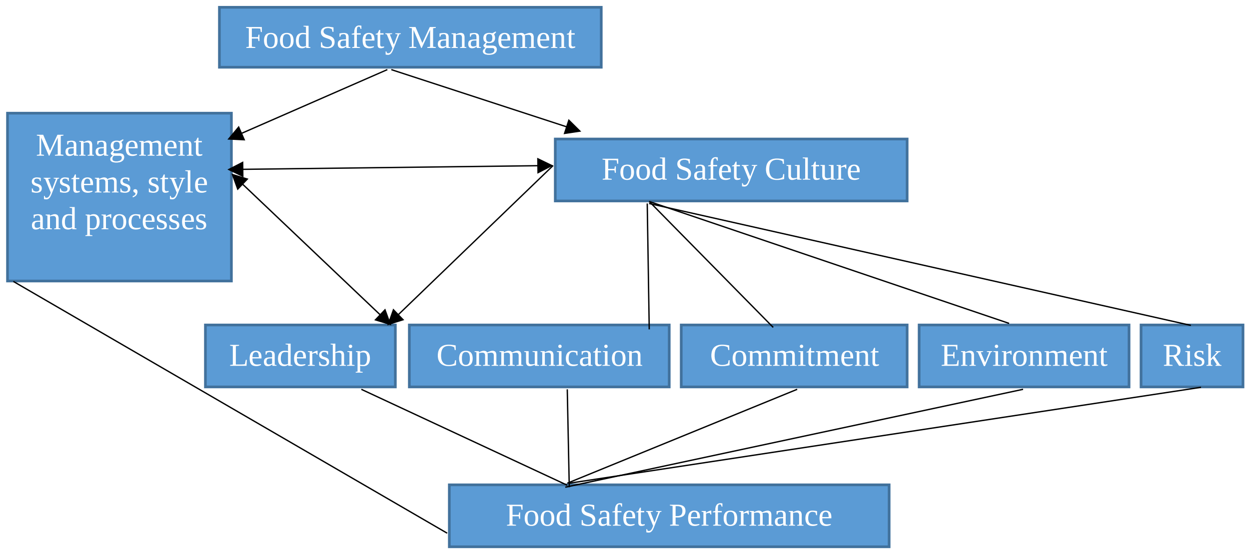

Figure 4.3. The relationship between FSC factors and food-safety performance (*62*).

4.5.4. FSC Themes and Factors by Ball et al.

Ball et al. use a qualitative approach to identify the factors that affect FSMS implementation by conducting 13 in-depth interviews at 5 meat plants as well as focus-group interviews with government and industry representatives (*5*, *6*). There are 219 pages of verbatim transcripts from these interviews that were analyzed using NVivo 7 software (*5*, *6*). The data reveal three main themes relating to FSMS implementation: production systems, operational characteristics, and employee characteristics. The production-system aspect focuses on the condition and/or appropriateness of the production facilities and equipment (*5*, *6*). This is done with process reviews and risk assessments for FSMSs, HACCPs, product characteristics, facilities, and equipment. The organizational- and/or operational-characteristics theme includes training (individualized, on-the-job, and formal), supervision of/feedback to employees (positive and verbal feedback, and financial incentives), management's commitment to FSMSs (walk the walk), and the approach to HACCP and FSMSs integration at the workplace (*6*). Last, employee characteristics include skills and knowledge related to food-safety and work tasks, attitude and outlook towards food safety, and the influence of others within (co-workers) and outside the workplace regarding food safety practices (*6*). Ball et al. further categorize these characteristics into 10 specific themes which are outlined in Table 4.1 (*5*).

At the 2016 International Association for Food Protection conference, Ball et al. presented a paper about a tool for measuring the food-safety climate (*7*). The questions in the climate tool focused on five areas: management's commitment to food safety (actions, leadership, and resource allocation), the work unit's commitment to food safety (supervisor, co-worker, and personal commitment), food-safety training, infrastructure for food safety (FSMS, food safety personnel, and production practices), and the workers' food-safety behavior (*7*).

Table 4.1. Themes and factors that facilitate or inhibit the successful implementation of FSMSs (*5*).

Conscientiousness	*Work ethic*, willingness to work; *company/customer focus*, employees showing positive attitudes towards FSMS compliance and looking beyond their job tasks.
Adaptability/willingness to change	Newer employees are more willing to adapt to the FSMSs as compared to people who have been in the industry for some time.
Work-unit factors	The *influence of peers* may affect an individual's attitude; *monitoring by food-safety personnel* will remind the production workers to complete records and to address day-to-day issues; *influence of supervisory personnel* to enforce/reinforce best practices; *personal support* through on-the-job feedback; and *financial incentives* to motivate FSMS compliance.
Senior manager's commitment to food safety	The *commitment* should be reflected in financial support and actions. The leadership and management teams should lead by example.
Workplace atmosphere	*Open, two-way communication* encourages people to share information and to contribute ideas for continuous FSMS improvement. Teamwork enhances the food-safety initiatives.
Training	In-house and hands-on training to strengthen the skills and knowledge needed for FSMS compliance.
Firm's production-system factors	*Product-characteristic* measurements and *production characteristics* (automation, productivity, functional equipment, and suitable facilities).
Firm's production priorities	Perceived or real-time constraints which create a sense of urgency may reduce the likelihood of FSMS compliance.
Firm's approach to FSMS implementation	*Gradual introduction* to minimize employees' resistance; *coordination of records* with streamlined tasks; and encourage *employee input* for FSMS changes.
Firm's food-safety program requirements	Reduced error rate due to *good manufacturing practices (GMPs), standard operating procedures (SOPs),* and *record keeping.*

4.5.5. FSC Excellence Model by Taylor et al.

In 2011, Taylor et al. showed that the concept of a food-safety culture is broad and multifaceted because there are many interlinking factors at play; these factors are more complex in a multi-cultural environment (*75*). The four major interlinked factors that Taylor et al. identified are mentioned in Table 4.2. These factors can be viewed as barriers to develop FSC when an organization is deprived of their continued presence in its work environment. In 2015, Taylor et al. partnered with Campden BRI to propose a Food Safety Culture Excellence model; this online measurement tool evaluates four pillars (people, process, purpose, and proactivity) of the organizational food-safety culture (*76*). These 4 categories include 20 dimensions (Table 4.3); 60 elements; and 1,000 data points to measure cultural excellence in organizations.

Table 4.2. Barriers and factors that influence the food-safety culture (*75*, *76*).

Level	**Barriers/Factors**
Knowledge level	Lack of awareness, food-safety knowledge, technical expertise, and training
Attitude/Psychological level	Lack of agreement, risk awareness, self-efficacy, outcome expectancy, reinforcement, motivation, perceived superiority, and national culture values
External level	Negative guideline factors, enforcement factors, and external factors (government/industry guidelines, inspection/audit, and customers/suppliers)
Internal behavioral level	Operation complexity and variability, a lack of resources, language skills, competence, management control and cueing mechanisms, and organizational culture (control, involvement, communication, etc.)

Table 4.3. Four pillars and dimensions for a successful food-safety culture (*10*, *76*).

	Dimension	**Explanation**
People	Empowerment	Empowering people to take appropriate food-safety actions
	Reinforcement	The reinforcement of food safety practices
	Teamwork	The effectiveness of food safety and HACCP teams
	Training	The effectiveness of food safety training and communication
	Communication	The effectiveness of communication related to food safety/quality
Process	Control	The effectiveness of food safety management control
	Coordination	The coordination of food safety across the company
	Consistency	The level of consistency and agreement in food safety practices
	Infrastructure	The level of fitness of premises, equipment, buildings, etc.
	Systems	The effectiveness of food safety management systems
Purpose	Vision	The role of food safety in the company's long-term vision
	Values	The inclusion of food safety in the company's core values
	Strategy	The strategic direction and plans for food safety
	Objectives	Setting and managing food safety objectives
	Metrics	The effectiveness of food-safety-related key performance indicators and metrics (new)
Proactivity	Awareness	An awareness of the external food-safety influences and issues
	Foresight	Having foresight regarding food-safety risks
	Change	The level of change, innovation, and investment in food safety
	Investment	Decision-making process related to capital expenditures and investments related to food safety/quality (new)
	Learning	Enabling organizational food-safety learning

Taylor et al. also reviewed Hofstede's six cultural dimensions that focus on national culture to consider the multi-cultural environment's influence on workers' food-safety behaviors. Taylor says, "National cultural values are considered harder to learn and unlearn than organizational culture values" (*75*). One dimension discussed is power distance. A belief about an unequal power distribution can exist within an organization. A high-power culture displays respect and acceptance for displays of authority as well as limited interaction and negotiation between the power levels (*38*, *75*). Hofstede explains that India and China are high power-distance cultures, whereas Canada and Australia have a low-power distance (*38*, *75*). It is assumed that high power-distance cultures may have more acceptance of food-safety rules and requirements, once directed, but there is also a smaller likelihood of questioning and challenging the authorities, especially when gaps are being identified within the food-safety management systems' performance and resources (*38*, *75*). This power-distance culture may explain the food-safety challenges being experienced in developing countries such as India and China.

