EVALUATING FOOD SAFETY SYSTEMS DEVELOPMENT AND IMPLEMENTATION BY QUANTIFYING HACCP TRAINING DURABILITY

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EVALUATING FOOD SAFETY SYSTEMS
DEVELOPMENT AND IMPLEMENTATION BY
QUANTIFYING HACCP TRAINING DURABILITY

DISSERTATION

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Agriculture at the University of Kentucky

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ABSTRACT OF DISSERTATION

EVALUATING FOOD SAFETY SYSTEMS
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HACCP-based food safety programs have been widely acclaimed, accepted and implemented as an effective means of managing food safety risks. While HACCP training is a cornerstone of managing HACCP programs, there is little information about the effectiveness of HACCP training and the durability of HACCP knowledge. Findings reveal a link between involvement level in HACCP activities and the accuracy of HACCP knowledge over time. Opportunities for peer training in HACCP, irrespective of overall experience in the food industry provide favorable circumstances for maintaining accuracy of HACCP knowledge. The optimal window for engaging employees in HACCP is directly following the completion of training for achieving the minimal depletion level of content knowledge. This study further reveals that refresher training in HACCP is necessary within three years. Furthermore, training standardization organizations likely need a formal process of monitoring and maintaining HACCP trainer and trainee qualifications to ensure uniformity in HACCP programming.
KEYWORDS: HACCP, Food Safety Training, Post-training Knowledge Retention, Process Improvement, HACCP Program Implementation.

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EVALUATING FOOD SAFETY SYSTEMS
DEVELOPMENT AND IMPLEMENTATION BY
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For My Parents
Remy and Leonie Anandappa
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TABLE OF CONTENTS

Acknowledgments ............................................................................................................. iii
List of Table ...................................................................................................................... vii
List of Figures .................................................................................................................. viii

Chapter One: Introduction ................................................................................................. 1
    Importance of Evaluating HACCP Training Durability ........................................... 3
    Objectives of this Study ........................................................................................... 5
    Conceptual Framework ........................................................................................... 5
    Outline ................................................................................................................... 6

Chapter Two: Food Business, Food Safety and Food Safety Management Systems .......... 8
    The Business of Processed Foods ............................................................................. 8
    Factors Influencing the Price of Food .....................................................................10
    Foodborne Illness .................................................................................................. 11
    Economic Cost of Foodborne Illness ..................................................................... 11
    International Trade of Food .................................................................................. 12
    Food Safety as an Economic Opportunity ............................................................. 14
    Overview of Food Safety Systems .......................................................................... 16
    HACCP-Based Food Safety Management Systems ................................................ 17
    Hazard Analysis and Critical Control Points Overview .........................................20
    Concepts of HACCP .............................................................................................21
    Developing a HACCP Plan ....................................................................................22
    Pre-requisite Programs ..........................................................................................24
    HACCP Training ...................................................................................................29
    HACCP Implementation .......................................................................................30
    Quality Management Systems ..............................................................................33
    Process ...................................................................................................................33
    Inspection/Regulatory .........................................................................................34
LIST OF TABLES

Table 2.1 Commonly Used Abbreviations Relating to Food Safety Management Systems .................................................................20
Table 3.1 HACCP-Related Product Recalls (FDA regulated products) ........................................42
Table 3.2 Concepts for Evaluation .................................................................................................47
Table 3.3 Curriculum Requirements/Recommendations .................................................................48
Table 3.4 HACCP Training Content Block 1 ..................................................................................50
Table 3.5 HACCP Implementation and Management Block 2- Part 1 ...........................................51
Table 3.6 HACCP Implementation and Management Block 2- Part 2 ...........................................52
Table 3.7 HACCP Implementation and Knowledge Translation ....................................................53
Table 3.8 Study Subject Recruitment .........................................................................................57
Table 4.1 Responders by Geographic Location .............................................................................59
Table 4.2 Summary of Gender, Ethnic and Education Background of Respondents .................60
Table 4.3 Company size, Age and Years of Food Industry Experience ........................................61
Table 4.4 Types of HACCP Courses Completed ........................................................................63
Table 4.5(a) Responses and Scoring ..........................................................................................66
Table 4.5(b) Responses and Scoring ..........................................................................................67
Table 4.5(c) Responses and Scoring ..........................................................................................68
Table 5.1 Basic HACCP Knowledge ..........................................................................................71
Table 5.2 Summary Table of HACCP Core Knowledge .................................................................73
Table 5.3 Secondary HACCP Knowledge ....................................................................................75
Table 5.4 Summary Table of HACCP Secondary Knowledge .......................................................77
Table 5.5 HACCP Principles Competency Over Time .................................................................80
Table 5.6 HACCP Principles Knowledge-Factors relating to HACCP Integration .....................84
Table 5.7 Knowledge Scores Improve with Increased Involvement ...........................................85
Table 5.8 HACCP Program Implementation Success .................................................................87
LIST OF FIGURES

Figure 1.1 Concept Knowledge Assessment Levels .............................................................. 6
Figure 2.1 Employment in the food manufacturing industries by segment ....................9
Figure 2.2 Distribution of Each Food Dollar .....................................................................10
Figure 2.3 Value of U.S. Imports and Exports .................................................................13
Figure 2.4 Quality Cycle ....................................................................................................15
Figure 2.5 Food Safety Controls Cycle (FSSCC), Identifying Gaps in Food Safety ..........18
Figure 2.6 Steps for Developing a HACCP Plan ..............................................................23
Figure 2.7 Prevention-based Practices are the Common Language of Food Safety Systems .24
Figure 2.8 Four Levels of HACCP Integration within a Company .................................33
Figure 2.9 Food Safety Systems are Built upon Training ................................................37
Figure 3.1 Logic Process for Developing Survey ..............................................................46
Figure 3.2 Systematic Recruitment of Study Participants ................................................55
Figure 5.1 Standard Score Interpretation ........................................................................71
Figure 5.2 Basic HACCP Knowledge Level since Training Completion .......................72
Figure 5.3 Probability Plots of Basic (Core) HACCP Knowledge since Training Completion ..........................................................74
Figure 5.4 Secondary HACCP Knowledge since Training Completion .......................76
Figure 5.5 Probability Plots of Secondary HACCP Knowledge since Training Completion .......................................................................................................78
Figure 5.6 Combined Probability Plot of Secondary HACCP Knowledge ....................79
Figure 5.7 HACCP Principles Knowledge by Duration since Training Completion ........81
Figure 5.8 Factors Relating to HACCP Integration ..........................................................83
Figure 5.9 Knowledge Competency is Closely Related to the Level of Involvement in HACCP ........................................................................................................86
Figure 5.10 HACCP Implementation .............................................................................88
Figure 5.11 Training Adequacy ....................................................................................89
CHAPTER ONE

Introduction

Hazard Analysis Critical Control Point (HACCP) programs are widely accepted globally as the most effective means of managing food safety (NACMCF, 1997; USDA/FSIS, 1999; WHO, 1999). Although HACCP has been criticized for several factors, it has proven valuable to society by reducing the estimated cases of foodborne illness over the past 15 years (CDC, 2011). Recent changes in U.S. food safety regulations require that HACCP principles be implemented in more industries and retail settings than ever before. A minimum of 4000 individuals are trained in HACCP each year (International HACCP Alliance, 2013) to meet the needs of HACCP programs. However, little is known about the effectiveness of HACCP training and post training knowledge. Since the success of HACCP hinges on HACCP training and relies on the subsequent knowledge of the workers involved in operating these programs, HACCP trainees become components of the HACCP program itself. This study seeks to establish the effectiveness of HACCP by assessing the knowledge gained from HACCP training and its durability over time among those entrusted with its implementation.

On average 28 million pounds of food corresponding to 41 Class I recalls (highest risk level), and 10 class II recalls are destroyed each year (USDA-ERS, 2012). The centers for disease control and prevention (2011) estimate that 3000 deaths, 128,000 hospitalizations and 48 million cases of foodborne illness occur each year. Twenty five percent of all cases of illness contracted within the borders of the United States arise from food contaminated with pathogenic bacteria and viruses. While the recall statistics focus on economic losses, the corresponding cases of illness and loss of life are even more significant indicators of failures in processes that should otherwise prevent the contamination, distribution and consumption of
adulterated food. Preventing foodborne illness, therefore relies on the adequacy of our food safety systems and HACCP programs are a foundational element of these systems.

To achieve food safety, practitioners are involved in developing quicker, more effective or cost efficient methods of preservation, elimination of pathogens, and detection and reduction of sources of all undesirable contamination. Over the past 50 years, quality systems (with the primary intent of ensuring safer food) have steadily grown into a discipline within food safety. Food safety training programs like HACCP play a large part in the practical application of these methods. Starting with the advent of human travel to space and the complexities and risks that could develop as a result of spoilage or contamination of rations in space, rigorous prevention-oriented HACCP based systems were developed and propagated throughout the food industry.

It is only within the past 15 years, however, that HACCP and other prevention-based systems have become deeply entwined with food laws, regulatory scrutiny and more recently widespread industry adoption either voluntarily or through federal or international mandates. The backbone of each program shares common themes of (1) prevention by identifying risk factors; (2) actions to mitigate risks; (3) monitoring and documentation of various aspects of processes; and (4) training of system managers and operators. Scientific literature provides a plethora of insights into hazard/risk management methods, the costs associated with developing and implementing HACCP programs, challenges associated with HACCP program development and technologies associated with effectively managing control points. One of the first observers of HACCP training (Mayes, T. 1994) described it as fulfilling 3 main roles that include

“1) imparting a common understanding of the practical implications of HACCP to food safety on a worldwide basis,

2) to impart the practical skills and knowledge necessary for HACCP application,

3) to provide the stimulus for further development and harmonization of HACCP.”
Since that time training efforts have endeavored to fulfill these roles. But training in HACCP has been voluntary and industry driven. As a result, there are few strong food safety cultures and many of the organizations that go through HACCP fail to explore the full benefits such a system may provide.

**Importance of Evaluating HACCP Training Durability**

While training is generally understood as a good approach to implementing HACCP, training is only mandated for a single individual associated with each operation by federal law under the Code of Federal Regulations, 9 CFR 417.5 (US GPO, 1997). Meat and poultry HACCP operators are strongly encouraged to obtain training at the level that provides a certificate of completion that is adorned with a seal from the International HACCP Alliance, the training standardization organization. However, once the training is completed, the certification is accepted with no expiration date, no requirement for further training, no requirements or guidelines for retraining when needed and no requirements for maintaining continuous food safety training of HACCP program operators. The implication of this situation is that once an individual is trained in HACCP, this knowledge is current, accurate and relevant, requiring no need for improvement over a lifetime. While this may in fact be true, data to support or disprove this understanding does not exist. Several other industries (project management, aircraft engineers, nursing, medicine etc.) have demonstrated that training must be followed by the practical application of knowledge and continued effort must be made to retain training and further one’s knowledge to ensure these professionals are competent.

Various aspects of HACCP program development have been studied, including its applicability to different operational settings, food safety knowledge of food workers, the economics of implementing HACCP programs and the challenges of designing and implementing HACCP programs (Bas et al, 2007; Bauman et al, 1990). The effectiveness or
performance of HACCP programs has been studied and these studies primarily focus on specific technical procedures, processing attributes, critical control measures or the end product quality and safety. Some examples of these studies include studies uncovering specific metrics that may be used for evaluating in-organization hazard identification and control (Kafetzopoulos et al., 2013), the need for product testing to evaluate the effectiveness of control measures used in seafood processing (Cormier et al., 2007), identification of prerequisite program effectiveness in retail and restaurants revealing low levels of contamination from *Listeria* in prepared or restaurant foods (Domenech et al., 2011) and the performance of HACCP in Japanese milk processing. These studies have revealed favorable results especially in technology assisted processes, and less challenges with managerial activities such as verification, monitoring and quality related procedures (Sampers et al., 2012).

The potential and practical applicability of this HACCP knowledge study has several implications on the food industry, food safety professionals and society. By better understanding the effectiveness of HACCP through training knowledge evaluation, food safety training professionals and HACCP practitioners alike will have data regarding aspects of HACCP training that can be used to enhance in-house training programs. This information can potentially be used to draw correlations between training and knowledge related changes with food safety incidents to elucidate possible gaps in knowledge that may ultimately translate into product or financial losses. Once gaps are identified, organizations may potentially benefit by having the data to train, retrain when needed and provide food industry professionals with the tools to minimize recalls and contamination events. In the case of smaller businesses, this study may potentially provide a framework for ‘how, when and who’ training needs to be provided to and elevate food safety and profitability in a manner independent (or minimally dependent) of major capital investments. Findings from this study could be used to further develop and refine future iterations of such studies that may potentially deliver larger data sets which would be of greater value to the industry. Additionally, enhancing food safety by understanding the training needs for managing food
safety processes could assist practitioners, trainers, regulators and most importantly lead to a better quality of life for humanity.

**Objectives of this Study**

As a pilot study, this effort broadly surveys post-training HACCP knowledge and is designed to obtain a baseline of information pertinent to HACCP knowledge over time by evaluating

a) HACCP knowledge from a concepts perspective,

b) assessing whether there are differences in HACCP knowledge with time,

c) if differences in knowledge exist, exploring in what areas of HACCP knowledge differences exist, and

d) exploring the adequacy of HACCP training for industrial application of those concepts.

**Conceptual Framework**

HACCP training includes specific principles and steps required to develop and implement a HACCP program. It involves a deep understanding of steps in the process, components of the products and technical knowledge of reasonable risks as well as less likely yet possible risks that are associated with a food product from the production line to the retail shelf. HACCP knowledge, therefore, must include a practical understanding of concepts inherent to developing the HACCP program and managing the operational aspects of that program which can be adapted to each and every product that is developed in the operation. This HACCP knowledge should then be applicable to any operation as is proposed by standards agencies, and the concepts imparted as the core of those principles can be reasonably expected to be retained for a longer duration by a trainee than specifics relating to the training, a specific product or process. This conceptual knowledge was used to assess HACCP knowledge given that the core or take home message of HACCP principles would be universal and attributing numerical values to HACCP knowledge over time would relate to all industry segments included in this study.
HACCP knowledge needs to be evaluated at all stages following the training events, considering that in most cases the training event may have been a single occurrence following which the trainee may serve in several capacities both on and off the multi-disciplinary HACCP team. Knowledge assessment take a concepts approach evaluated by surveying foundational concepts from the training curriculum and concepts drawn from the basic regulatory requirements for HACCP.

**Outline**

The following chapters are presented to provide an overview of food safety and HACCP; describe the concepts and rationale for developing the survey instrument, discuss methods, limitations and advantages of performing this study; and finally, to discuss the findings of this study and future studies related to advancing food safety through training.
related factors. Chapter 2 will outline the importance and economics associated with food safety, introduce HACCP principles and best practices for implementation as a background upon which this study design was selected. Chapter 3 presents the methods and limitations of this study. Chapter 4 presents the results of this assessment. Chapter 5 summarizes the research, draws conclusions, and makes recommendations for both further research as well as possible changes in the HACCP regimen.
CHAPTER TWO

Food Business, Food Safety and Food Safety Management Systems

The complexity of food safety systems requires the commitment of all stakeholders involved for success. The following sections in this chapter are provided to lay the groundwork for the importance of food safety, in the context of where training related to food safety fits into the system, and the importance of firm-level commitment to quality and safety that are in the best interest of the public as well as the firm, and to justify focusing our attention on the durability of HACCP training knowledge.

The Business of Processed Foods

According to the Economic Research Service of the U.S. Department of Agriculture (USDA-ERS, 2010) 9.4% of the disposable income of Americans, or an average of $151 per week is spent on food (Mendes, 2012). Remarkably, this is a drop from $214 per family in 1987 (adjusted for inflation). Furthermore, the average American spends 25% of their grocery bill on purchasing processed foods (NPR, 2012). In February 2013 alone, Americans spent $114.6 Billion on retail sales of at-home-foods and $102.9 Billion on food away-from-home (USDA-ERS, 2013). In all, the food industry is the largest industry in the nation despite its relatively low level of contribution to the $15.851 Trillion (4th Quarter 2012) of the U.S. Gross Domestic Product (GDP), primarily due to the low cost of food in the United States. The U.S. food manufacturing sector employs 11,977,000 workers as of February 2013 (Bureau of Labor Statistics, 2013a) and supports the largest portion of manufacturing jobs (Figure 2.1) in the nation.
Figure 2.1 Employment in the Food Manufacturing Industries by Segment
Source: U.S. Census Bureau, 2010 Annual Survey of Manufacturers.
Factors Influencing the Price of Food

Industry standards for processed foods must meet a sizeable number of safety criteria while being acceptable and pleasing to the consumer. Food price setting is a science in its own right including factors as highly volatile as the weather conditions that dictate production yields, or the cost of labor and shipping associated with the manufacturing area. The U.S. Department of Agriculture, Economic Research Service (USDA/ERS, 2011) reports in its “Food Dollar Series”, how every Dollar spent on food gets distributed across the supply chain (Canning, 2011). Food processing receives about 18.6¢ on each Dollar (Figure 2.2) and the cost of ensuring the safety of that food has to fit into that 18.6¢, with a scattering of costs being incurred within the 33.7¢ incurred in the Food Services sector.

Figure 2.2 Distribution of Each Food Dollar
Foodborne Illness

The Centers for Disease Control (CDC, 2011) estimates that 47.8 million people get sick annually from foodborne disease, 127,839 are hospitalized and 3,037 die as a result of contracting the illness. While this is a reduction in estimated number of deaths related to foodborne illness in comparison with the estimate of 5000 deaths in 1999 (Scallan et al., 2011), the causes of foodborne illness are not always clear. For those cases that can be traced to their origins, many of the cases of advanced foodborne illness and death are traceable to an outbreak either from the consumption of processed food, restaurant food (Hedberg et al., 2006) or in home contamination of food, while several others are caused by new or emerging pathogens (Todd, E.C., 2004). Additionally, it is estimated that for each reported case of illness, there are 35 cases of foodborne illness that go unreported due to their shorter duration, lower level of severity, medical complications or insurance issues. The majority of these cases arise from contamination with Salmonella spp., E.coli spp., Listeria monocytogenes, Norovirus, Toxoplasma, Campylobacter and Clostridium perfringens. A recent report on foodborne illness acquired within U.S. borders (Scallan et al., 2011) indicates that of the 36.4 Million cases of illness acquired in the nation (Scallan et al., 2011), 9.4 Million (25%) were foodborne.

Economic Cost of Foodborne Illness

The cost of foodborne illness was estimated at $1,626 per case on average, which equates to an aggregate annual cost of $77.7 billion (Scharff, 2012). The total cost of foodborne illness, in fact, is composed of health-related costs, loss of productivity that is captured with this enhanced model that accounts for pain, suffering and functional disability in addition to the cost of illness, medical costs and productivity losses. Additionally, societal and business costs may also be considered as lawsuits, insurance costs, outbreak investigations, laboratory and analytical costs and food waste from recalls and regulatory action amount for significant losses, that are attributable to foodborne illness, yet not directly borne by the ill individual. The cost to the company responsible for propagating foodborne
illness is often too crippling to survive through, particularly for small businesses. Between 1988 and 1997, 55 plaintiffs afflicted with a case of foodborne illness were paid $7,330,412, reflecting a 31% success rate from the perspective of the plaintiffs (Buzby et al., 2001).

International Trade of Foods

For the last 500 years international trade has been growing consistently, and while the first explorers indeed sought out new lands, flavors and fragrances, these early trade years were bursting with spices, alcohol and dry ingredients. However, the last century has given rise to increased trade opportunities that have led to an exponential increase in food trade between nations. Over the past dozen or so years that trade has shifted from primarily dry and preserved products to increased amounts of produce, processed food and ready to eat foods that are transported into the United States as well as out of the country. To keep up with the food safety needs that arise from larger scale production, and international transportation, U.S. regulatory bodies as well as international regulatory or standards agencies have pushed forward the need for food to be produced under stringent quality and safety conditions.

Overall the increase in U.S. imports between the year 2000 and 2010 is 120% and U.S. exports overall have increased by 102% indicating a growing pattern of increases in both exports and imports (Figure 2.3) of food and manufactured food products (US Dept. of Commerce, 2011). During this period the U.S. population increased by 9.7% between 2000 and 2010 (U.S. Census Bureau, 2010), demonstrating a clear increase in trade not necessarily linked to population growth, but from changes in food choices and consumption habits. While food trade is no doubt constantly growing under current settings, a lack of common food safety standards, for years, has been criticized as a hindrance to fluid international trade in food products. The USDA-ERS (Buzby, 2003) reports that differences in regulations exist due to differences in the manner in which nations respond to their own food safety crises and trade disputes that arise from a variety of sources. Some of these causes
include changing regulations (Aruoma, 2006), difficulties in determining equivalencies, and difficulties in separating safety issues from consumer preferences, new or unfamiliar hazards and foods from unproven sources. U.S. Seafood trade has been one of the largest industries dealing with international standards and a shortage of common values led to serious consequences. Seafood safety violations related to microbial contamination, poisonous chemicals, filth, the use of unapproved aquaculture drugs or unsanitary conditions and general failures in HACCP comprise some of the most common and largest detentions or confiscation of products and recalls.

Figure 2.3 Value of U.S. Imports and Exports

The chart data represents trade of items under the North American Industry Classification System (NAICS) as code 311 designated to the food manufacturing industry (NAICS 311) transforms livestock and agricultural products into products for intermediate or final consumption. Subsectors in this category include animal food manufacturing (NAICS 3111), grain and oilseed milling (NAICS 3112), sugar and confectionery product manufacturing (NAICS 3113), fruit and vegetable preserving and specialty food manufacturing (NAICS 3114), dairy product manufacturing (NAICS 3115), meat product manufacturing (NAICS 3116), seafood product preparation and packaging (NAICS 3117), bakeries and tortilla manufacturing (NAICS 3118), and other food manufacturing (NAICS 3119).
In keeping with the need for higher mobility of foods, regulatory agencies have stepped up inspection requirements, documents, and certifications of importers, manufacturers, third party shippers and food safety related certifications. The majority of these safety requirements are HACCP and HACCP-related systems based, including verification and validation of processes, facility inspections and pre-requisite programs especially those pertaining to supplier certifications. Some of the most aggressive safety systems are administered in a safety-quality format that combines the concepts of HACCP with product quality and a stronger emphasis on traceability. WalMart’s requirement of vendors to adopt management systems incorporating Total Quality Management (TQM) has propelled food manufacturers (Noordhuizen, 2002) to adopt higher levels of food safety practices while incorporating customer satisfaction and defect minimization through statistical quality targets like Six Sigma. Similarly industry-driven global initiatives like the Global Food Safety Initiative (GFSI), are spearheading changes in safety and quality that channel through the supply chain and require HACCP principles to be adopted broadly (Fulponi, 2006).

**Food Safety as an Economic Opportunity**

Over the past century manufacturing operations throughout the world have taken giant leaps in capacity building, improving turn-around, quality and capabilities. While markets for electronics, automobiles and durable goods have grown dramatically to meet the demands of the worlds’ growing population, the food production and processing industries have had to meet the daily consumption needs of that population by exponential proportions. Deming’s Chain Reaction (Deming, 1986) demonstrates how manufacturing operations must strive to improve quality because profits, productivity and costs are functions of quality. Improving quality leads to lower costs, which in turn leads to increased productivity that then leads to higher returns on investment and yields more profits. However, because food is still a commodity and a necessity to fuel human life, price is the
ultimate driver of most food sales (Figure 2.4). Quality metrics in food directly involve consumer acceptability from the visual appearance of the food to taste and satisfaction, are embodied in total quality management (TQM) and similar systems that strive for measurable quality with an emphasis on continuous improvement, again in a measurable manner. Utilizing this rationale in food, then allows the production of less wasteful, higher quality foods that consumers want, in a more profitable manner.

![Figure 2.4 Quality Cycle - Adapted from E. Edwards Deming (1986)](image)

Economists report that organizations look at HACCP and preventive technologies as innovations (Ropkins and Beck, 2000). Business decision making on adopting and the level of adoption of such technologies, has been continually puzzling food
safety advocates. Surprisingly, the business justification for the general category of “innovations” (whether they are related to health and safety or not) has primarily considered purely financial justifications and profit potential alone in the adoption of such technologies. As a result the benefits of quality and safety aspects of a products’ competitive advantage(s) often garner far less value on the balance sheet when their consequences are viewed on short term rates of return on investment. This reluctance to adopt such competitive technologies has been well documented in many industries (Gruber and Brand, 1991; Sutherland, 1991) to the dismay of business analysts. In the case of foods, agro-processing industries carry the largest possible impact potential for affecting massive numbers of the general population, and therefore, should bear a social responsibility to provide consistently non-harmful products to their customers. To improve public health and for businesses to leverage the profitability that food safety can provide, businesses need to view food safety and preventive technologies not from the viewpoint of an innovation, but rather from a quality improvement or process improvement perspective that looks at food safety technologies as risk mitigation tools which lead to improved quality, reduced rework or reduced waste and higher profits that have public health consequences linked to brand integrity.

Overview of Food Safety Systems

The most rudimentary processes that historically have been used to preserve foods, have also been used to keep foods safe. The general principles of heating, cooking, drying, cooling and salting that were relevant thousands of years ago are still the methods by which food safety can be managed in the most basic of settings. As food businesses and their customer base grew larger, distanced by both space and time the needs for food manufacturers to consider preservation as a means of maintaining quality products has led to the evolution of modern food safety systems and their accompanying programs. In today’s international marketplace acceptable standards for food safety that use a common language and achieve quality standards of practice are the goals that food safety practitioners focus their attention upon.
HACCP-Based Food Safety Management Systems

Food safety systems based on HACCP have been widely acclaimed as the most effective means for producing safe food. HACCP has been endorsed by the National Academy of Sciences, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), and internationally by the Codex Alimentarius Commission (Codex, 2009) and the International Commission on Microbiological Specifications for Foods among others. From production to processing and retiling food, applying food safety practices as intended allows the best chance for delivering safe high quality food to the consumer. While HACCP application on a global scale has prompted the notion that HACCP can be applied as a cure-all to our food safety woes from farm to table, this approach is highly flawed (Sperber, 2005).

Alternately the application of pre-requisite programs to achieve farm to table food safety has far more promise. Pre-requisite programs take a preventive approach to food safety, instead of a tollgate approach. Each caters to various aspects of the food and the conditions it passes through, while applying various combinations of preventive measures to curtail the relevant threat factors at each step in the food system; production, processing, transportation or storage and consumer interface. This relationship is described in Figure 2.5 and will be referred to as the Food System Safety Controls Cycle (FSSCC). It summarizes the categories of food as it exists/moves through the food system, and identifies the preventive control measures that may be used in each respective control area. It is of interest to note how consumer access may occur at any step towards creating a processed food product and the burden of securing the safety of the food passes along to the consumer at the purchase point.