Another dimension is individualism vs. collectivism, which is "the degree to which individuals are integrated into groups" (*38*, *75*). In an individualistic culture (the United States and western Europe), people are integrated through loose ties with the individual only looking after his/her immediate family as compared to collectivist cultures (China and Japan) where there is (a) strong, cohesive group(s), including extended families (*38*, *75*). Some of Hofstede's other cultural dimensions include masculinity vs. femininity (contrasting assertiveness and competitiveness with modesty and caring), uncertainty avoidance (the degree of intolerance for uncertainty and ambiguity), long-term vs. short-term orientation, and indulgence vs restraint (*38*, *75*).

4.5.6. FSC factors by Neal et al.

Neal et al.'s research uses a questionnaire based on five key areas: management's commitment to food safety (leadership and resource allocation), the work unit's commitment to food safety (supervisor, co-worker, and personal commitment), food-safety training, infrastructure for food safety (food-safety management system, food-safety personnel, and production practices), and workers' food-safety behavior (*56*). There were other demographic-factor-based questions that included years of working in the industry, food-safety training, food-safety certification, and personal demographics (age, gender, and ethnicity) (*56*).

4.5.7. The Food Standards Agency's (FSA) Toolkit

The 2005 publication of the public inquiry report about the *E. coli* O157 outbreak in South Wales highlighted the issues of culture and behaviors for businesses and enforcement bodies as well as industry's role to influence compliance with food-hygiene legislation (*91*). In January 2012, the Food Standards Agency (FSA) commissioned a diagnostic toolkit to assist local food-hygiene inspectors with identifying aspects of food-safety culture and management attitudes at food-manufacturing and service organizations in the United Kingdom (*91*). This toolkit was developed by Greenstreet Berman Ltd., through an extensive review of the existing food-safety-culture research and tools. The FSA toolkit has eight elements and five typologies for a food-safety culture. The elements are as follows:

1. Priorities and attitudes: "Food business's attitudes towards food safety and the degree to which food safety is prioritized within the organization" (*91*).
2. Risk perceptions and knowledge: "Food business's (management and staff) perceptions and knowledge of the risk associated with food hygiene (and whether they are significant enough to justify the requirements)" (*91*).

3. Confidence in food-safety systems: “The extent to which the business perceives the food hygiene regulations to be valid and effective” (*91*).
4. Ownership: “The extent to which they see food hygiene to be the responsibility of the regulator and adopt a reactive approach, as opposed to accepting that the business is responsible for taking a lead in food safety” (*91*).
5. Competence: “Knowledge and understanding of the risks and subsequent risk management throughout the organization” (*91*).
6. Leadership: “The extent to which there is clear and visible commitment and leadership of food safety from management” (*91*).
7. Employee involvement: “The extent to which there is involvement, ownership and accountability for food safety across staff at all levels of the business” (*91*).
8. Communication: “The extent to which there is open communication and freedom to challenge and discuss practices” (*91*).

4.5.8. FSC Factors and Themes in a Food-Service Setting

Fatimah et al. conducted focus-group studies with 31 food-service employees. The focus-group sessions’ recorded audio was transcribed by experienced transcriptionists. The transcribed data were further analyzed by experienced researchers to identify nine themes/factors that influence FSC: leadership (the extent to which leaders visibly demonstrate their food-safety commitment), communication (food-safety messages and knowledge-transfer quality among mangers, supervisors, and coworkers), self-commitment (each employee’s food-safety values and beliefs), management system and style (policies, procedures, and processes to control food safety), environmental support (adequate infrastructure support for a food-safety culture), teamwork, accountability (checks and balances in place to achieve the desired food-safety outcomes), work pressure (time constraints and workload constraints that affect food safety), and risk perception (risk awareness and judgement for food-safety decision making) (*83*).

4.5.9. Determinants of FSC Research

Nyarugwe et al. conducted a study to identify the determinants for conducting food-safety-culture (FSC) research using a structured-system approach to review the available literature on national and organizational safety cultures in the context of food safety as well as the interdependence and relationships between the identified system components (*58*, *59*). The study proposed determinants for FSC research which can also be factors and dimensions that influence the FSC. For a food-manufacturing organization, there is a need to acknowledge the national culture where the company operates as well as the national culture of the employees who work for the organization. An organization's ability to recognize the mechanisms of the FSC's influence on food-handling behavior and food-safety performance can develop a strong FSC (*59*).

The crucial elements for an FSC assessment are as follows: employee characteristics (attitudes, perceptions, knowledge, and risk awareness), group characteristics (analysis of shared perceptions), organizational and administrative characteristics (food-safety vision, leadership, and commitment; communication style; food-safety/hygiene procedures; training; and work pressure), technical/technological facilities/resources (personal-hygiene facilities, zoning, food-safety and hygiene tools, equipment and facilities, sanitation, and maintenance), and food-safety management-system characteristics (design and assurance of crucial controls) (*59*). A methodological technique for FSC assessments that utilize a systems approach and multiple methods may enhance an assessment's validity (*59*). Nyarugwe et al. suggest the measurement of prevailing FSC as continuously evolves within an organization. Demographic variables should also be considered as a factor in the FSC evaluations.

4.5.10. FSC Dimensions by Zabukosek et al.

Zabukosek et al. (2016) used seven dimensions in their research to evaluate the FSC at Slovenian food-manufacturing plants (*95*). Each dimension included questions/items that covered nine factors: leadership and employee support (management commitment, employee collaboration, and management control), communication, employee engagement and self-commitment, support, work pressure, risk judgement, and training efficiency (*95*). The measurement scales used in the research were subjected to validity and reliability tests (*95*).

4.5.11. Maturity Model and Dimensions by Jespersen et al.

Jespersen et al. proposed a maturity model to assess the FSC at food-manufacturing plants (*41*). Maturity models are tools that could evaluate the current state of an organization's culture, systems, and business practices and could provide an improvement plan on the scale of maturity (*41*). These models have been used in other industries, such as information technology, healthcare, and occupational health and safety (*41*). The maturity models allow an organization to understand where it stands compared to the industry standards for a given subject matter (*41*). Five capability areas (perceived value, people system, process thinking, technology enabled, and tools and infrastructure) and five stages (1 through 5: doubt, react to, know of, predict, and internalize) form the basis of the maturity model (*41*).

Perceived value is the extent to which food safety is viewed as a regulatory requirement vs. business performance and sustainability (*41*). The people system describes organizations which lack clearly defined accountabilities, i.e., task-based vs. clearly defined accountabilities and behavior-based working groups (*41*). Process thinking describes the problem-solving approaches (*41*). Technology-enabled capability area describes the extent to which a business uses data and information throughout the organization (*41*). The tools and infrastructure describe the resources which are available for employees (*41*). Later in 2017, Jespersen et al. also reviewed eight FSC evaluation systems for validity and reliability, proposing five FSC dimensions (*42*).

Table 4.4. The food-safety maturity model's capability areas and stages (*41*).