With the recent drive to develop local food economies that ideally reduce in-transit times and storage of foods, the relationships between each sector of the FSSCC has taken on
new dynamism that calls for less processing with a higher degree of safety right within the field or the farm environment. The FSSCC may be used at a high level by food businesses, to identify where they fit with respect to the practical application of preventive measures to ensure food safety, thereby putting into perspective the relevance of each preventive measure.

Figure 2.5 Food System Safety Controls Cycle (FSSCC), Identifying Gaps in Food Safety
This new emphasis on traceability calls for enhanced preventive controls-related (HACCP principles) training to be used in all parts of the food system, starting at the farm and all the way through to the restaurant and retailers, to assist workers and businesses achieve higher food safety goals. The Food Safety Modernization Act of 2011 (FDA, 2013), effectively put food safety on the list of federal priorities elevating regulatory scrutiny and targeting the focus of scientific efforts on improving food safety efforts. The proposed preventive controls rule proposes putting into effect title 21 CFR part 117\(^1\) which requires that HACCP principles to be adopted by small businesses previously not required to do so. Good Agricultural Practices (GAP) are now being combined with quality management concepts and delivered through Safety Quality Food Standard (SQF) programs geared at the primary producer (SQF1000). The idea of programs like SQF 1000 is to work with HACCP principles in the context of the production environment, and thus relies on sets of specialized HACCP-based training programs to achieve these goals. While these are still primarily industry driven in the U.S., similar programs in the European Union (British Retail Consortium Standard, FSSC22000 and ISO22000) are encouraged in order to strive for a uniform level of quality that can assist in trade. It is therefore, no surprise that such initiatives are driven by industry; like the Global Food Safety Initiative (GFSI) that works to standardize quality by driving the adoption of standards that meet specific benchmarks.

\(^1\) 21 CFR part 117 (current good manufacturing practice and hazard analysis and risk-based preventive controls for human food) which requires food manufacturing facilities (FDA facilities registered under section 415 of the FD&C act) have a written preventive controls plan, specific verification, validation activities, environmental testing and mandates that appropriately qualified individual prepare the food safety preventive control plan (FSPCP). Generally many previous recommendations will be required and no longer optional. This law also proposes the addition of supplier verification programs (FDA. 2013).
Table 2.1 Commonly Used Abbreviations Relating to Food Safety Management Systems

<table>
<thead>
<tr>
<th>Standard Abbreviation</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAP</td>
<td>Good Agricultural Practices</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard Analysis Critical Control Point</td>
</tr>
<tr>
<td>TQM</td>
<td>Total Quality Management</td>
</tr>
<tr>
<td>GMPs</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>SSOP</td>
<td>Sanitation Standard Operating Practices</td>
</tr>
<tr>
<td>PRPs</td>
<td>Pre-Requisite Programs</td>
</tr>
<tr>
<td>ISO9000:2005</td>
<td>International Standards Organization</td>
</tr>
<tr>
<td>SQF</td>
<td>Safe Quality Food (SQF1000, SQF2000 standards)</td>
</tr>
<tr>
<td>BRC</td>
<td>British Retail Consortium</td>
</tr>
</tbody>
</table>

Hazard Analysis and Critical Control Points Overview

HACCP is a program for critically identifying, minimizing and mitigating food safety risks. In effect, HACCP is the food processing related risk management tool that can be implemented in a food business. Since the adoption of these concepts at the Pillsbury* Company in the 1960s during the era of manned space exploration, HACCP principles have been relied upon by the food processing industry, restaurants (starting in 2006), and more recently assisted living and day care facilities (2011) to minimize and mitigate all foreseeable food safety risks by putting into place procedural controls that are effective and reliable. HACCP systems must be based on the 7 principles of HACCP (NACMCF, FAO) listed as:

1) Hazard Analysis
2) Critical Control Point Identification
3) Establishment of Critical Limits
4) Monitoring Procedures
5) Corrective Actions
6) Record Keeping
7) Verification Procedures
These principles of HACCP, in combination encompass the heart of the risk management system in a food business that is focused purely on the safety of the food. HACCP and its related programs, thereby, work as the key component that has the greatest impact on the public; preventing harm to the consumer. It is important to note that indeed, while food businesses must strive to achieve aesthetics, flavor and overall quality at a level that elicits a purchase, the ultimate burden of a food business lies in its ability to provide a usable product that causes no harm. It is to reach this objective that programs like HACCP were developed, to ensure the safety of the product. HACCP is a key component of the holistic quality management system and therefore, must work with other parts of the business. While it is focused on the prevention of hazards in a food product, monitoring and documenting the steps taken to prevent such hazards, it must also generate the appropriate systems that allow corrective measures to be taken in the event that a problem does occur. It is a system of preventive controls with documentation and procedures that demands swift action to minimize the production and release of unsafe food to the consumer.

**Components of HACCP**

While the seven principles of HACCP are the core of a HACCP program, and are executed by conducting HACCP training, followed by developing a HACCP plan that is implemented in the organization, HACCP’s success is often managed to a great extent through vital pre-requisite programs. In recent years the HACCP plan itself tends to receive the greatest deal of attention in a functional setting due to regulatory requirements that involve HACCP monitoring and validation procedures and documents to be the paper trail that deem a process as functional or not. It receives a high level of attention, although it is widely asserted by experts that pre-requisite programs and their stringency are the foundation upon which a solid HACCP system can exist. Pre-requisite programs include (but not limited to) a Sanitation Program; Good Manufacturing Practices (GMPs); allergen control program; supplier verification and inspections; water, air and environmental control;
training; equipment maintenance, verification and validation of the pre-requisite programs, record keeping and both internal and external audit programs.

**Developing a HACCP Plan**

The term HACCP program has been used interchangeably with HACCP Plan by some, and indeed depending on the type of application and size of business a HACCP plan may be the appropriate way to handle operations. Technically, the HACCP plan is restricted to the 7 steps of HACCP and its basic pre-requisite programs (sanitation standard operating procedures, GMPs, allergen and environmental controls). A HACCP program on the other hand, should include comprehensive pre-requisite programs including recall management, tracking and traceability, safety, comprehensive HACCP training and validation of training, together with a strong audit system. Figure 2.6 outlines the general steps in the HACCP process from product development to HACCP program development to HACCP in the operational setting. Figure 2.6 further describes the specific steps common to all HACCP (food safety preventive controls programs) providing a practical approach to achieving HACCP success.
Figure 2.6 Steps for developing a HACCP plan.

**Hazard Analysis**
- **Goal**: Identify what, where, when and how a hazard (physical, chemical, biological or radiological) may enter the food.
- **Best Practice**: Create a sequential process map, identifying each step, duration, location and environmental conditions at the action steps.

**Critical Control Point Identification**
- **Goal**: Distinguish between control points and critical control points.
- **Best Practice**: Justify controls and identify which controls warrant being upgraded to critical control points. Omit including controls in HACCP that are met through pre-requisite programs.

**Establishing Critical Controls**
- **Goal**: Identify best method of minimizing the risk.
- **Best Practice**: Set critical limits that can be rather easily accomplished under normal operating conditions. Identify operational limits such as temperature and volume so that critical limits fall within those operational limits and are achievable.

**Monitoring Procedures**
- **Goal**: Identify how you will check each point that has a risk associated with it and the relevant tools or techniques for accomplishing this.
- **Best Practice**: Balance effectiveness against ease of use for the specific operation.

**Corrective Actions**
- **Goal**: Identify how product will be dealt with if the required standards are not met at the critical control point, if and how the product will be reprocessed, held or disposed of.
- **Best Practice**: Define alternatives that are reasonable from a business perspective.

**Record Keeping**
- **Goal**: Maintain accurate, real-time records that help identify issues so they may be corrected quickly.
- **Best Practice**: Train all operators in obtaining, maintaining and utilizing records in a timely manner and with transparency.

**Verification Procedures**
- **Goal**: Ensure that the system works by checking each step, equipment and process.
- **Best Practice**: Use a secondary source of inspection, random checks, reviews and cross checks and validation procedures for challenging the system to ensure all steps function according to plan.
Pre-requisite Programs - Pre-requisite programs are essential programs that are run on a facility wide basis, as opposed to concentrated on the food product and processing, which are essential for the safety of the food. The World Health Organization (WHO) describes pre-requisite programs as programs that are necessary before, during and after the implementation of a HACCP program. Federal agencies require that various programs that fall under pre-requisite programs are not only maintained by the food processing establishments, but that these programs are a source of data that requires inspection. The Food Safety Inspection Service (FSIS) directive 5000.2, and the Code of Federal Regulations, under Title 9 section 417.2 referring to the development and use of HACCP systems, requires that records relating to pre-requisite programs be maintained and reviewed (USGPO, 1997). Despite the overwhelming evidence to support the need to implement pre-requisite programs, there is a gap in the understanding of pre-requisite concepts, and even a fear that the strength of HACCP may be diluted by pre-requisites (Wallace and Williams, 2001).

*Figure 2.7 Prevention-based Practices are the Common Language of Food Safety Systems.*
Current Good Manufacturing Practices (cGMPs) - Good manufacturing practices can be characterized as a system, or group of procedures by which the company may ensure high quality products are produced in a manner that minimizes potential for adulteration from any chemical, physical, microbiological or radiological hazards. GMPs include items like employee hygiene, environmental management, water quality, maintenance, building and grounds management as well as addressing equipment performance and safety programs.

Rodent and Pest Management Program - A pest management program is designed to minimize the populations of pests (insects, rodent etc.) that may lead to adulteration of the product both directly in the food processing areas and in the surrounding grounds, storage, and shipping areas. Rodent and pest management programs share a close relationship with environmental control, chemical controls and sanitation in their sharing of spaces and resources which at times may be in conflict with each other. Managing such programs, therefore, requires expertise and knowledgeable leadership to regularly monitor all parameters avoiding duplications or passing along responsibilities to another person or group.

Environmental Control Program - The integrity of the environment that surrounds the food processing operation, plant and critical areas are maintained by an environmental control program. In many cases, segregating processes by dividing into compartments or rooms, the use of screens, air locks, positive airflow or segregating raw from cooked or separating processing areas or workers are all parts of the environmental control program.

Sanitation Program - Cleaning and sanitation activities are performed with the goal of allowing safe and legal products to be produced in the food processing environment, while ensuring that the chemicals, equipment and materials used in cleaning and sanitizing the plant and equipment are properly stored and do not pose a risk to or contaminate the product being produced. Worker training is an essential part of sanitation, and includes
elimination of debris, cleaning and sanitization. The use of appropriate equipment for each purpose, the proper handling of those cleaning and sanitization agents as well as safety equipment and safe handling are all important parts of a robust sanitation program. Sanitation is likely the most basic of pre-requisite programs that any food business must include and is relevant for all food contact surfaces as well as non-food-contact surfaces and areas, common areas, and especially restrooms. The cumulative group of activities prescribed and/or recommended with methods and frequency of carrying out these activities are compiled into documented standards (SSOPs- sanitation standard operating practices).

**Chemical Controls Program** - Food processing environments include a variety of specialized equipment; silos and storage areas, packaging areas that include chemicals for maintenance, gluing, printing, sealing, solvents, lubricants, laboratory supplies, chemicals for sanitation as well as chemicals in the form of ingredients. A control program to manage these chemicals by restricting their use, ensuring personnel use appropriate methods and correct amounts within the appropriate plant is important to ensuring the product is not contaminated with hazardous chemicals. Standard use guidelines, storage methods conditions and locations as well as poison control information, safety precautions and vendor information should be clearly documented, marked on the containers and clearly posted where appropriate.

**Allergen Control Program** - Ingredients that have been identified as known allergens must be controlled from entering products in which they are not used as an ingredient. Allergen control includes appropriate sanitation, separation of equipment, separation and proper storage of ingredients, comprehensive labeling, inspection and segregation of packaging materials as well as supplier verification programs and laboratory testing to verify procedures are being followed and cross contamination is managed.

**Supplier Verification Program** - Agreements and understandings with suppliers may include laboratory testing, product and packaging specifications, as well as guarantees to ensure the
processor receives the product, raw materials or packaging items from suppliers that was agreed upon and that the quality and standards agreed upon are maintained on each and every batch of items delivered. By maintaining an effective supplier verification program, processors can manage allergens; maintain consistent product quality, trace back products and ingredients within a narrow range to manage costs and risks associated with possible errors, as well as track products, ingredients and their costs in a more efficient manner.

**Customer Feedback Program** - Customer complaints, distributor complaints and feedback from retailers or anyone downstream from the processing environment is a flag for quality issues that may have arisen during the creation of the product, packaging, storage or any number of issues. In general, customer feedback can be categorized into preference-related and quality-related issues. While preference feedback is useful information for the product development and marketing operations of a company, any and all quality related issues should be monitored for their relevance to product, contamination, safety from adding too little and too much of a certain ingredient, to weight differences or quality issues that may signal temperature abuse, packaging damage etc.