Capability area(s)	***Stages***				
	Stage 1 Doubt	Stage 2 React to	Stage 3 Know of	Stage 4 Predict	Stage 5 Internalize
Perceived value	Complete tasks due to regulators; no food-safety performance data reporting.	Little-to-no investment to prevent fire-fighting mode.	Food-safety issues solved one at a time to protect the business.	Prevent the recurrence of food-safety issues.	Continuous improvement and business growth that is enabled by food safety.
People system	Task completion due to fear and when senior leader demands.	Problems solved by using negative consequences	Positive and negative consequences used to manage problems.	Processes developed include consequences.	Defined strategic direction, accountabilities, and responsibilities.
Process thinking	Unstructured problem solving.	Plan, do, check, an act with an emphasis on the check phase; expect a 100% perfect solution.	Structured problem solving; risk of over analyzing.	Plan, do, check, and act with an emphasis on the study's phase.	Proactive risk identification and mitigation plans.
Technology enabled	Little tech adoption.	High reliance on individuals to utilize data.	Standard technology and training; no incident prevention with data.	Data collected for process improvement; limited use of automation.	Integrated global information systems with automated workflows.
Tools and infrastructure	Minimal tools.	Finding tools in a hurry results in rework.	Investment when needs arise during problem solving.	Continuous improvement for ease of use and cost.	Long-term investments and priorities for food safety.

Table 4.5. Dimensions and factors based on a comparative analysis of FSC evaluation systems (*42*).

Dimension(s)	**Factors**	**Evaluation systems**
Values and mission	Management and employee commitment to food safety	Ball et al., De Boeck et al., and Taylor et al.
	How leadership sets objectives, motivates employees, and addresses food safety	De Boeck et al.
	Direction for the organization	Denison et al.
	The organization's perceived value and priorities related to food safety	Jespersen et al. and Wright et al.
	Food-safety ownership	Wright et al.
People system	Knowledge, qualifications, and team effectiveness	Ball et al.
	Training, integration of new employees, and expectations of competency level	Ball et al., De Boeck et al., Jespersen et al., and Taylor et al.
	Leaders and employees' communication about food safety	De Boeck et al. and Wright et al.
	Actual and expected involvement, autonomy, and degree of membership input	Denison et al., Taylor et al., and Wright et al.
	Expectations for tasks or behaviors	Jespersen et al.
	Knowledge of risk	Wright et al.
Consistency	Degree of following rules	Ball et al. and Taylor et al.
	Good procedures and instructions are in place.	De Boeck et al.
	Systems are enforced vs. allowance for by-passing.	Denison
	Technology-enabled behaviors	Jespersen
	Access to the right tools and an investment in infrastructure	Jespersen
Adaptability	How the organization embraces, or resists change	Denison and Taylor
	How problem solving is approached	Jespersen
Risk awareness	Risks are known and under control, and employees are alert to the actual and potential food-safety risks.	De Boeck and Wright

4.6. FSC Assessment Methods and Studies

Risk-assessment and measurement approaches, such as HACCP, have been instrumental in quantifying and managing the foodborne hazards within manufacturing systems. Assessment techniques, such as inspections and audits (internal and external), have been widely used to assess the FSMS performance in the food-safety industry. However, these technical, scientific, and managerial approaches are not enough to combat the global burden of foodborne illness (*61*, *94*). Measuring the psychological and behavioral aspects of FSMSs is equally important for much-needed FSC change and awareness (*75*).

Evaluating a food-safety culture is a transparent approach to highlight an organization's strengths and weaknesses for having a sound food-safety-oriented decision-making ability (*42*, *43*). The FSC measurement allows senior business leaders to invest the appropriate resources in enhancing the FSC and achieving the ultimate food-safety goal of reducing foodborne illnesses and mortalities (*42*). Griffith et al. highlight the reasons to measure FSC, including assessing potential compliance with FSMS to prevent food-safety errors and their economic impact, raising food-safety awareness, best-practices benchmarking within an organization's sites/units, data-driven decisions about training/remedial action and resource prioritization, promoting a food-safety commitment, identifying weakness and evaluating the involved risks, and evaluating the results of food-safety initiatives (*30*). For regulators and inspectors, FSC measurement can assess the likelihood of an outbreak and a food-recall occurrence (*30*).

Griffith et al. describe the four stages that an organization takes to measure the FSC. The first stage is to decide which components of the FSC will be assessed, followed by the methodology to utilize. The methods can be categorized as qualitative (focus groups, interviews, discussion groups, and narrative interviews) and quantitative (questionnaires and surveys) approaches. The quantitative methods are preferred over qualitative techniques due to the ease of use, time constraints, and resource constraints. The third stage involves identifying the levels for the study because the FSC may vary at an organization's different levels, units, and sites. Finally, it is important to consider the time for the study's design, the data analysis, and the communication aspects for the study's results (*30*).

The food-safety culture within an organization has been viewed from the organizational-leadership and food-safety-behavior perspectives. Hence, the organizational-culture research methodology and tools can be applied to fulfill the FSC's measurement needs. Measurement systems have emerged from regulatory and industry perspectives. Measurements for an organization can be done using quantitative, qualitative, and mixed-methods (*21*, *92*). This section reviews some research methodologies and outcomes for FSC measurement.

4.6.1. Quantitative-Measurement Approach

The quantitative-measurement approach is important to achieve food-safety goals and to improve the food-safety-culture performance (*94*). "Without measurements, the interpretation on whether or not a goal is being achieved is subject to bias. When establishing a food safety goal related to a specific behavior or condition, if you don't have a measurement system already in place to track progress, create one" (*94*). The quantitative approach gathers and analyzes data using computational methods (*40*). Questionnaires and surveys are the most often-used technique for data gathering, and statistical methods are used to process the data (*40*, *92*). For this type of research, the output quality is influenced by the researcher's statistical knowledge (*40*). Quantitative research methods offer a significant advantage because they can be administered and evaluated quickly (*92*). They also generates data that allow a comparison between organizations (*92*). As a limitation, the quantitative approach may create issues related to the participants' interpretation of questions (*92*). In FSC research, the most common quantitative methods are questionnaires and surveys which use Likert scales and maturity models to measure the FSC performance.

4.6.2. Qualitative-Measurement Approach

Qualitative research is subjective in nature and is used to explore several areas, including human behavior (*21*, *64*). Qualitative research's exploratory nature involves the collection, analysis, and interpretation of data by observing human behavior (*21*, *64*). The qualitative research methodology is a "soft science" because it is not directly quantifiable as compared to quantitative research which is a "hard science" (*64*). Qualitative research provides a more real-world feel for the researchers because it can probe for underlying values, beliefs, and assumptions (*64*, *92*). Qualitative research uses broad, open-minded inquiries where participants can raise issues that matter to them (*92*).

The advantages of qualitative methods include a high degree of flexibility, extensiveness and diversity within the gathered data, the scope and depth of exploration, and the possibility of performing a historical analysis (*40*). Qualitative data are a collection of words extracted through document reviews, interviews, participant observations, focus groups, or related methods (*21*, *92*). The primary purpose of interviews and focus groups is to obtain input from employees and managers about the organization's unique aspects (e.g., culture) by asking people to explain the meaning of various cultural artifacts (*92*).

Table 4.6. The health-check questionnaire for food-safety culture in FSA toolkit (*91*).

Food-Safety Area(s)	**Questions**	**Scale**
Leadership/Vision	How important do you think food safety is in the business?	It's not thought about much; it becomes important when something goes wrong; ensuring food is safe is always a top priority
	Who is responsible for making sure the food is safe?	The owner; specific people (e.g., quality-assurance officer, managers, and the owner); everyone at all levels
	How committed are managers (including the owner or other senior staff) to food safety?	Not committed; somewhat committed; very committed
	What's the general situation like in the workplace, especially in terms of staff reporting problems, questioning procedures, or suggesting improvements?	Minimal engagement; fair but formal; strong and flexible; very strong and supportive
	How are food-safety problems or complaints addressed?	Negative response; minimal response; strong response; strategic and proactive
Staff knowledge and actions	How much training about food safety is available for the staff? Scale: No food-safety training offered	No food-safety training offered; induction training for new staff; induction training and refresher training.
	Do the staff members show an awareness of food safety in their daily jobs, every time? That is, do they always put their knowledge and training into practice?	Probably not; I assume they do; their supervisor or peers make sure they do; everyone has food safety as their top priority and does things properly every time.
Date collection and assessment	Is food-safety information checked and used to make improvements?	No/not really; yes, sometimes; yes, quite a lot; yes, all the time
Relationships with regulators	What's the business' relationship with food regulators like?	Minimal; fair; close collaboration.