**Trace Forward and Trace Back Program** - Tracing a product once it has left the processing facility can assist processors in rapid recall or to quarantine a product in the event of a possible risk of any type. Similarly, a trace back program can assist with tracking down the source of risk entry into a product or simply provide the sourcing information needed to trace back and look at liability in a specific manner. Traceability is becoming an important component of HACCP’s pre-requisite programs that supports the entire HACCP system and can serve to minimize critical control points and manage an agile food safety program.

**Recall Program** - Having a pre-designed plan for handling a possible recall situation can make the difference in a food company’s ability to cope with, bounce back from and survive through a recall. Removal of the suspected product from the market swiftly with minimal
consumer impact is the primary focus followed by handling media, employees, and forensic process analysis in an efficient and effective manner.
HACCP Training

Training is likely the first step and most essential component of HACCP, and arguably should be categorized as a requirement, rather than a recommendation in developing a HACCP program. These training programs are currently offered in the United States by many individuals and organizations. Curricula have been developed and standardized by the International HACCP Alliance, Seafood HACCP Alliance, and the Juice HACCP Alliance. CODEX guidelines for HACCP emphasize training as a necessary part of implementing a HACCP system. However, CODEX does not provide specifics on the material individuals should be trained on, nor on who or how they should be trained. The United Kingdom and now many European Union countries are taking a widespread HACCP based approach for food manufacturing businesses and restaurants with curricula and the administration of examinations to qualify for certification. The International HACCP Alliance reviews proposed curricula by food safety professionals wishing to conduct HACCP training providing guidance, a database of scientific information to assist trainers and by issuing endorsements (seals) per HACCP trainee so they may be certified. Similarly, the seafood HACCP alliance conducts standardized trainings via authorized instructors that are followed by testing and issuance of a certificate. These standardized programs have evolved significantly from the initial concept of HACCP in food during the 1960’s and takes the approach of systematically analyzing the process, taking steps along the way to ensure safety so the final product does not require testing. As a preventive methodology, training for HACCP must then incorporate the practical aspects of applying the principles into any setting, given that manufacturers ultimately are the most knowledgeable about their processes. The training program therefore, is delivered with practical implications and examples and often hands on activities to fully train practitioners in taking charge of their HACCP operations. Additionally, online HACCP training programs are now becoming relatively more abundant allowing for ease of access to training for a greater number of individuals. The benefits of online access to HACCP training are many, especially with
tablet technology and the many mobile options making it a possibility to allow more food organizations to have more individuals be trained in food safety.

HACCP training is offered via a number of sources and presented in a variety of formats and durations. Examples of these are listed below:

- Introduction to HACCP (Typically a 1 day training program)
- HACCP Training (2-3 day training program)
- HACCP for Juice Processors
- HACCP for the Seafood Industry
- HACCP for the Meat and Poultry Industry
- HACCP for Restaurants and/or Retail Markets
- HACCP for Daycare
- HACCP for the Pharmaceutical Industry
- HACCP for Cosmetics
- Advanced HACCP Training
- Train the Trainer approach

**HACCP Implementation**

United States Federal regulations addressing meat, poultry, seafood and juices currently require that processors implement and maintain a HACCP plan (Martin & Anderson, 2000), and that monitoring records related to that plan are inspected on a regular basis. In developing a HACCP plan, practitioners are trained to conduct a “HACCP study”, which walks through the processing steps in their particular operations paying close attention to specific types of hazards that the product may encounter at any time. Hazards to be included in the HACCP plan are those items that would not otherwise be addressed through a pre-requisite program. Once this hazard analysis step is complete and control points are identified, control points can then be analyzed so they can be upgraded to critical control points (CCP) or remain as a control point (CP). The major difference between “critical
control points” and “control points” is that critical control points must meet the critical limit, or benchmark value (temperature, time, yes or no etc.) and failure to meet or be within that critical limit would result in re-evaluation of the product’s safety and ability to enter the market if reprocessing is allowable.

When designing and implementing a HACCP system guidelines for success have been widely propagated throughout the industry (NACMCF, 1997; USDA/FSIS, 1999; WHO, 1999). Additionally new FDA educational materials include several guidelines for preparing HACCP-principles related food safety plans and developing good manufacturing practices (GMPs), and criteria/standards to be used for monitoring the environment, surfaces, critical controls for microbiological controls, allergen management, food labeling, packaging claims, water purification, processing or usage parameters for various food types, food dyes and additives and other programs that are critical to HACCP’s success. While many standards provide a good framework for developing a food safety management system, the practical applications of such a system are often conducted using the following approach:

1) Utilizing a team based approach
2) Developing a strong system of pre-requisite programs
3) Developing a strong in-house self auditing protocol
4) Assigning responsibilities and authority to practitioners

To enable companies in better implement HACCP and related quality standards, guidance documents and manuals, electronic systems, software and sophisticated tracking methods have been commercialized by forward thinking organizations. Many of these systems are in use especially in larger organizations. Indeed, these systems are often able to meet the demands of regulators and other gate keepers with easier means of data gathering and maintenance. The basics of HACCP when implemented in combination with the technology to support traceability and tracking systems should then be capable of conducting business in an aggressively defensive manner, capable of tracking and minimizing waste and acting swiftly and precisely in the event of an emergency. True success in such a setting should
never give rise to a recall or a case of foodborne illness. However, real world problems with food safety often ensuing in a public incident tend to be far better examples to learn from. For instance, the FSIS Class I recall\(^2\) in February 2013 (FSIS-RC-015-2013) of frozen fully cooked country fried steak produced by an Oklahoma company, demonstrated the lack of several critical features of HACCP and its accompanying programs. While it is known exactly how many pounds of product were recalled (15,328 pounds), this incident demonstrates that no measures to prevent contamination were taken in the first place (a plastic bin was ground in with the product), and once the plastic was introduced, no measures were taken to stop the processing, or prevent shipping out the product. After being distributed through Walmart stores across 29 states, the presence of the plastic was detected by two consumers which prompted the recall. While this company is required to operate under a HACCP plan with federal inspectors on site, this is an example of several check points that either did not exist, were mismanaged or more likely an example of a worker who observed the incident and failed to report it.

\(^2\) Class I: Dangerous or defective products that could cause serious health problems or death (eg: food contaminated with *Clostridium botulinum* toxin, or labeled with undeclared allergens)
Class II: Products that might cause a temporary health problem, or slight threat of a serious nature.
Class III: Products that are unlikely to cause adverse effects or that violate labeling laws.
Quality Management Systems

As a component of the quality management system, HACCP implementation fulfils several needs that are internal and external to the organization, and must conform to work effectively for each unique organization. While it is important to distinguish between quality concepts and food safety (with HACCP primarily designed to fulfill safety needs), when applied as a component of the quality management system (QMS), HACCP has 4 levels at which it must integrate into the company; 1) Process, 2) Inspection/Regulatory, 3) System Integration and 4) Cultural Integration

![Figure 2.8. Four Levels of HACCP Integration within a Company](image)

Process

Assembly, preparation, processing and packaging are processes that have discrete characteristics for each product being manufactured. A meat processor producing raw sausages may be concerned with the cuts of meat, seasonings and casings that are used in the product, the time and temperatures to ensure the product is safe, minimizing microbial growth and to ensure no metal shavings, bone or non-conformant casing parts get into the final product. A processor of cheese, on the other hand may be concerned with storage temperatures, enzymes and salt to achieve the quality and product identity that he desires, paying much closer attention to worker hygiene and environmental conditions than the sausage manufacturer. These activities are process-related factors that can be included in the
HACCP plan, but with very different control steps in each establishment. While sanitation in a dairy plant may be addressed a little differently in each operation, the concepts relating to sanitation remain the same; cleaning to remove food and debris, followed by sanitization with specialized chemical agents to ensure pathogens are no longer present and finally ensuring no chemical residues are transferred into the food. The concepts taught in a HACCP training program pertain to the appropriate use of cleaning and sanitation to minimize the need for critical control points. In other words, if a sanitation program (pre-requisite program) is properly designed and executed, the needs for sanitation related controls are still needed, but no longer critical. In practical applications, then, a failure in sanitation, should be corrected, but does not have a go/no-go effect on the product. Proper storage and use of cleaning agents, then becomes an auditable step either in HACCP or in the pre-requisite program.

**Inspection/Regulatory**

Meat and Poultry operations from slaughter to primary and downstream processing use monitoring and record keeping data ready for inspection. From the perspective of meeting the requirements relevant to daily or regular inspection, HACCP plans need to be designed so the standard operational plan is a relatively easy goal to meet every day. Deviations from the norm, such as not meeting a critical control point need to be considered and possible corrective protocols need to be clearly defined. Often the prompt for HACCP training and implementing HACCP programs comes from a regulatory requirement that eventually leads to HACCP being viewed purely as a means of appeasing the regulator, rather than a tool for managing organizational risk and mitigating product and thereby financial losses.

**System Integration**

HACCP systems don’t exist by themselves in any food business. Although standards have been designed to help the process take components of quality management in bite size
chunks, by offering separate stand alone standards (ISO:22000, FSSC:22000), they are related to other processes and interactions that go on within businesses. Human resource availability has a direct bearing on HACCP. Monitoring procedures require work to be performed on a consistent basis by employees. Short staffing, or the reduction in processing staff due to illness, vacation or reassignments need careful consideration so food safety process needs can be met. In this instance, HACCP programs are compromised by human resource dictates if priorities are not focused on essential quality.

**Cultural Integration**

Management support to safety has been studied in correlation to the success of safety and quality programs in several industries including woodworking, medical, construction, nursing and others. Developing a safety culture involves providing ample access to training and knowledge. Heightened vigilance is prioritized as an organizational goal to actively engage employee and provide organizational support. For achieving a high level of workplace safety organizations have drawn from other industries such as automobile manufacturing and the 5S system at Toyota (sort, sweep, shine, standardize & Sustain) to help maintain an organized operation, and encourage discussion to consistently improve. Developing this culture of workplace safety has also been widely studied and correlations have been made linking a strong safety culture to success in quality management (Brown & Holmes, 1986; O’Toole, 2002). Indeed, several organizational benefits are gained with higher levels of safety practices, but the improved employee attitude, better job performance and higher relative individual productivity (Cohen, 1993) are large influencers of nurturing positive work cultures.

While each of these factors (process, inspection, systems and cultural integration) are vital and occur on some level in all organizations, it is ultimately the culture of an organization that either facilitates or adds roadblocks to successfully implementing any program such as HACCP. As Figure 2.8 illustrates, the largest platform for supporting each
part of HACCP implementation into a successful system lies within the culture of the organization. Putting together a process can therefore, only work when the culture allows and supports it. Similarly, each type of organization requires varying degrees of training support. The common feature to each is training and adopting a prevention-centric approach to food safety (Figure 2.9).
Figure 2.9 Food Safety Systems are Built upon Training

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CHAPTER THREE

Rationale and Study Design

Application of HACCP

HACCP has been applied in a variety of settings, requiring that training needs to be provided to those individuals in each setting, adapting the program accordingly and ensuring it can be managed successfully. A survey of existing literature indicates that implementing HACCP requires variations in the level and depth of training to achieve higher success. For example, personnel in the airline catering industry needed food handlers to be actively involved in the “HACCP study” to identify critical control points, and to review best methods of cleaning, so that science-based training on foodborne diseases and hygiene could replace learning from peers or colleagues as they typically provide inadequate training (Beumer et al., 1994). This population of food handlers requires that HACCP training delivery occurs in a manner that is conducive to the practical understanding and application of those principles with an emphasis on hygiene. Similarly, applying HACCP to retail food stores considers the complexities of that environment by identifying facility design, centralized training and standardized processing of ready to eat products as production activities that are performed by individuals trained in each specific product area. The higher staff turnover, shelf space limitations, and limitations in the amount of HACCP related training that can be feasibly delivered have been identified as challenges, while success factors include built-in technologies like alarms and data loggers, reducing paper record keeping and the use of centralized training methods (Reimers, F., 1994). The application of HACCP has also been studied in the pasteurization of milk, ethnic foods, hospitals, large

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3 A HACCP study is conducted with each new product to ensure no new hazards are introduced into the processing environment. When new hazards are identified methods for controlling them are determined, prerequisite programs are updated as needed, critical control points are set or revised accordingly and updates are made to existing HACCP plans or a new HACCP plan is developed by addressing the remaining HACCP principles.
scale food service operations, red meat, fermented sausage, animal production, bakeries, chocolate, meat and poultry processing and several others. Some common threads in each of these studies include the critical nature of training all involved personnel, the need for specific examples in keeping with the operation and that inspection cannot serve as a means for ensuring safety even if the operators are compliant. Food safety requires an inclination for food workers to operate hygienically at all times, and this can only be achieved through appropriate training.

The economics of implementing HACCP have been critically evaluated by several in the light that HACCP is now being required by so many regulatory agencies, and particularly in the interest of supporting international commerce. Post implementation costs of HACCP and SSOP’s have been quantified at $0.009 per pound for small meat processors (Boland et al., 2001). However, clear resistance to HACCP implementation has been documented (Pansiello & Quantick, 2001; Taylor, 2001; Taylor & Taylor, 2004; Jevsnik, Hlebec & Raspor, 2006, 2008; Bas et. al., 2007; Taylor, 2008). A study (Herath & Henson, 2010) identified four areas of concern with varying levels of importance to different types of businesses with respect to barriers to HACCP implementation:

1) Perception of questionable appropriateness
2) Scale of change required for implementation
3) Food safety controls receiving low priority
4) Financial constraints

Several other studies have focused their attention on the administration of HACCP from the perspective of its applicability and relevance to certain classes of businesses and the regulatory burden that inspection requires. A cost-benefit analysis of HACCP implementation in Mexico4 reported that the largest investments took the form of new equipment and

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4 The Mexican meat processing industry does not mandate HACCP implementation for the domestic market.
microbiological testing, and that staff training posed a significant problem (Maldonado et al., 2005).