4.6.3. Mixed-Method Approach

The mixed-method approach involves analyzing the same phenomenon from multiple perspectives, allowing an increased understanding of the subject. Such methods were developed as researchers realized that all methods have limitations and that the biases in a single method could neutralize or cancel the biases of other methods (*21*). A researcher may begin with a qualitative view for exploratory purposes and follow up with quantitative, survey methods that utilize a large sample to generalize the results to a population (*21*). The researchers may concurrently converge or merge quantitative and qualitative data in order to provide a comprehensive analysis of the research problem (*21*). The use of mixed methods led to the development of "triangulation," a means for seeking convergence across qualitative and quantitative methods (*21*). The ability of triangulation to determine if there is a convergence increases the findings' validity (*21*, *45*).

Triangulating methods is a vehicle for cross-validation when multiple methods produce comparable data (*92*). Triangulation also allows a better assessment of socially desirable responses for sensitive and complex topics, such as culture studies and evaluation (*45*). Jespersen et al. conducted a triangulation study with five multi-national North-American-based food-manufacturing companies (*45*). As part of this study, three data sets were used: FSC maturity self-assessment responses, food-safety documents, and semi-structured interviews with plant leaders (*45*). The results from the data analysis of these three methods were aggregated and plotted on a food-safety maturity scale (*45*). The plotted data show that reliance on a single evaluation method to evaluate the food-safety culture can give inaccurate results and should be treated with caution (*45*).

Nyarugwe et al. conducted a mixed-methods study using a techno-managerial approach with a concurrent analysis of technological and managerial factors (*58*). Four key elements (microbiological safety performance, actual behavior, technological- and organizational-enabling conditions, and employee characteristics) were studied to systematically analyze the prevailing FSC at three Zimbabwean dairy companies (*58*). The study utilized six methods to measure the FSC in order to gather information about the four key elements: microbial analysis, observations, card-aided interviews, questionnaires, storytelling, and document analysis (*58*). The mixed-method approach is preferred for FSC research due to the evolving nature of the FSC phenomenon and its complexities that vary from one organization to another (*45*, *58*).

Table 4.7. Examples of quantitative, qualitative, and mixed-method approaches and studies about FSC (*5*, *7*, *24*, *36*, *41*, *43*, *56*, *58*, *73*, *75*, *76*).

Study	**Setting**	**Factors**	**Methods**	**Outputs**
Hinsz et al. (2007)	Turkey processing plant located in the Midwest; 162 workers	General self-reported behaviors, behavioral intentions, attitude towards behavior, subjective-norm perceived behavioral control, work habits (i.e., habit strength and work routines), and social desirability	Quantitative: A survey based on a self-reporting questionnaire (7-point Likert scale); regression analysis	Attitude and subjective norms contribute significantly to predict intentions to engage in behaviors to prevent contamination; perceived behavior did not affect the prediction of intentions; works habits are a critical factor.
Wilcock et al. (2010)	Eight food companies (meat, wine, baked goods, flavors, and minimally processed fruits and vegetables)	Identified factors that influence HACCP implementation: Management commitment, external support, employee involvement, effective communication, right staff, and training	Qualitative: Semi-structured, in-depth interviews	The main motivating factors to implement HACCP include the likelihood of future regulation, the marketing value of HACCP certification, the improvement of training schemes for SOPs, and the value of HACCP to avoid potential litigation (*87*).
Ball et al. (2010)	Five meat-processing plants in Ontario	Management commitment to food safety (leadership and resource allocation); work-unit commitment to food safety (supervisor, co-worker, and personal commitment); food-safety training; infrastructure for food safety (food-safety management system, food-safety personnel, and production practices); workers' food-safety behavior (5, 7)	Mixed methods: qualitative approach using 13 semi-structured, in-depth interviews and 2 focus groups to identify themes. Quantitative approach using self-administered survey (7-point Likert scale)	The qualitative data analysis identified themes (production systems, operational characteristics, and employee characteristics) and sub-themes that influence the implementation of FSMSs (5). There were 124 useable surveys that revealed work-unit commitment, food-safety training, and infrastructure as high-order factors that influence the implementation of FSMSs (7).

Table 4.7. Examples of quantitative, qualitative, and mixed-method approaches and studies about FSC (*5*, *7*, *24*, *36*, *41*, *43*, *56*, *58*, *73*, *75*, *76*). (continued)

Study	**Setting**	**Factors**	**Methods**	**Outputs**
Neal et al. (2012)	Food service; 103 students majoring in hotel and restaurant management at the University of Houston	Management's commitment to food safety (leadership and resource allocation); the work-unit commitment to food safety (supervisor, co-worker, and personal commitment); food-safety training; infrastructure for food safety (food-safety management system, food-safety personnel and production practices; and workers' food-safety behavior (*56*).	Quantitative: food-safety climate survey with a 5-point Likert scale	The role of management's commitment and the workers' food-safety behavior are the most critical factors for a food-safety culture, whereas demographic factors had no significant effect on the food-safety culture (*56*).
Taylor et al. (2015)	A large catering organization in Abu Dhabi, Dubai	Includes four categories (process, purpose, proactivity, and people); 20 dimensions; and over 1,000 data points to evaluate a business' food-safety and quality culture	Mixed-methods: A psychological-narrative interview method was used to develop an online data-gathering tool	Online data-gathering tool enables large amounts of data to be gathered and analyzed quickly (*76*). It also allows the easy comparison of scores over time (*76*).

Table 4.7. Examples of quantitative, qualitative, and mixed-method approaches and studies about FSC (*5*, *7*, *24*, *36*, *41*, *43*, *56*, *58*, *73*, *75*, *76*). (continued)

Study	**Setting**	**Factors**	**Methods**	**Outputs**
CEB/Srinivasan and Kurey (2014)	60 multi-national companies; surveyed more than 850 employees at different levels of the organization and various functional units	Four attributes that predict a culture of that drive quality as a cultural value: leadership emphasis, message credibility, peer involvement, and employee ownership of quality issues (*20*, *73*).	Quantitative: culture-of-quality benchmarking survey	Nearly 50% of employees surveyed reported insufficient leadership emphasis on quality; only 10% found their company messages credible; 38% reported high level of peer involvement and only 20% mentioned their company created a sense of empowerment and ownership for quality outcomes (*20*, *73*).
De Boeck et al. (2015)	Eight affiliated butcher shops (management and operators)	Five components of food-safety climate (leadership, communication, commitment, resources, and risk awareness) and five-to-six indicators (questions) for each component (*20*, *73*).	Mixed methods: expert validation of a food-safety-climate self-assessment tool (5-point Likert scale)	A high level of food-safety climate was measured, and no significant difference was noticed between the centralized management and employees (*24*).
Nyarugwe et al. (2018)	Three Zimbabwean dairy companies of different size (multi-national, large, and medium)	Microbiological safety performance, actual behavior, technological- and organizational-enabling conditions, and employee characteristics (*58*).	Mixed methods: microbial analysis, observations, card-aided interviews, questionnaires, storytelling, and document analyses	The results revealed a superior food-safety culture at a multi-national company, whereas a large and medium company exhibited a moderate and poor microbial safety performance, respectively (*58*)

Table 4.7. Examples of quantitative, qualitative, and mixed-method approaches and studies about FSC (*5*, *7*, *24*, *36*, *41*, *43*, *56*, *58*, *73*, *75*, *76*). (continued)

Study	**Setting**	**Factors**	**Methods**	**Outputs**
Jespersen et al. (2016)	Canadian food-manufacturing company (19,000 employees, 47 plants) that produces bakery and meat products; 1,030 employees in supervisory and leadership roles within the food-safety and quality, and manufacturing teams at different plants.	Five capability areas: perceived value, people systems, process thinking, technology enabler, and tools and infrastructure (*41*).	Mixed methods: Maturity model where the scoring scale for each capability area could range between 1 and 5, with 1 indicating the doubt stage and 5 indicating an internalized state of maturity.	A significant difference exists for the maturity perceived by the food-safety and quality personnel vs. the manufacturing personnel. The senior leaders rated highest maturity, followed by functional leaders and supervisors on the maturity scale. For technology enabler, the manufacturing function rated as higher maturity than the quality and food-safety function (*41*).

4.7. Developing a Positive Food Safety Culture

In a food-manufacturing or service organizations, the responsibility for food safety lies with all stakeholders, but it is the leaders who have the primary responsibility to create, strengthen, or sustain a food-safety culture within an organization (*94*). As per Edgar Schein, "Organizational cultures are created by leaders, and one of the most decisive functions of leadership may well be the creation, the management, and–if and when necessary–the destruction of culture" (*70*, *94*). A food-safety culture must take precedence over other business priorities (*29*, *31*). To create a strong food-safety culture, the best management as well as the best science and communication systems need to be practiced within food-manufacturing and service organizations (*62*, *94*). A food-safety culture starts at the top and funnels down to the organization's other levels (*94*). The leaders need to consider the food-safety culture to be a core value, rather than a priority for an organization, because priorities may change, but the value should not change (*94*). Powell et al. state that a food-safety culture is grounded in shared values among staff and operators for safe food production. FSC development will require an intentional commitment and hard work by leaders at all levels of the organization, starting at top (*94*). "Values are deep seeded principles or beliefs that guide how an organization makes decision and conducts business" (*94*).

Creating a culture of food safety also requires commitment from an organization's leaders, middle managers, and food handlers (*31*, *62*, *94*). A survey conducted by Massey experts revealed that commitment from top management is the most important factor to implement a good food-safety culture (*18*, *29*). The business leaders also need to use variety of tools and incentives to demonstrate their awareness of and recognition for food safety (*62*). Yiannas emphasizes the importance of an organization's leaders documenting a set of guiding food-safety principles, goals, and beliefs because it is a good starting point when creating a food-safety culture and is more effective than just verbal commitments (*94*).

Five important considerations are suggested to establish food-safety goals for an organization with some components of the SMART goal-setting model. The goals need to be specific, targeting specific behaviors or conditions to improve. An example of a "specific" goal could be reducing the incidence of *Listeria*-positive places in the plant by 60%. The goals need to be "achievable" because setting unrealistic goals can make them unachievable. It is important that the goals are "measurable" in quantitative terms because that would allow the development of a system to measure performance and afford opportunities to continuously improve (*94*). The goals need to be "risk based" because it is important to focus on conditions and behaviors that have scientifically been associated with foodborne illness. Knowing and understanding the risks associated with the business' practices as well as how to effectively manage the risk was reported to help businesses maintain a culture of food safety (*62*). Finally, these food-safety goals should be clearly documented in quantitative terms and should be shared with responsible stakeholders; there should be frequent monitoring and feedback (*94*).

Yiannas shared a behavior-based, food-safety management-system continuous improvement model which is a people- and process-focused, total-system approach based on the scientific knowledge of human behavior, organizational culture, and food safety (*94*). The first step for creating a behavior-based food-safety management system is to ensure that high-quality, documented food-safety performance expectations are clear, achievable, and understood by all the stakeholders (*94*). The U.S. FDA food code can be used as a science-based guide to establish those food-safety performance expectations along with issues beyond regulatory compliance, such as food defense and food allergies (*94*).

In terms of training, food-safety training and education materials need to be designed in a persuasive manner with positive behavior changes as the end goal (*94*). The training needs to communicate that there is “real risk with real consequences” (*94*). This can be done by using personal testimonials or individual case studies, rather than group statistics, because they are much more persuasive (*94*). The training and education need to be risk based to emphasize topics, tasks, and behaviors that are more frequently associated with foodborne diseases (*94*). The food-safety-culture concepts need to be simple because complex concepts are less likely to be understood or followed (*94*). This can be achieved more effectively by converting these concepts and ideas into images, rather than words (*94*). If using posters, signs, and symbols to promote the food-safety culture, it is important that they are simple, communicate the desired behavior, are placed where the desired behavior should occur, and are changed often enough to prevent desensitizing (*94*).

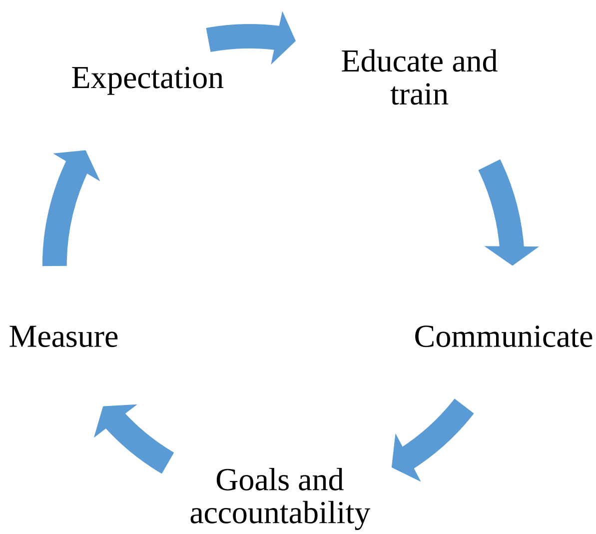

Figure 4.4. Yiannas’ behavior-based food-safety management model (*94*).

In terms of communication, a good food-safety culture exhibits behavior that is reflective of the shared values; there is openness to challenge one another when food-safety failings occur. Communication from the leadership and management teams needs to include food-safety messages that are frequent, compelling, rapid, relevant, and reliable (*62*). Such an environment not only enhances people's food-safety knowledge, but also encourages them to come forward when gaps and system failures are identified (*62*). Enhancing the FSC can be viewed as a preventive measure that shares values throughout the organization by providing daily reminders, incentives, and food-safety priorities to the employees (*62*). Encouraging communication with frontline employees can help mitigate high-risk situations, such as recalls and outbreaks, because employees would be more upfront with the identified food-safety risk within the manufacturing processes (*62*).

Guchait et al. confirm that a leader's high behavioral integrity for food safety can improve error reporting and error management, leading to a reduced risk of foodborne illnesses (*35*). Managers who consistently demonstrate integrity through adherence to food-safety priorities and protocols by reporting their own food-safety incidents and errors enhance employees' trust and willingness to learn (*35*). The manager must "walk the talk" (*35*, *56*). Powell et al. suggest tips (Table 4.8) to create a good food-safety culture; this process involves food processors going above and beyond the minimal government and audit standards (*62*).

Table 4.8. FSC aspects and practices to consider when creating a good food-safety-culture system (*62*)

FSC aspect(s)	**Practices**
Risk awareness	know the risks associated with the foods they handle and how those should be managed
Supplier control	dedicate resources to evaluating supplier practices; stay up-to-date on emerging food safety issues
Value system	foster a value system within the organization that focuses on avoiding illnesses
Communication	communicate compelling and relevant messages regarding risk-reduction activities and empower others to put them into practice
Preventive approach	promote effective food safety systems before an incident occurs
Accountability	do not blame customers (including commercial buyers and end consumers) when illnesses are linked to their products

Fatimah et al. suggested intervention strategies to enhance the food-safety culture for food-service operations which involves management support to ensure consistent enforcement and accountability of food safety policies and procedures through interdisciplinary team work within the food service organizations (*1*, *83*). Observing the operators' food-safety practices is one of the most reliable measures for effective FSC-supporting interventions (*17*, *61*). A beef processor. JBS, used 16 strategically placed video cameras as part of its monitoring and auditing efforts. JBS' initiative not only improved compliance rates, which exceeded the 99% mark within days, but also provided opportunities to develop effective food-safety training tools for employees (*22*, *61*). The video-monitoring technology is not new; it is widely used to collect data for process optimization to improve production yield and throughput planning. In the case of JBS, the video-surveillance application for food-safety-practice monitoring allows third-party auditors to provide immediate feedback in order to eliminate and to minimize the identified risks (*22*).

Yiannas mentions that we are good at measuring the risk and food safety via audits, process control, and product analyses, but we are not trained much about how to use these measurements to achieve goals. This could be further improved by focusing on problem solving and encouraging the development of innovative solutions (*94*). An example could be a drain located in a production area that has repetitive positive tests for a contaminant; involving the production operators, maintenance technicians, and quality personnel provides an interdisciplinary approach to problem solving. Such an exercise may allow the identification of work, sanitation, and maintenance patterns that contribute to the problem. This communication also limits the risk of spreading contamination to other areas of the facility.