The scientific literature further provides a large array of knowledge pertinent to various food processing and preparation operations with a focus on training. The vast number of studies relating to food safety and HACCP related training knowledge focuses on food handler training, food safety knowledge level or competence as it relates to retail or restaurant operations, and the application of food safety practices following training activities. A few recent studies spearheaded by Wallace and colleagues have begun evaluating HACCP knowledge and HACCP team dynamics (Wallace and Williams, 2001; Wallace et al., 2005; Wallace et al., 2012). Much of this work provides insights into international HACCP team knowledge, with the most recent work revealing how HACCP team decisions could potentially be faultier than those of individual contributors. It has also been noted that personality attributes play a role in HACCP plan administration and decision making that could potentially limit team operation. This suggests that HACCP team member selection requires care to include “the correct blend of technical and HACCP principle application expertise, practical experience, team-working, administration and leadership skills, and that HACCP teams are allowed sufficient time to perform their important role in food safety management” (Wallace et al., 2012)

**HACCP Related Product Recalls**

Both USDA and FDA use a Class I, Class II and Class III recall designation with I being the most severe, and III being the least severe in terms of the contaminated food's potential for causing illness or harm. Table 3.1 provides a snapshot of the causative agents that prompted product recalls in recent years. The primary reason for food safety (critical) recalls is related to contamination by an identified hazard, and rightly so, due to the grave nature of illnesses (from microbial agents) or harm (from metal, plastic or chemical contamination) that can occur with consuming the contaminated food. The next largest
recall prompter (almost as large as from hazards) can be categorized as the lack of or failures in pre-requisite programs. Unlike the hazards identified by HACCP, a large proportion of these (pre-requisite related) recalls comes from contamination by mislabeling and the largest proportion from failure to declare an ingredient, mostly allergens. Many of these recalls can be linked to team members’ non-adherence to a component of the HACCP program (Azanza et al., 2005). Unlike a tangible hazard that yields the product unsafe for consumption, labeling related recalls have high financial costs and massive product waste even though the allergen containing product itself essentially had no other defect. It is these recalls that ultimately lead to absurd losses on a regular basis and have an opportunity for minimization through the reduction of human error through process control.
Table 3.1 HACCP-Related Product Recalls (FDA regulated products)

<table>
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<th>FDA Recalls Classified by Cause</th>
<th>2010</th>
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<th>2012</th>
<th>2013*</th>
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<tbody>
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<td>Allergen (labeling related)</td>
<td>65</td>
<td>102</td>
<td>98</td>
<td>15</td>
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<td>Chemical Hazards</td>
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<td>Physical Hazards</td>
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<td>8</td>
</tr>
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<td><em>Clostridium botulinum</em></td>
<td>7</td>
<td>26</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td><em>E.coli</em></td>
<td>11</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>26</td>
<td>46</td>
<td>86</td>
<td>11</td>
</tr>
<tr>
<td><em>Salmonella Sp.</em></td>
<td>111</td>
<td>57</td>
<td>115</td>
<td>2</td>
</tr>
<tr>
<td><em>Bacillus cereus</em></td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Quality/Safety Issues</td>
<td>3</td>
<td>5</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Mislabling/Exceeding Chemical Limits (Sulfites, Incorrect Content, Nitrites etc.), misleading labeling</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Other (No HACCP plan, HACCP failure, Other microorganism)</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>237</strong></td>
<td><strong>268</strong></td>
<td><strong>352</strong></td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recalls Classified by the Relevant HACCP Focus Area</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-requisite Programs (Sanitation, GMP, Allergen Management)</td>
<td>65</td>
<td>104</td>
<td>99</td>
<td>15</td>
</tr>
<tr>
<td>Hazards Controllable by HACCP (Physical, Chemical, Microbiological Hazards)</td>
<td>164</td>
<td>156</td>
<td>237</td>
<td>22</td>
</tr>
<tr>
<td>Quality</td>
<td>3</td>
<td>5</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>3</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>237</strong></td>
<td><strong>268</strong></td>
<td><strong>352</strong></td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>

*2013 recalls include incidents from Jan1- March 8 (FDA recall database)
Training Program Assessment

Evaluating various aspects of training programs, in the classroom setting or with online delivered classes, is not a new practice. In most cases training programs are evaluated for a wide range of factors. The post training evaluation often is short and pointed, aimed at retrieving responses for specific areas that are important to the trainers or organizers of the course.

Following is a list of areas that a post-training assessment often involves:

1) Course delivery location
2) Trainer competence
3) Relevance of training material
4) Style of delivery
5) Instructor likeability
6) Test of materials covered
7) Evaluation of concepts understanding

Of the above areas that could be addressed through a post training assessment, the test of concepts understanding (take home message) was chosen as the most important and relevant to this study and expanded upon in this web-based survey.

HACCP pre-requisite programs’ training is evidently an area that needs more focus. In fact, poor food safety training, the lack of food safety training, the high cost of food safety training and the limits to accessibility of food safety training have been criticized as factors upon which foodborne disease outbreaks, antibiotic resistance and the development of new strains of pathogenic microorganisms have emerged (Sofos, 2008). Controlling all types of hazards in food production and processing environments rests upon the people that do the work, manage the system and conduct routine functions, including design, implementation and testing of the food safety processes and system. As previously illustrated, training is the most basic component needed to get personnel on board with managing these programs and
managing risks. Many smaller food businesses provide a one-time training in HACCP if at all, with few opportunities for continued educational support. Additionally, few food safety standards require retraining as discussed previously. While each type of food safety system component has serious implications to the business and its costs, the limitations in our understanding of the durability (ability to last without significant deterioration) of HACCP training has not been uncovered.
Hypotheses

To evaluate the progression of HACCP knowledge use, retention and practical translation into a living HACCP program, this study focused on two research questions;

1. What is the durability of HACCP knowledge?
   Null hypothesis 1: There is no relationship between time since HACCP training and knowledge retained.

2. What factors influence the durability of HACCP knowledge?
   Null hypothesis 2a: There is no relationship between HACCP concepts and their retention.
   Null hypothesis 2b: There is no relationship between socio-demographic characteristics of trainees and retention of HACCP knowledge.

Since this was a measurement of the longevity of the HACCP knowledge some assumptions about HACCP training were necessary:

a) HACCP training is conducted by competent, qualified individuals who are skilled at teaching.

b) HACCP training is generally conducted in a standard manner in keeping with the guidelines for appropriate food safety standards, covering all required concepts.

c) Trainees were present for the entire HACCP training program.

d) Finally, it is important to define the meaning of “durability” in the context of this study, which for our purposes will be the useable knowledge following the training event that is retained over a period of time. The interval duration of time following training at which point useable knowledge loses or begins to lose its accuracy, marks the time period where durability changes and HACCP knowledge is no longer durable.
Approach

A web-based survey (Appendix B) was used to collect the data to assess these research questions. Survey development required identifying specific goals/concepts to be evaluated so that meaningful conclusions could be made about HACCP knowledge and factors involved in its durability. The following logic process (Figure 3.1) was used in developing the survey questions:

Figure 3.1 Logic Process for Developing Survey

Step 1: Identifying HACCP Concepts

The survey questions were developed to include key HACCP and HACCP pre-requisite content areas that are either required by curriculum standardizing organizations (International HACCP Alliance, Juice HACCP Alliance, Seafood HACCP Alliance, ISO22000:2005) or, included in U.S. regulations as necessary to HACCP and therefore should be included in HACCP instruction and in food safety programs. The following
(Table 3.2) is a grouping of question areas that would be considered key “take home message” concepts after completing a HACCP training program.

**Table 3.2. Concepts for Evaluation**

<table>
<thead>
<tr>
<th>General Concept Area</th>
<th>Concepts to be evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Analysis</td>
<td>What are/are not hazards</td>
</tr>
<tr>
<td>Critical Control Point</td>
<td>Designation of “Critical” Control Points</td>
</tr>
<tr>
<td>Identification</td>
<td></td>
</tr>
<tr>
<td>Establishment of Critical</td>
<td>What is a critical limit and how to identify critical limits for your operation</td>
</tr>
<tr>
<td>Limits</td>
<td></td>
</tr>
<tr>
<td>Monitoring Procedures</td>
<td>Monitoring devices</td>
</tr>
<tr>
<td>Corrective Actions</td>
<td>Handling corrective actions, and deviations to the process</td>
</tr>
<tr>
<td>Record Keeping</td>
<td>Do’s and Don’ts of record keeping</td>
</tr>
<tr>
<td>Verification Procedures</td>
<td>Validation and Verification of HACCP system, who, what, how it may or may not be done</td>
</tr>
<tr>
<td>Pre-requisite Programs</td>
<td>Customer Feedback, Complaints, Allergen Management, Good Manufacturing Practices,</td>
</tr>
<tr>
<td></td>
<td>Environmental Conditions, Pests Control, Water Quality, Cleaning and Sanitation, Supplier</td>
</tr>
<tr>
<td></td>
<td>Verification</td>
</tr>
<tr>
<td>Traceability</td>
<td>The relevance of traceability and relevant procedures to HACCP</td>
</tr>
<tr>
<td>Safety</td>
<td>Safety environment, ergonomics and general support for (worker safety and) food safety</td>
</tr>
<tr>
<td>Training and Organizational</td>
<td>Access to training, work instructions and relevance of work instructions to achieving</td>
</tr>
<tr>
<td>Support</td>
<td>food safety, management support for HACCP</td>
</tr>
<tr>
<td>General HACCP program areas</td>
<td>Process maps, Revisions, Overall Impressions, Perceptions about business support available for HACCP</td>
</tr>
</tbody>
</table>

HACCP training program curricula typically consist of the 7 principles of HACCP, pre-requisite programs, verification and validation methods as recommended by the Food Safety and Inspection Service (USDA/FSIS, 2008, 1999), Food and Drug Administration (FDA, 2006), as well as Codex (Codex, 2009) and ISO22000:2005 (Harrigan, 1993), as minimum requirements. These HACCP standards also correlate to other food safety
standards and the proposed food safety preventive controls program concepts, as well as including some content about the legal requirements of HACCP. These regulatory requirements are outlined in Table 3.3 and are HACCP curriculum recommendations corresponding to HACCP or prevention based food safety programs described in the Federal register.

Table 3.3 Curriculum Requirements/Recommendations

<table>
<thead>
<tr>
<th>Common Regulatory Agency Requirements Used for Concept Evaluation in this Study</th>
<th>USDA./FSIS HACCP Guidance (Meat &amp; Poultry)</th>
<th>FDA/Seafood HACCP Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary Steps</td>
<td>Assemble HACCP team (1 HACCP-trained), Develop flow diagram, Describe food, Decide product grouping categories.</td>
<td>21 CFR Part 110</td>
</tr>
<tr>
<td>Pre-Requisite Programs</td>
<td>9 CFR Part 417.2</td>
<td>21 CFR Part 123.10</td>
</tr>
<tr>
<td>Possible Hazards -Natural toxins, microbiological contamination, chemical contamination, pesticides, drug residues, zoonotic diseases, decomposition, parasites, unapproved use of color additives and physical hazards</td>
<td>9 CFR Part 417</td>
<td>21 CFR Part 123.6</td>
</tr>
<tr>
<td>Preventing Re-occurrence</td>
<td>9 CFR Part 417.3</td>
<td>21 CFR Part 123.8</td>
</tr>
<tr>
<td>Corrective Actions</td>
<td>9 CFR Part 417.3</td>
<td>21 CFR Part 123.7</td>
</tr>
<tr>
<td>Re-evaluate HACCP plan (Deviations, Changes in Vendors)</td>
<td>9 CFR Part 417.4</td>
<td>21 CFR Part 123.9</td>
</tr>
<tr>
<td>Monitoring activities, Ongoing validation</td>
<td>9 CFR Part 417.4</td>
<td>21 CFR Part 123.7</td>
</tr>
<tr>
<td>Calibration, Record Keeping, Operating within Critical limits</td>
<td>9 CFR Part 417.4</td>
<td>21 CFR Part 123.11</td>
</tr>
<tr>
<td>Record Keeping</td>
<td>9 CFR Part 417.5</td>
<td>21 CFR Part 123.11</td>
</tr>
<tr>
<td>Supplier Certification</td>
<td>9 CFR Part 417.5</td>
<td>21 CFR Part 123.9</td>
</tr>
<tr>
<td>Monitored CCPs</td>
<td>9 CFR Part 417.5</td>
<td>21 CFR Part 123.11(b)</td>
</tr>
<tr>
<td>Actions following deviations at a CCP</td>
<td>9 CFR Part 417.5</td>
<td>21 CFR Part 123.7</td>
</tr>
<tr>
<td>Employee training records maintained</td>
<td>9 CFR Part 417.5</td>
<td>21 CFR Part 123.7</td>
</tr>
<tr>
<td>Criteria for Inadequate HACCP system</td>
<td>9 CFR Part 417.6</td>
<td>21 CFR Section 402</td>
</tr>
<tr>
<td>Cleaning and Sanitation</td>
<td>9 CFR Part 417.6</td>
<td>21 CFR Part 123.11</td>
</tr>
<tr>
<td>Employee health, hygiene and education</td>
<td>9 CFR Part 417.7</td>
<td>21 CFR Part 123.5</td>
</tr>
</tbody>
</table>
Step 2: Develop Concept Questions