Jespersen et al. also highlighted the need for technical and behavioral tools to focus on the food-safety culture. One recommended technical tool is a risk analysis framework, which guides through risk assessment, risk management and risk communication to enhance risk awareness aspect of FSC. Other technical tools may include advanced traceability, pathogen reduction and analytical testing platforms. On the other hand, behavioral analytical tools may include management tools like ‘ABC model’ (Figure 4.5) which is often used in cognitive behavioral therapy (*52*). In ABC tool, the desired behaviors (B) are achieved through a required set of antecedents (A) that occur before behavior. In psychology, the A is considered as an activating event or a situation (*52*). Whereas, the consequences (C) which could be either positive or negative reinforcement occurs after the behavior and will have a profound effect on continuance or discontinuance of the behavior.

Figure 4.5. ABC model used in behavior analyses. (*43*, *52*, *94*).

Jespersen et al. outlined Maple Leaf Foods’ approach to food-safety-culture transformation after the Listeria outbreak. Maple Leaf Foods provided a consistent direction and shared a common purpose with its employees using a long-term food-safety strategy (43). Five areas of focus (Table 4.9) were formulated to drive the needed changes that were identified with the food-safety strategy and to continuously improve the behaviors embedded in Maple Leaf Foods’ culture (43).

Table 4.9. Five focus areas and Maple Leaf Foods' actions after the *Listeria* recall (*43*).

Focus Area	**Action Implemented**
Governance and portfolio	A leadership council (internal), comprised of senior leaders, was established to govern the food-safety strategy and its executions. An advisory council of experts was created to provide expertise and to critique on regular basis. The chief food safety officer (CFSO) chaired both councils using the portfolio management approach to ensure routine review and governance for the effective execution of the long-term (3-5 year) strategy.
Education and training	A five-tier, food-safety education program was created: Tier 1, senior executives; Tier 2A, middle management; Tier 2B, leadership and salaried staff at all manufacturing sites; Tier 3, in-plant associates; and Tier 4, support staff throughout the business. An electronic learning platform (SISTEM) was implemented for consistent messaging.
Communication	Consistent messaging about food-safety and quality performance, industry news, and key "must know" processes was initiated. Food-safety communication kits were developed to provide "must-know process" information to hourly employees. Monthly notes from the CFSO were given to employees in order to highlight wins and individual contributions to food safety as well as industry challenges and learnings.
Systems and processes	A senior-management commitment was made to have all manufacturing sites certified with the Global Food Safety Initiative (GFSI) benchmarked scheme. There was an improved focus on internal audits and upgrades for the food-safety and quality-management systems (FSQMS).
Action measures	Food-safety performance measurements and discussions were enhanced. Daily meetings between operations and quality on Listeria finding data and actions resulted in a drop for the average Listeria prevalence from 3.14% (early 2009) to 0.13% (2014). The ABC model was used to deliver appropriate and timely consequences in order to support desired human behaviors.

Food-safety infosheets, a communication tool proposed by Dr. Benjamin Chapman, consist of relevant and timely food-safety narratives from media sources to supplement the traditional food-safety training (*17*). The text in these infosheets focused on the consequences and the food handlers' behaviors, e.g., connecting the foodborne-outbreak story with food-handler behaviors using a section called "What You Can Do" (*17*). Chapman led a study to evaluate the efficacy of food-safety infosheets as a training tool by assessing behavior charge affecting the WHO's food handling side factors (improper cooking procedures, incorrect storage temperature, a lack of hygiene and sanitation, cross-contamination between raw and ready-to-eat foods, and acquiring food from unsafe sources) (*17*). The hypothesis stated that posting properly designed food-safety infosheets and using storytelling to generate dialogue in highly visible locations (kitchen work areas and hand-washing stations) will positively influence the food-service staff's safe-handling behaviors (*17*). The baseline food-safety behaviors were compared with behaviors after introducing the food-safety infosheets at real-life food-service operations by using video observations for 8 weeks (*17*).

A total of 47 food handlers were observed, resulting in 348 hours of video data; statistical tests revealed that there were significant differences between pre- and post-food safety infosheet introduction (*17*). These infosheets were based on four emotion-generating factors that supported the FSC development within the workforce: storytelling (draws attention to the consequences of particular actions and circumstances), generating dialogue, using elements of surprise (graphic images and sobering data), and providing a relevant context for food handlers (*17, 62*). The results showed that introducing the food-safety infosheets had a significant, positive effect on risk reduction for the food-handling practices at the manufacturing plants (*17*).

4.8. Role of Regulatory Agencies and Technology in Developing the FSC

According to Taylor et al., government authorities play a critical role in enhancing the food-safety management systems (*76*). They are responsible for identifying and understanding the prevailing risks within the food industry and set the appropriate legislation to mitigate the risks (*76*). In the United Kingdom, environmental health practitioners (EHPs) are responsible for assessing the management's commitment at audited firms in order to determine the confidence in management systems (*31*). It is important for the government to work closely with global industry to align with the international best-practice standards (*76*). Food Standards Australia New Zealand (FSANZ) designed a resource kit, a two-step process to help food business do a health check of their business' food-safety culture to identify improvement opportunities by using food-safety questionnaires and a checklist (*25*). The heath-check questions are designed as a simple ranking/scale in key food-safety areas for food manufacturers (*25*).

In the U.S. food industry, adopting the GFSI standards should not have been a reactive approach to the Peanut Corporation of America's (PCA) outbreak; rather, a preventative approach using a proactive partnership with benchmarked standards, such as FSSC, ISO, and BRC, should have been taken years prior to the outbreak. The government needs to develop strategies to facilitate compliance and to effectively use inspections in order to continuously monitor and to reduce the inherent risks (*76*). From a resource-need standpoint, it is also important to focus on small and/or less-developed businesses for much-needed support because they have greater challenges to manage the food-safety risks (*76*).

A white paper published by Shawn K. Stevens, a global food-safety attorney, outlines the FDA's recent policy and perspective changes about pathogens' presence in food-manufacturing facilities (*74*). The agency is now initiating criminal investigations against food companies that distribute food products with the potential to cause human illness (*74*). Now, the FDA has technical capabilities, including the PulseNet system and whole-genome sequencing, which allow the agency to effectively link any foodborne illnesses to a specific food product or company (*74*).

In 2009, the FDA created the Reported Food Registry (RFR), an electronic portal which requires a responsible party to report when there is a reasonable probability that an article of food will cause serious, adverse health consequences (*74*, *82*). A 'Responsible party' is defined as "the person who submits the registration information to FDA for a food facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States which may include" (*82*). The RFR system was established by Section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085) to allow regulators to have involvement and control at the initial stages of a contaminated food being in commerce (*82*). Prior to this system, customers receiving and testing a supplier's product were simply rejecting the product when it was identified as having high-risk pathogens such as *Salmonella*, *Listeria*, or *E. coli* O157. Since 2011, any such findings need to be reported to the FDA, via the RFR system which is available online, within 24 hours (*82*). However, the legal liability involved with an RFR situation may discourage customers from testing the supplier's products for high-risk pathogens.

Table 4.10. Foodborne outbreaks' criminal investigations and outcomes (*72*, *74*).

Organization	**Pathogen**	**Year of outbreak**	**Criminal-investigation outcomes**
PCA	Salmonella	2008	The owner, Stewart Parnell, 61, was sentenced to 28 year; the peanut broker, Parnell's brother, was sentenced to 20 years; and the QA manager was sentenced to 5 years.
Quality Egg	Salmonella	2010	Company executives were sentenced to 3 months in jail and significant fines.
Jensen Farms	Listeria monocytogenes	2011	The owner was not imprisoned but was sentenced to 5 years of probation; 6 months of home detention; 100 hours of community service; and was given individual fines of $150,000.
ConAgra	Salmonella	2007	ConAgra pled guilty to charges for falsifying records. There were over $11 million in fines.
Blue Bell	Listeria monocytogenes	2015	The investigation is still in progress; there is no action yet, but the FDA is closely involved with findings at the plant level.
Chipotle	E. coli	2015	The investigation is still in progress.

According to Michael R. Taylor, the FDA's deputy commissioner for foods and veterinary medicine, the FSMA was an initiative led by a broad coalition of stakeholders, including produce growers, food processors, growers, regulators, and consumers who were disturbed by a series of foodborne illnesses and outbreaks (*72*, *77*). Prior to the FSMA, the food industry started to recognize the importance of much-needed food-safety management systems to better control foodborne hazards at manufacturing facilities. This need was primarily driven by retailers such as Walmart that started requiring its suppliers to have Global Food Safety Initiative benchmarked food-safety schemes at their manufacturing facilities.

The FSMA also considers the complexity and diversity of the current food systems because there is a need for clear enforcement on a global scale (*77*). With the FSMA's new import safety mandate, there is a strong focus on imported food (*77*). Diversity is also acknowledged in terms of business scale because Congress recognized several small-scale growers and processors that are an integral part of the U.S. food system and supply (*77*). FSMA implementation has also allowed the FDA to develop international collaborations for common food-safety goals (*77*). An example of such collaboration is the Produce Safety Partnership which was launched in 2014; there is a Mexican regulatory counterpart with shared goals and interest in produce safety as well as a commitment to the FSMA's success (*77*). Prior to the FSMA, the lack of proactive collaboration may have been a gap because such interactions between regulatory bodies were reactive in nature and usually formed because of an outbreak.

According to Sklamberg, the FDA's deputy commissioner for global regulatory operations and policy, "FSMA empowers FDA to facilitate the growth of a food-safety culture, working with federal and state agencies, and with farmers, food manufacturers and importers, to bring about widespread compliance with the new regulations mandated by the food safety law" (*72*). The

FSMA gives more power to the FDA, including the ability to seek civil action or criminal prosecution when consumers are at risk, to issue mandatory recalls when a company fails to do voluntary recalls, to detain products which are at risk, and to suspend the registration of facilities with a potential risk to produce contaminated foods (*72*).

In terms of technology, regulatory and industry professionals are continuously improving their abilities to support FSC enhancements. The technical advancements have been in the food-safety management systems and operations. For pathogen detection, manufacturers are investing in more-sensitive and accurate rapid techniques as compared to the traditional FDA Bacteriological Analytical Manual (BAM) method. Some of these technologies include rapid molecular-based systems, such as Polymerase Chain Reaction (PCR) and Enzyme-linked Fluorescence Assay (ELFA)-Vidas, that allow manufacturers to detect pathogens in their food products and environment within 48 hours. These methods allow quicker actions to manage any identified risks within the products and processing environments.

One of the most recent advancements is whole-genome sequencing. Along with sanitation and GMPs, the environmental control program is now being viewed as a foundation for pathogen control at food-manufacturing plants. The program includes periodic sampling of food-contact and non-food-contact environmental surfaces to screen for hygienic indicators and pathogens. In the event of a non-conformance finding, prescribed actions are taken to further investigate the finding and to minimize/eliminate the contamination spread by performing prescribed sanitation activities. Combining the rapid techniques and pro-active sampling can be helpful to prevent contamination incidents, but the behavior aspect of managing the program can influence the program’s success and failure.

PulseNet is a national laboratory network that allows regulators to detect an outbreak and to alert the public sooner. The network, established in 1996, contains DNA fingerprints collected by local, state, and federal health authorities to accelerate the investigations (*12*). The FDA used technologies such as Pulse Field Gel Electrophoresis (PFGE) and Multilocus Sequence Typing (MLST) to identify links between pathogen strains detected during investigations (*12*). In 2010, whole-genome sequencing was used for the first time with an investigation of three samples from a *Vibrio Cholerae* outbreak that killed thousands in Haiti (*12*).

After Congress passed the FSMA in 2011 and directed the CDC to expand national foodborne-disease surveillance systems, PulseNet scientists started using whole-genome sequencing methods to study foodborne illnesses caused by *Listeria* (*12*). As of 2015, the CDC routinely uses whole-genome sequencing to investigate foodborne illnesses caused by *Listeria*, Campylobacter, Shiga toxin-producing *E. coli*, and *Salmonella* (*14*). As per an economic evaluation done by the *American Journal of Preventive Medicine*, "PulseNet prevents at least 270,000 illnesses from *Salmonella*, *E. coli*, and *Listeria* and saves $500,000 US dollars every year" (*12*, *69*). In the coming years, the goal is to use whole-genome sequencing at all 50 state public-health laboratories for routine surveillance. WGS will become the "new PulseNet gold standard" for subtyping pathogens that cause foodborne illness (*12*).

Laura Dunn Nelson, director of industry relations for Alchemy systems, introduces the concept of interactive training which is based on a concept that food-safety culture is best accomplished when the workforce is engaged. This type of training involves new training technologies that incorporate auditory, kinesthetic, and visual learning styles, encouraging better learning comprehension, team building, and information retention (*57*). Nelson highlights five best practices for a learning environment: consistently deliver up-to-date information about critical food-safety content; develop interactive and engaging content; provide training content in multiple languages to ensure comprehension; implement company content, tests, and evaluations; and automatically document and report results (*57*). Alchemy systems provides automated solutions to build a strong food-safety and operation culture by offering effective communication and employee engagement opportunities across all levels of an organization (*2*). The training includes knowledge checks and fun games for maximum retention (*2*). It offers tools for supervisors and managers to generate efficiencies in the audit and training activities. For example, there is a mobile app to facilitate and to document audits and on-the-job training (Alchemy coach) activities (*2*). ConAgra Foods reported a 32% increase in production efficiency since the adoption of Alchemy systems (*2*).

Maple Leaf Foods has also adopted Alchemy systems and has provided positive feedback about its training system effectiveness: “One of the fundamentals to creating a safety culture is to make sure employees understand it by training properly. Alchemy was able to take Maple Leaf’s program objectives and tailor their solution around them. Alchemy gives us the ability to not only correct behaviors, but it also allows front-line workers to offer insights into how the program can be better” (*2*). Alchemy systems’ learning courses cover a wide range of topics that can be customized for a company’s needs: cleaning and sanitation, *Salmonella* control, food allergens, food contamination, GMPs for maintenance, hand washing, personal hygiene, environmental monitoring, basic food-facility defense, and Preventative Control Qualified Individual (PCQI) (*2*).

5. DISCUSSION

Foodborne-illness burden estimates provide good insight about the effect of foodborne hazards in our food-manufacturing and service systems. However, there is limited research on the economic consequences of foodborne illnesses and diseases. There is an opportunity for health economists to study the economic factors not only for the foodborne-illness burden, but also for the economic gains with positive food-safety initiatives and culture. The economic-burden literature and data would be a much greater motivator for companies with a weak food-safety culture. The companies' middle management can influence the senior leadership by accounting for and sharing the costs due to FSMS failure and a downgraded product. It is important to highlight the root causes of such failures and to focus on preventing a recurrence.

The food-safety initiatives which involve upgrades for food-safety management systems have certainly improved the overall food-safety performance. However, the trends for the foodborne-disease burden have not changed much. The reason might be the fact that FSMS is process focused as compared to the behavior-based food-safety management systems that are people focused (*94*). Yiannas' total systems approach is based on the scientific knowledge of human behavior, organizational culture, and food safety (*94*). An interdisciplinary approach to improve an organization's FSC would be a much more efficient response to reduce foodborne-outbreak and recall problems.

The FSC definitions have evolved in the work published by several researchers, but there is still no formal consensus-based definition that exits today. Organizations such as GFSI should lead the initiative to define FSC and to influence factors because food industries across the globe have adopted the GFSI's benchmarked food-safety management schemes. An FSC working group exists at GFSI, and it is expected that the group may release a formal FSC definition, factors, and dimensions as a guidance for the food industry (*27*).

The senior leadership and management teams need to recognize that a strong food-safety and quality culture leads to fewer mistakes. A research study done by Corporate Executive Board (CEB) reveals that companies with a high culture of quality have employees who make 46% fewer mistakes, 75% fewer significant mistakes, and 75% fewer customer-facing product mistakes compared to companies with a low culture of quality (*20*). "For the average CEB member, this difference can lead to more than $350 million in added employee productivity" (*20*). Once the leadership and management teams acknowledge the significance of FSC, it is important for them to create an FSC strategy as part of their strategy and value systems.