The questions were randomized and placed in either a True/False response format for direct HACCP concepts, a 5 point Likert scale format or a 7 point Likert scale format (Strongly agree to Strongly disagree) for more objective questions (Burns and Burns, 2008). The following Tables (3.4, 3.5, 3.6 and 3.7) list each question from the survey and matches them with the corresponding content area/support system and approach taken in implementing HACCP.
Table 3.4 HACCP training content Block 1

<table>
<thead>
<tr>
<th>Basic HACCP Content Areas</th>
<th>Pre-Requisite Program</th>
<th>CP/CCPs</th>
<th>Validation</th>
<th>Monitoring &amp; Record Keeping</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial validation of the HACCP program should be completed by a team of individuals from manufacturing.</strong></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Chemicals used for cleaning and sanitation purposes should be stored close to the area where they will be used.</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemicals are not considered a source of contamination in food products.</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is important to include as many critical control points as possible in a HACCP plan.</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trace forward and Trace back procedures are related to HACCP.</td>
<td>x</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Customer feedback is not considered a pre-requisite program for food safety.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>A HACCP plan can be skillfully developed through process mapping that accounts for all steps in the operation.</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Utilizing Good Manufacturing Practices (GMPs) and sanitation can minimize the number of critical control points.</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All control points should be designated as critical control points in a HACCP plan.</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>The critical limits must be set for the process before operational limits are determined.</td>
<td>x</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>For a product that must be cooled to ensure its safety, critical control temperature must be higher than operational temperatures.</td>
<td>x</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Customer complaints are not considered an indicator of issues with food safety.</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Initial validation of a HACCP plan must be conducted by independent experts.</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Chemicals should be stored away from food processing areas.</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintaining a cold chain is an effective method for controlling the growth of pathogens.</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>For a product that must be heated to ensure safety, operational temperatures must meet or exceed the critical temperature that is set at a Critical Control Point.</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Secondary HACCP Content Areas, Food Safety Culture and HACCP Operational Support</td>
<td>Culture</td>
<td>Systems Integration</td>
<td>Inspection</td>
<td>Process</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Maximum Score Per Question = 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am given time by my supervisor to participate in food safety training activities.</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I participate in the HACCP team/committee or activities during the year.</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Company Management (production manager, supervisors) visibly demonstrates a commitment to food safety.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My immediate supervisor actively encourages the reporting of all unsafe conditions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel comfortable reporting quality and safety issues to my immediate supervisor or a member of the operations/leadership team.</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>When I observe a food safety concern, I report it.</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When improper environmental and/or safety conditions are reported, they are prioritized and addressed in a timely manner.</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>When time/temperature readings do not fall within critical limits, immediate action is NOT taken to correct the issue.</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>I am given time by my supervisor to participate in process improvement activities.</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-requisite programs such as sanitation, supplier verification and allergen management are critical to implementing an effective HACCP system.</td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Sanitation is NOT an important part of the HACCP program.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning is a pre-requisite to sanitization.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3.6 HACCP Implementation and Management Block 2- Part 2

<table>
<thead>
<tr>
<th>Secondary HACCP Content Areas, Food Safety Culture and HACCP Operational Support</th>
<th>Part 2</th>
<th>Maximum Score Per Question = 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am encouraged to report early, any signs of pain or discomfort (ergonomic) as soon as I first notice it, even if it is just a small pain.</td>
<td></td>
<td>x x</td>
</tr>
<tr>
<td>Appropriate corrective actions are implemented after accidents or near misses to prevent re-occurrences</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>I am comfortable to perform my job function.</td>
<td>x</td>
<td>x x</td>
</tr>
<tr>
<td>My work team pays special attention to review paperwork and make the necessary changes to adjust temperature and time chart values only when a food safety audit is due.</td>
<td></td>
<td>x x x</td>
</tr>
<tr>
<td>When new ingredients or vendors are chosen a member of the HACCP team is involved in those decisions.</td>
<td>x x x x x x</td>
<td></td>
</tr>
<tr>
<td>My supervisor has provided me with information on how my job function relates to food safety.</td>
<td>x x</td>
<td>x x</td>
</tr>
<tr>
<td>I spend additional time preparing paperwork or my work area for a food safety inspections or audits.</td>
<td></td>
<td>x x x</td>
</tr>
<tr>
<td>The HACCP team re-evaluates the company HACCP plan whenever a new product is being developed for production.</td>
<td></td>
<td>x x x</td>
</tr>
<tr>
<td>I receive the results of food safety audits performed in my work area.</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Monitoring water quality is NOT important to the HACCP system.</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>The costs of maintaining a HACCP system are too great for the benefits it offers.</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>My supervisor has provided me the necessary tools and information on how to perform my job safely.</td>
<td>x</td>
<td>x x</td>
</tr>
<tr>
<td>All monitoring equipment must be frequently calibrated and kept in good working condition.</td>
<td>x</td>
<td>x x x</td>
</tr>
<tr>
<td>I am satisfied with my contribution to food safety at my organization.</td>
<td></td>
<td>x x</td>
</tr>
</tbody>
</table>
### Table 3.7 HACCP Implementation and Knowledge Translation

<table>
<thead>
<tr>
<th>Adequacy of Training Material</th>
<th>Ability to Translate Training into Action</th>
<th>Operational Support for HACCP</th>
<th>Overall Value Perception</th>
</tr>
</thead>
<tbody>
<tr>
<td>HACCP training provided me the information and knowledge needed to successfully prepare a HACCP plan at my organization.</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>HACCP training provided me the knowledge to effectively contribute to the HACCP team.</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>HACCP training was insufficient to contribute to developing the HACCP system at my organization.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>It was important for my organization to have a HACCP consultant work with us to verify our HACCP plan.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP training is a necessity for all employees of a food business.</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Upper management support is important for effectively managing a strong food safety system.</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>HACCP training is only needed for those who are involved in quality assurance.</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>HACCP training is only needed for those who are involved in production and processing.</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>HACCP training is NOT necessary for those involved in sourcing or distribution.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP training has helped my organization to produce a higher quality product.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>HACCP can minimize the risks of a product recall.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Questions could be categorized by specific area of HACCP, management, organizational support, access to or support for training, operational factors etc. and the relevance of each area to each question can be found in Table(s) 3.4, 3.5, 3.6 and 3.7. Each question was carefully framed in order to evaluate concept\(^5\) understanding, as opposed to

\(^5\) A concept refers to a generalized understanding of a topic, a thought or notion that is derived as a result of an interaction or experience (Merriam-Webster Dictionary)
specifics of the training materials. For instance, monitoring of products, equipment and environmental conditions is an important component of HACCP and is designated as Principle #4 of the 7 Principles of HACCP (International HACCP Alliance). This principle of HACCP during training is addressed with specifics about monitoring methods (temperature measuring devices, labeling, packaging, pH, pathogens of concern etc.). The concept, in this context, is that monitoring of important aspects of the food and the environment it was produced in or a method by which contamination can be minimized has to be measured and recorded in order that a paper trail of monitoring can be established.

Step 3: Complete Survey and Post Electronically

Once the questions were developed, they were organized into a survey, taking care to distribute topics in an alternating manner in order to simulate randomness of concepts. The online questionnaire was built to include logic functions to allow respondents be directed to the end of questionnaire if they had not completed HACCP training, or to other parts of the survey based on their responses. This survey was then launched through Qualtrics® survey analysis tool (www.qualtrics.com) and tested for ease of use and functionality, modifications were made as needed and the study was initiated.

The questionnaire was designed to test a defined group of HACCP training concepts and HACCP program development/implementation (HACCP knowledge translation) content areas as outlined in (Appendix B). To answer the question of durability it was deemed fitting to gather data from as diverse a group of trainees as possible, defined as those who had received training from a variety of individuals/organizations. A web-based questionnaire was chosen as the most appropriate method of gathering this information effectively and relatively quickly. Choosing to administer this study online also provided some valuable information on the accessibility of web-based services (while at work) to food processing workers, while being more cost effective than a mailed out survey. Figure 3.2 summarizes the recruitment method.
The target respondent number was set at 1000 responses. Previously HACCP trained individuals with no restrictions on how, where, or when they had received their training were invited to participate in this study via an e-mail invitation that was distributed either via HACCP trainers, or members of the HACCP/quality team at a variety of food manufacturing businesses. Once the content areas to be queried were identified, questions were developed and trial surveys were completed to estimate duration, navigation, logic and ease of use. In keeping with obtaining the relevant information about training, the survey outputs would provide summative data on “if” and “when” an expiration date exists for HACCP knowledge with respect to the lapse in time post training and the conditions that play a role in knowledge retention and HACCP program success.

Subject Recruitment

This survey research was conducted following a review and approval of the study protocol (Appendix C) by the IRB (Institutional Review Board), (Appendix A, IRB Approval #12-0343-P4S). Since a significant portion of HACCP training and certification is closely linked with the International HACCP Alliance (IHA) by trainers needing to purchase
registration seals and then providing names of trainees back to the HACCP alliance for 
registration, the recruitment process initially included recruiting participants in collaboration
with the IHA. But surprisingly, the IHA does not maintain a database of HACCP certified
individuals, nor their work roles or contact information. Therefore, IHA was unable to
directly recruit study subjects, but did agree to forward the recruitment invitation to trainers
who were registered with them who would then invite their own respective groups of
trainees. However, this approach as well proved to be unsuccessful so no further action was
taken by IHA to assist with this study.

Hence, to recruit study subjects, invitations were sent to participants of HACCP
training programs conducted by the University of Kentucky, and by recruiting the assistance
of HACCP trainers listed on the IHA website. The response rate was less than 10% from in-
house trainees during the initial survey launch and those invited through state food safety
partners. Since the only incentive study participants could receive was a written report
summarizing the findings of the study, it was decided that a more attractive/popular option
should be included to encourage participation. To incentivize responses study participants
would now be entered into a lottery for an Apple iPad® device and the new procedure was
implemented (Appendix E). The modified IRB was obtained (Appendix D) to reflect the
incentive change and study invitations were then sent directly to HACCP trainers listed on
the International HACCP Alliance website and by contacting state HACCP coordinators or
other recognized HACCP trainers. Trainers were asked to forward the message by e-mail to
their respective trainees, and provide the investigator with an estimated number of
individuals receiving the invitation. Through this method of recruitment study participants
were able to maintain anonymity if they chose to do so and to restrict providing contact
information for the express purpose of the lottery. Study participants were also provided the
opportunity to express interest in participating in future work related to this study.
This purely voluntary study allowed participants to skip questions or leave the study at any point. In the process of contacting these HACCP trainers, it was found that a significant number of trainers listed on the IHA website were either not currently attached to the organization listed, no longer conducting HACCP trainings, or their contact information was incorrect and as a result could not be included in this study. Several HACCP trainers also indicated that records of trainees were often not maintained by trainers and a list of trainees was often submitted to the IHA with the expectation that such records were maintained by IHA. Additionally, several trainers were attached to private businesses as internal HACCP trainers and two of these organizations had recently been involved in a product recall or contamination event and thus were unwilling to participate in this study.

In total 32 HACCP trainers were invited by email and/or telephone to assist with this study by forwarding the recruitment message to their contacts. Of these trainers, sixteen agreed to forward the message and others provided no feedback. Through feedback from trainers and survey respondents it was estimated that 2200+ individuals were invited to participate in the study. Of them 248 individuals responded to the study and 206 of them provided sufficient information to be considered valid. 172 provided a full set of data points. Table 3.8 summarizes the recruitment process and numerical landmarks.

Table 3.8 Study Subject Recruitment

<table>
<thead>
<tr>
<th>Trainee Recruitment</th>
<th>IHA</th>
<th>%</th>
<th>Direct/Trainer Assisted Recruits</th>
<th>%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invited</td>
<td>0</td>
<td>0</td>
<td>2200</td>
<td>100</td>
<td>2200</td>
</tr>
<tr>
<td>Response Rate</td>
<td>0</td>
<td>0</td>
<td>248</td>
<td>11</td>
<td>248</td>
</tr>
<tr>
<td>Valid Responses</td>
<td>0</td>
<td>0</td>
<td>206</td>
<td>83</td>
<td>206</td>
</tr>
<tr>
<td>Complete Responses</td>
<td>0</td>
<td>0</td>
<td>172</td>
<td>69</td>
<td>172</td>
</tr>
</tbody>
</table>

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CHAPTER FOUR
Overview of Sample Characteristics and Approach to Analysis

Introduction

This chapter will present the sample population in this study including demographic information, educational background, geographic location, prior training, and educational background of the participants. The summary of these factors provides a landscape upon which the analyzed data can be interpreted. The remaining portion of this chapter will comprise of model responses to the survey instrument and scoring template for each of the sections of the survey.

Description of Sample

Respondents to this survey included HACCP trainees from across the United States including Alabama, California, Connecticut, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, West Virginia, and Wisconsin. These respondents were clustered by geographic region and are listed in Table 4.1. The majority of the respondents to this survey were located in the southern states which includes Kentucky and its neighbors. Respondents included those from all business sizes, ethnic and educational backgrounds, and varying durations since completing their last training event or HACCP training as well as geographic location.
Table 4.1 Responders by Geographic Location

<table>
<thead>
<tr>
<th>U.S. Region</th>
<th>Number of Respondents</th>
<th>Percentage</th>
<th>U.S. Region</th>
<th>Number of Respondents</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>South</td>
<td>107</td>
<td>52%</td>
<td>Midwest</td>
<td>22</td>
<td>11%</td>
</tr>
<tr>
<td>Alabama</td>
<td>5</td>
<td></td>
<td>Wisconsin</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Florida</td>
<td>33</td>
<td></td>
<td>Illinois</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Georgia</td>
<td>8</td>
<td></td>
<td>Indiana</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Louisiana</td>
<td>1</td>
<td></td>
<td>Iowa</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td>2</td>
<td></td>
<td>Kansas</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Tennessee</td>
<td>4</td>
<td></td>
<td>Minnesota</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Kentucky</td>
<td>49</td>
<td></td>
<td>Missouri</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Texas</td>
<td>1</td>
<td></td>
<td>Ohio</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>District of Columbia</td>
<td>2</td>
<td></td>
<td>Northeast</td>
<td>35</td>
<td>17%</td>
</tr>
<tr>
<td>West Virginia</td>
<td>1</td>
<td></td>
<td>Connecticut</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Maryland</td>
<td>1</td>
<td></td>
<td>New Jersey</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>15</td>
<td>7%</td>
<td>New York</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>New Mexico</td>
<td>8</td>
<td></td>
<td>Pennsylvania</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>6</td>
<td></td>
<td>Rhode Island</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Utah</td>
<td>1</td>
<td></td>
<td>Location undisclosed</td>
<td>27</td>
<td>13%</td>
</tr>
</tbody>
</table>

Total Valid Responses | 206 | 100%

Table 4.2 provides a summary of the gender, racial/ethnic background of respondents. The majority of respondents were white, males who had completed a four year degree, while the least represented groups were females and multi-racial or Asian individuals. 21% of respondents were high school graduates or those with a two-year degree, while 1% had less than a high school education. 35% chose not to disclose gender while 24% and 21% chose not to disclose ethnic origin or educational background, respectively.
Table 4.2 Summary of Gender, Ethnic and Education Background of Respondents

<table>
<thead>
<tr>
<th>Study Participant Characteristic</th>
<th>Number</th>
<th>% Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>94</td>
<td>46%</td>
</tr>
<tr>
<td>Female</td>
<td>38</td>
<td>19%</td>
</tr>
<tr>
<td>Undisclosed</td>
<td>71</td>
<td>35%</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>130</td>
<td>64%</td>
</tr>
<tr>
<td>African American</td>
<td>7</td>
<td>3%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>15</td>
<td>7%</td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Multi-Racial</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Undisclosed</td>
<td>49</td>
<td>24%</td>
</tr>
<tr>
<td><strong>Education Level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctoral degree</td>
<td>7</td>
<td>3%</td>
</tr>
<tr>
<td>Masters degree</td>
<td>32</td>
<td>16%</td>
</tr>
<tr>
<td>Four year college degree</td>
<td>76</td>
<td>37%</td>
</tr>
<tr>
<td>Two year degree</td>
<td>20</td>
<td>10%</td>
</tr>
<tr>
<td>High school graduate</td>
<td>23</td>
<td>11%</td>
</tr>
<tr>
<td>Less than high school</td>
<td>3</td>
<td>1%</td>
</tr>
<tr>
<td>Undisclosed</td>
<td>42</td>
<td>21%</td>
</tr>
</tbody>
</table>

The total number of study participants that provided full demographic information is listed in Table 4.3 (62%) and includes a wide range of business sizes represented, age and years of experience in the food industry. Twenty one percent of study participants worked in businesses with less than 10 employees while 54% of respondents worked in businesses with less than 100 employees. Fifty five percent of the respondents were between 33 and 52 years of age. Sixty percent of respondents were below 42 years of age and the highest level of responses (34%) were received from those between 38 and 47 years of age. Those with over 10 years of experience working in the food industry formed 64% of survey participants and those with less than 2 years of experience were represented by 10% of respondents.
Table 4.3 Company Size, Age and Years of Food Industry Experience

<table>
<thead>
<tr>
<th>Respondent’s Company Size (Employees)</th>
<th>Respondent’s Age Distribution</th>
<th>Respondent’s Years in Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees</td>
<td>Number</td>
<td>% of Total</td>
</tr>
<tr>
<td>&lt;10</td>
<td>22</td>
<td>21%</td>
</tr>
<tr>
<td>11-20</td>
<td>9</td>
<td>8%</td>
</tr>
<tr>
<td>21-50</td>
<td>13</td>
<td>12%</td>
</tr>
<tr>
<td>51-100</td>
<td>12</td>
<td>13%</td>
</tr>
<tr>
<td>101-250</td>
<td>12</td>
<td>12%</td>
</tr>
<tr>
<td>251-500</td>
<td>8</td>
<td>8%</td>
</tr>
<tr>
<td>501-1000</td>
<td>4</td>
<td>5%</td>
</tr>
<tr>
<td>1001-10,000</td>
<td>12</td>
<td>12%</td>
</tr>
<tr>
<td>10,001-20,000</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td>&gt;20,000</td>
<td>8</td>
<td>9%</td>
</tr>
</tbody>
</table>

This sampling represents a small portion of those who have been HACCP trained. The International HACCP Alliance estimates approximately 4000 individuals are HACCP trained each year with a collective number of 64,000 as of February 2013 (IHA, 2013). Additionally, HACCP training is conducted by several other groups, either for non-meat and poultry products or as an add-on to a larger scale quality initiative. Respondents to this survey included those from businesses who had been trained by a wide range of organization not all linked to the IHA and many trained in seafood, juice or with a focus on baking or retail operations. Of those responding to this survey, the majority of responses were obtained from individuals playing a role as HACCP practitioners. Forty eight percent had completed an introductory or short HACCP certification course with fewer completing an advanced
HACCP training program (Table 4.4). 50.8% of respondents had completed a HACCP course three or more years previously.
Table 4.4 Types of HACCP Courses Completed

<table>
<thead>
<tr>
<th>Duration of HACCP Training Programs</th>
<th>1 Day</th>
<th>2 Days</th>
<th>3 Days</th>
<th>4 Days</th>
<th>5 Days</th>
<th>Don’t recall</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced HACCP</td>
<td>3</td>
<td>5</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>16</td>
<td>9%</td>
</tr>
<tr>
<td>Dairy HACCP</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>2%</td>
</tr>
<tr>
<td>HACCP Certification for food processors</td>
<td>5</td>
<td>49</td>
<td>26</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>89</td>
<td>48%</td>
</tr>
<tr>
<td>HACCP for restaurants</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>3%</td>
</tr>
<tr>
<td>Introductory HACCP</td>
<td>1</td>
<td>31</td>
<td>11</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>44</td>
<td>24%</td>
</tr>
<tr>
<td>Juice HACCP</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>3%</td>
</tr>
<tr>
<td>Retail and Food Service HACCP</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>6</td>
<td>3%</td>
</tr>
<tr>
<td>Seafood HACCP</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>13</td>
<td>7%</td>
</tr>
<tr>
<td>Train the Trainer</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1%</td>
</tr>
</tbody>
</table>

HACCP Teams

A common approach to HACCP program development is the use of a team-based approach. While support for HACCP teams goes back to the early days of HACCP, recent findings in international organizations have shown that HACCP team decisions may not be more superior than those of an individual contributor, contrary to conventional belief that team decisions are usually better than those of an individual (Wallace et al. 2012). To understand the deciding factors of HACCP teams that contribute to concept understanding or the durability of HACCP knowledge, the composition of HACCP teams was uncovered. While HACCP teams of all sizes ranging from two or more than five members and those with yet undefined HACCP teams, HACCP knowledge was correlated to the size of HACCP team and a general composition of HACCP teams was compiled.
The data suggest that HACCP teams consist of members holding the following broad functional roles and this mix is most prevalent:

- 20% Production/Manufacturing
- 20% Quality
- 20% Sanitation
- 10% Research and Development
- 10% Management/Finance/Other

This general distribution is similar in all industries including seafood, dairy, meat and poultry, food services, as well as retail and Juice HACCP.

**Survey Validation**

As in any study, surveys with human subjects must be validated using appropriate methods. Because this study’s primary focus was to assess the durability of HACCP domain knowledge, universally accepted food safety concepts that are part of HACCP were used to validate the questionnaire. These three questions are listed below.

1) “Please choose if the following statements are TRUE or FALSE. - Chemicals are not considered a source of contamination in food products”
   Correct response – “False” (97% correct)

2) “Please select the most appropriate response to the following statements. - Cleaning is a pre-requisite to sanitation”
   Response range “Strongly Agree to Strongly Disagree”
   Correct response – “Agree” or “strongly agree” (92% correct)

3) “Please select the most appropriate response to the following statements. - HACCP can minimize the risks of a product recall”
   Response range “Strongly Agree to Strongly Disagree”
   Correct response - “Agree”, or “strongly agree” (99% correct)
A tolerance level was established at 68% allowing 1 response of 3 to be incorrect and still be included in the study. This allows those who may have selected “neither agree nor disagree” as an acceptable response to be included in the study. This choice of threshold was selected specifically for this study in the context of the 3 questions that were asked as validation questions; all three questions did not require specialized knowledge in order to elicit a correct response and they included general pre-requisite programs knowledge that anyone working in a food processing environment should respond to correctly. In practical terms we would expect the respondents to achieve correct responses 2 out of 3 times. All responses that did not include correct responses to two of the three reference questions were eliminated from further analysis.

**Scoring**

Responses were scored on a raw and weighted score basis. Raw scores were obtained by assigning a value of “1” to each correct response or a score of “0” to each false response to each of the true or false questions (question block 1). A HACCP knowledge score was obtained using the 15 True/False questions regarding core HACCP concepts with a possible weighted maximum score of 20 (question 3, 5, 8, 10 and 11 received 2 points each) in question block 1 corresponding to the HACCP content areas addressed by each question. No weights were assigned in the analyses for HACCP areas addressed in question block 2 and 3.

A maximum score of “1” for the most correct response was assigned to each question receiving Likert scale responses and a score of “0” to the most incorrect response with a sliding scale of points allocated to responses between the most correct and most incorrect responses that fell between 0 and 1 (see Tables 4.5a, 4.5b, and 4.5c). Each question category was clustered into the broad HACCP and HACCP pre-requisite categories and scores were assigned based on the number of HACCP areas each question related to (Table 4.5a). Scores for HACCP concept knowledge were calculated as a proportion (% correct) and are reported by duration since HACCP training (Table 4.7).
### Table 4.5 (a) Responses and Scoring

<table>
<thead>
<tr>
<th>Question</th>
<th>Most correct response</th>
<th>Possible scores (1=highest score possible for most correct response)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemical Hazards</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemicals used for cleaning and sanitation purposes should be stored close to the area where they will be used.</td>
<td>FALSE</td>
<td>0 or 1</td>
</tr>
<tr>
<td>Chemicals are not considered a source of contamination in food products.</td>
<td>FALSE</td>
<td>0 or 1</td>
</tr>
<tr>
<td>Chemicals should be stored away from food processing areas.</td>
<td>TRUE</td>
<td>0 or 1</td>
</tr>
<tr>
<td><strong>Critical Control Points</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is important to include as many critical control points as possible in a HACCP plan.</td>
<td>FALSE</td>
<td>0 or 1</td>
</tr>
<tr>
<td>Utilizing Good Manufacturing Practices and sanitation can minimize the number of critical control points.</td>
<td>TRUE</td>
<td>0 or 1</td>
</tr>
<tr>
<td>All control points should be designated as critical control points in a HACCP plan.</td>
<td>FALSE</td>
<td>0 or 1</td>
</tr>
<tr>
<td><strong>Traceability</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trace forward and Trace back procedures are related to HACCP.</td>
<td>Strongly Agree</td>
<td>0 or 1</td>
</tr>
<tr>
<td>Customer complaints are not considered an indicator of issues with food safety.</td>
<td>Strongly Disagree</td>
<td>0 or 1</td>
</tr>
<tr>
<td><strong>Critical Limits</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The critical limits must be set for the process before operational limits are determined.</td>
<td>Strongly Disagree</td>
<td>0 or 1</td>
</tr>
<tr>
<td>For a product that must be cooled to ensure its safety, critical control temperature must be higher than operational temperatures.</td>
<td>Strongly Agree</td>
<td>0 or 1</td>
</tr>
<tr>
<td>For a product that must be heated to ensure safety, operational temperatures must meet or exceed the critical temperature that is set at a Critical Control Point.</td>
<td>Strongly Agree</td>
<td>0 or 1</td>
</tr>
<tr>
<td>Management Support</td>
<td>Most correct response</td>
<td>Possible scores (1=highest score possible for most correct response)</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>-----------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>I am given time by my supervisor to participate in food safety training activities.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>Company Management (Production Mgr, Supervisors) visibly demonstrates a commitment to food safety.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>My immediate supervisor actively encourages the reporting of all unsafe conditions.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>I am given time by my supervisor to participate in process improvement activities.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>My supervisor has provided me the necessary tools and information on how to perform my job safely.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>My supervisor has provided me with information on how my job function relates to food safety.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>Operational HACCP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate corrective actions are implemented after accidents or near misses to prevent re-occurrence.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>My work team pays special attention to review paperwork and make the necessary changes to adjust temperature and time chart values only when a food safety audit is due.</td>
<td>Strongly Disagree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>When new ingredients or vendors are chosen a member of the HACCP team is involved in those decisions.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>I spend additional time preparing paperwork or my work area for a food safety inspections or audits.</td>
<td>Strongly Disagree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>The HACCP team re-evaluates the company HACCP plan whenever a new product is being developed for production.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>Monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All monitoring equipment must be frequently calibrated and kept in good working condition.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>Monitoring water quality is NOT important to the HACCP system.</td>
<td>Strongly Disagree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>Table 4.5 (c) Responses and Scoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question</strong></td>
<td><strong>Most correct response</strong></td>
<td><strong>Possible scores</strong> (1=highest score possible for most correct response)</td>
</tr>
<tr>
<td><strong>Corrective Actions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When time/temperature readings do not fall within critical limits, immediate action is NOT taken to correct the issue.</td>
<td>Strongly Disagree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td>I receive the results of food safety audits performed in my work area.</td>
<td>Strongly Agree</td>
<td>0, 0.16, 0.33, 0.5, 0.66, 0.83 or 1</td>
</tr>
<tr>
<td><strong>Safety Culture</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When improper environmental and/or safety conditions are reported, they are prioritized and addressed in a timely manner.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td>I am encouraged to report early, any signs of pain or discomfort (ergonomic) as soon as I first notice it, even if it is just a small pain.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td><strong>Participation/Confidence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I participate in the HACCP team/committee or activities during the year.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td>I feel comfortable reporting quality and safety issues to my immediate supervisor or a member of the operations/leadership team.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td><strong>Pre-Requisites</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-requisite programs such as sanitation, supplier verification and allergen management are critical to implementing an effective HACCP system.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td>Sanitation is NOT an important part of the HACCP program.</td>
<td>Strongly Disagree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td>Cleaning is a pre-requisite to sanitization.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td><strong>Training Adequacy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP training provided me the information and knowledge needed to successfully prepare a HACCP plan at my organization.</td>
<td>Strongly Agree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
<tr>
<td>HACCP training was insufficient to contribute to developing the HACCP system at my organization.</td>
<td>Strongly Disagree</td>
<td>0, 0.25, 0.5, 0.75, 1</td>
</tr>
</tbody>
</table>
Approach to Analysis