Lessons can be learned from the Occupational Safety and Health Administration (OSHA) culture that already exists at all manufacturing plants and where special emphasis has been put on senior leadership teams for safety-oriented vision and mission. The food-safety vision needs to be clear and should set the direction for the organization to achieve the desired food-safety goals (*42*, *94*). Often, priorities may change, but if food safety is in the organization's value system, it increases the commitment at all levels of the organization (*42*, *94*). For the leadership team, the commitment should be reflected through the proper allocation of financial and infrastructural support to develop a strong food-safety culture (*42*, *94*).

Measuring the FSC is a preliminary step to develop a positive food-safety culture. The FSC evaluation systems described in this review include a wide array of practices from simple, qualitative assessments to more complex, mixed-method approaches such as maturity models. These techniques allow a manufacturer to get a snap-shot of the strengths and weaknesses of the food-safety systems and to take appropriate actions to improve those systems (*42*). When using

FSC measurement tools, it is important to ensure that the methods have optimized quality and trustworthiness in order to generated accurate data about the prevailing food-safety culture within an organization (*42*). Jespersen et al. evaluated the validity and reliability of eight food-safety measurement models: Ball et al., CEB, Denison, De Boeck et al., Jespersen et al., National Science Foundation (NSF), Taylor Shannon International (TSI), and Wright (*42*). Jespersen et al.'s recently proposed dimensions (values and mission, people system, consistency, adaptability, and risk awareness) are the most inclusive in terms of capturing the factors which influence the FSC at a food-manufacturing organization.

Jespersen et al. also identified a gap in the FSC evaluation systems: social desirability bias, which is a "social science research issue that describes the tendency of survey respondents to answer questions in such a way as to be viewed favorably by other" (*44*). This bias can lead to over-reporting good behavior and under reporting bad behavior (*42*, *44*). Jespersen et al. developed a social desirability scale (FSDRS, Food Safety Desirability Response Scale) to capture the degree of social-desirability responses by stakeholders when evaluating the food-safety culture at manufacturing organizations (*42*, *44*).

There are limited FSC measurement tools for food-service organization as compared to food-manufacturing organizations. The research surveys done with food-service operations revealed high-agreement scores for self-commitment and environmental support, whereas there were low scores for risk judgment and management support (*83*). For food-service employees, optimized onsite operations and accessibility to adequate high-quality infrastructure were identified as strengths, but when reviewing multiple foodborne-outbreak case studies at manufacturing plants, it appeared that a lack of infrastructure was one of the contributing factors (*83*). Fatimah et al.'s study identified the influence of demographic variables on the employees' food-safety culture perception, providing a scope to identify sub-cultures based on age, education level, work experience, etc. and to create specific intervention for each sub-group (*83*). However, manufacturing studies have placed less importance on the demographic sub-groups as variables in developing a food-safety culture.

The majority of the FSC research has not recognized the national-culture aspect (*59*). As part of food-safety-culture implementation strategies, it is important to consider the fact that different cultures require different approaches for a desired change (*38*, *59*, *75*). Nyarugwe et al. recognize the need for specific hierarchical levels, strategic, tactical, and operational, because the personnel at these levels encounter varying food-safety tasks, responsibilities, and decision making (*59*). For example, the senior management is responsible for creating food-safety policies and objectives regarding sanitation effectiveness and resource investments, but middle management and front-line operators may focus on executing the required sanitation standards (*59*). FSC research should be based on the companies' food-production context and food risks, rather than generalizations across the industry because different products put various demands on an organization's FSC (*59*).

An opportunity exits to improve the messaging about food-safety-related priorities and information (*42*, *94*). Some common messaging platforms may include the company website, the intranet, emails, focus groups, safety committees, shift meetings, and bulletin boards (*42*, *94*). It is also important to consider how the communication and messaging may vary from one business setup to another. For example, the sanitation processes and scale may differ between manufacturing companies and the food-service industry. The lack of risk communication with front-line employees does not allow a company to develop a strong FSC (*42*, *94*). The risk assessment is usually delegated to technical and subject-matter experts within the organization who have a great understanding about the severity of the risks in identified with non-conforming situations, but front-line employees can also contribute to such assessments and preventive solutions (*42, 94*). This involvement will enhance the food-safety risk awareness and the sense of ownership among the front-line employees.

The food-regulatory bodies' involvement is critical to shape an industrywide FSC culture. The United Kingdom, Australia, and New Zealand have shown their commitment to promote the FSC, but the FDA still lacks any clear guidelines or framework on this subject. However, it is believed that the Food Safety Modernization Act (FSMA) may positively influence the FSC because the law focuses on preventive control and gives more authority and power to the inspectors during an audit, providing access to information which was previously disputed by the organizations. The FSMA involves the creation of a new food-safety system, has a broad prevention mandate, and creates accountability for food manufacturers (*77*). FSMA inspectors are using risk-assessment tools and training to conduct thorough assessments of the facilities in order to identify foodborne hazards in the food-processing systems. The technological advantage of taking environmental and product samples for molecular testing and whole genome sequencing (WGS) will allow the inspectors to discover immediate and future risks. For example, an identified pathogen in a manufacturer's environment can be tied to an outbreak that may occur in the future due to the consumption of contaminated food. A challenge for adequate resourcing may exist for the FDA because these FSMA audits are quite extensive, and proper staffing may not be there to support the inspection needs.

The technological advancements can aid the FSC performance at the food-manufacturing and service-organization levels. The success of the technological training tools shared by Alchemy systems really focuses on the food-safety training elements and can be customized for any company’s processes. Such tailored training, with engaging content and flexibility to access the material using computerized systems, will enhance the overall FSMS performance and create positive food-handling behaviors. Alchemy systems’ tools also facilitate real-time communication and feedback, which can improve trust and confidence within the front-line workforce. However, such advanced tools come at a cost and may not be feasible for small- to medium-sized companies.

This paper discusses several aspects of FSC and its growing needs within the industry. The senior management’s leadership and commitment to food-safety-oriented operations influence the FSC most. This commitment, when communicated through actions (walk the walk), will create an even stronger commitment within the workforce. It is unfortunate, at times, that the only way the leadership awakens is when a catastrophic failure occurs within the organization. The effect of such failures is huge for consumers and the industry at the national and global levels due to complex food systems. The food industry and regulatory bodies need to clearly recognize FSC as an emerging risk, developing a system and resources to work towards the FSC’s positive prevalence. However, there is need for future research on how FSC measurement tools can be standardized and used across the industry to provide better benchmarking opportunities. Such a standardization may also allow to collect evidence on impact and continuous improvement of FSC within food manufacturing and service organization.

6. CONCLUSIONS

The food-safety practices that solely focus on food-safety management systems have been unable to improve the burden of foodborne illnesses. Researchers and industry experts now recognize the importance of human behavior to generate a more preventative environment that allows the hazards and risks to be identified and mitigated in an effective manner. Food safety culture is being identified as an emerging risk factor for the food industry. The evidence for FSC's relevance can be seen in recent foodborne outbreaks and recalls where the FSC has been identified as an underlying cause that contributed to food-safety-system failures. The elements and dimensions that influence the FSC culture can be adapted from the available literature about organizational and safety-culture studies. Identifying these factors not only allows organizations to create specific strategies, but also enables the companies to measure their FSC performance for continuous improvement.

Measuring FSC is a critical step to identify gaps and to dedicate resources accordingly. A wide range of tools and methodologies are now available to measure FSC, but there is still a need for a more standardized and mixed-method approach to ensure quality and trustworthiness. A behavior-based food-safety management system is proposed to continuously improve an organization's FSC. This review also captures the positive influence of the recent regulatory and technical advancements because they are instrumental for developing a successful food-safety culture. The FSC concept is evolving within food industry but there is lack of consensus on definitions, measurement and development techniques. It is important for industry associations such as GMA and GFSI to drive and standardize this concept to allow manufacturers enhance their FSC and FSMS performance.

Overall, the leadership at food-manufacturing and food-service organizations needs to acknowledge FSC as an organizational risk and demonstrate the commitment and values by providing adequate resources, systems, and communication for employees to successfully achieve the ultimate food-safety goal, i.e., continuously reduce and eliminate foodborne hazards to decrease the global foodborne-illness burden.

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