Responses to each question by each respondent were assigned a numerical score based on the scoring system described in aforementioned sections of this chapter and each of the subsection scores was calculated. The overall HACCP knowledge scores were obtained using the cumulative scores from responses to questions in Tables 4.5a, b and c, and were used in testing hypothesis 1, for identifying the durability of overall HACCP knowledge while clusters of questions in each of these tables were then used to identify if areas of concern exist and what those specific HACCP knowledge areas may be. Furthermore, responses to clustered questions in Tables 4.5a, b and c, were correlated with demographic information as summarized in Table(s) 4.1, 4.2, 4.3 and 4.4 to test hypothesis 2a and 2b.

In summary, this section presented a description of the survey participants, questions included in the survey instrument with logical separations to each questioning cluster used in evaluating HACCP knowledge with the corresponding scores. Data preparation methods and analyses performed will be discussed further in chapter five.

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Hypotheses:
1. What is the durability of HACCP knowledge?
   Null hypothesis 1: There is no relationship between time since HACCP training and knowledge retained.

2. What factors influence the durability of HACCP knowledge?
   Null hypothesis 2a: There is no relationship between HACCP concepts and their retention.
   Null hypothesis 2b: There is no relationship between socio-demographic characteristics of trainees and retention of HACCP knowledge.
CHAPTER FIVE

HACCP Knowledge Results

Introduction

This chapter will address the statistical methods used in analyzing the results of the survey responses following the attribution of numerical scores to the responses. Scores are presented in graphical and table formats with statistical charts to further illustrate the distribution of the results of this study.

Analysis of Hypothesis 1:

There is no relationship between time since HACCP training and knowledge retained.

HACCP knowledge scores were obtained and assigned numerical values. Scores were converted into proportions (for the purpose of graphical representations) and proportions were converted into scaled score values by performing an arcsine square root transformation using the following equation. This data transformation was performed to eliminate possible biases and provide a score range for performing valid statistical analyses of proportional data. SS represents the arcsine value; S represents the HACCP knowledge score.

$$SS = \text{ARCSIN} \sqrt{S} = \frac{1}{\sin \sqrt{S}}$$

These resulting values were used to create probability plots corresponding to each of the post-training duration categories and an analysis of variance (ANOVA) between each sample group was performed. Scaled Scores (SS) presented in the following data analysis sections range from 1 to 2 with values nearing “1” representing the highest HACCP knowledge scores (best scores) and scores closer to “2” representing a lower HACCP knowledge (Figure 5.1).
Individual HACCP scores were grouped by duration since HACCP training completion. Business size, level of involvement in HACCP processes and grouped results are presented in the following tables and Figures. Mean knowledge scores for each group are presented in Table 5.1 and graphically in Figure 5.2. Probability plots of basic HACCP knowledge (Figure 5.3) illustrate the expected spread of the scores with a 95% level of confidence for core HACCP knowledge (Block 1 questions only).

Table 5.1 Basic HACCP knowledge

<table>
<thead>
<tr>
<th>Duration since HACCP training</th>
<th>Mean Score</th>
<th>% Mean Score</th>
<th>N</th>
<th>Standard Deviation</th>
<th>SS (Scaled Score) *</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month ago</td>
<td>14.33</td>
<td>71.67</td>
<td>24</td>
<td>0.1213</td>
<td>1.3453 A</td>
</tr>
<tr>
<td>1-6 months ago</td>
<td>12.97</td>
<td>64.83</td>
<td>29</td>
<td>0.1217</td>
<td>1.4037 A</td>
</tr>
<tr>
<td>6-12 months ago</td>
<td>14.29</td>
<td>71.43</td>
<td>21</td>
<td>0.0989</td>
<td>1.3453 A</td>
</tr>
<tr>
<td>1-3 years ago</td>
<td>13.98</td>
<td>69.89</td>
<td>45</td>
<td>0.1272</td>
<td>1.3621 A</td>
</tr>
<tr>
<td>3-5 years ago</td>
<td>13.5</td>
<td>67.5</td>
<td>14</td>
<td>0.1046</td>
<td>1.3805 A</td>
</tr>
<tr>
<td>&gt;5 years ago</td>
<td>13.30</td>
<td>66.52</td>
<td>23</td>
<td>0.1782</td>
<td>1.5011 A</td>
</tr>
</tbody>
</table>

* Tukey’s multiple means analysis groupings are represented by letter designation in the SS column. ARCSIN √Mean values that share a letter are not significantly different (i.e. all A’s are the same). Standard score (SS) values most proximate to “1” correlate to the highest level of HACCP concepts competency.
As illustrated in Figure 5.2 HACCP knowledge levels shown as percent scores of respondents clustered by the time duration since completing HACCP training are plotted with X coordinate valued ranging from less than one month to greater than five years since training and Y coordinate representing HACCP knowledge scores ranging from 0% to 100%. The overall knowledge scores are highest immediately following completion of the HACCP training (72% competency), and taper off over time. A noticeable reduction in scores is observed on the plotted curve during the one to 6 month interval following the HACCP training. However, these scores, when compared against each other by using an analysis of variance and Tukey’s multiple means analysis, do not represent significant changes over time. Therefore, when comparing the entire group of respondents in this study, overall HACCP knowledge does not significantly deplete over the 5 year period following training and scores ranges move from 71.67% at less than 1 month to 66.52% after 5 years following the completion of the training program.
In order to understand cluster patterns in each group of trainees based on the duration since the completion of HACCP training a series of probability plots were generated using statistical methods and the Minitab™ statistical software package.

Table 5.2  Summary Table of HACCP Core Knowledge

<table>
<thead>
<tr>
<th>Probability Plot</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>N</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month ago</td>
<td>1.318</td>
<td>0.09377</td>
<td>24</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>1-6 months ago</td>
<td>1.324</td>
<td>0.0904</td>
<td>29</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>6-12 months ago</td>
<td>1.289</td>
<td>0.08546</td>
<td>21</td>
<td>0.005</td>
</tr>
<tr>
<td>1-3 years ago</td>
<td>1.292</td>
<td>0.06851</td>
<td>53</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>3-5 years ago</td>
<td>1.294</td>
<td>0.06104</td>
<td>15</td>
<td>0.122</td>
</tr>
<tr>
<td>&gt;5 years ago</td>
<td>1.396</td>
<td>0.05658</td>
<td>22</td>
<td>&lt;0.005</td>
</tr>
</tbody>
</table>

Probability plots of each group of trainees provides a graphical representation to illustrate the distribution of the sample grouping while also providing comparable values to assess the significance of the distribution. In the case of this core HACCP knowledge all groups have significant differences between the highest scoring respondents and those scoring the least (<=0.005). The probability plots echo the multiple means analysis from Table 5.1 indicating that the highest HACCP competency levels exists in the group 3-5 years following the training event. Figure 5.3(f) of respondents with over 5 years since the completion of HACCP training are clustered tightly with one significant outlier that represented a very low HACCP score (standard scores 3.9). Similarly all other groupings, except the 3-5 years groups also include one significant outlier with standard scores in the range of 1.5-1.7.
Figure 5.3 Probability Plots of Basic (Core) HACCP Knowledge Since Training Completion

While pooled scores for HACCP knowledge in the basic principles section dipped at the 1-6 months post training time period (64.83%), the standard deviation of scores was
widest for those with over 5 years of experience (1.5011) and ANOVA values indicated no significant differences between the clusters of trainees based on the time duration since completing HACCP training as presented in Table 5.1. The probability plots, however, illustrate that while the majority of values fall within the expected range (95% confidence), each grouping except those trained 3-5 year previously included a very small number of outlier. This indicates that the trend in overall HACCP knowledge clusters together 3-5 years following training and individuals with less confidence in HACCP knowledge that may have fallen into lower scores brackets during the 1-6 months following HACCP training, either went through HACCP knowledge recovery or were no longer participating in a HACCP programs.

Table 5.3 Secondary HACCP knowledge

<table>
<thead>
<tr>
<th>Duration since HACCP training</th>
<th>Mean Score</th>
<th>% Mean Score</th>
<th>N</th>
<th>Standard Deviation</th>
<th>SS (Scaled Score) *</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month ago</td>
<td>16.45</td>
<td>72</td>
<td>20</td>
<td>0.1595</td>
<td>1.3589 A</td>
</tr>
<tr>
<td>1-6 months ago</td>
<td>16.79</td>
<td>73</td>
<td>17</td>
<td>0.178</td>
<td>1.3562 A</td>
</tr>
<tr>
<td>6-12 months ago</td>
<td>17.25</td>
<td>75</td>
<td>18</td>
<td>0.16</td>
<td>1.3307 A</td>
</tr>
<tr>
<td>1-3 years ago</td>
<td>16.79</td>
<td>73</td>
<td>32</td>
<td>0.1786</td>
<td>1.3596 A</td>
</tr>
<tr>
<td>3-5 years ago</td>
<td>17.02</td>
<td>74</td>
<td>6</td>
<td>0.1867</td>
<td>1.3425 A</td>
</tr>
<tr>
<td>&gt;5 years ago</td>
<td>15.41</td>
<td>67</td>
<td>11</td>
<td>0.1919</td>
<td>1.4044 B</td>
</tr>
</tbody>
</table>

* Tukey’s groupings are represented by letter designation in the SS column. ARCSIN \( \sqrt{\text{Mean}} \) values that do not share a letter are significantly different. These standard score (SS) values most proximate to “1” correlate to the highest HACCP concepts competency.
Figure 5.4 Secondary HACCP Knowledge since Training Completion

As illustrated in Figure 5.4 HACCP secondary knowledge levels shown as percent scores of respondents clustered by the time duration since completing HACCP training are plotted with X coordinate values ranging from less than one month to greater than five years since training and Y coordinate values represent HACCP secondary knowledge scores ranging from 0% to 100%. These scores peak at the 6-12 month period following training. However a decline in secondary knowledge is observable after five years. The knowledge drop in secondary knowledge is significant after five years in contrast to the core HACCP knowledge as indicated by Tukey’s multiple means analysis and groupings (Table 5.3).
Table 5.4 Summary Table of HACCP Secondary Knowledge

<table>
<thead>
<tr>
<th>Probability Plot</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>N</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month ago</td>
<td>1.359</td>
<td>0.1273</td>
<td>20</td>
<td>0.0255</td>
</tr>
<tr>
<td>1-6 months ago</td>
<td>1.356</td>
<td>0.1579</td>
<td>17</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>6-12 months ago</td>
<td>1.331</td>
<td>0.1244</td>
<td>18</td>
<td>0.057</td>
</tr>
<tr>
<td>1-3 years ago</td>
<td>1.360</td>
<td>0.1588</td>
<td>32</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>3-5 years ago</td>
<td>1.342</td>
<td>0.01431</td>
<td>6</td>
<td>0.247</td>
</tr>
<tr>
<td>&gt;5 years ago</td>
<td>1.404</td>
<td>0.1661</td>
<td>11</td>
<td>0.720</td>
</tr>
</tbody>
</table>

The following probability plots of the secondary HACCP knowledge for each group of trainees provides a further graphical representation to illustrate the distribution of the sample grouping while also providing comparable values to assess the significance of the distribution. In the case of secondary HACCP knowledge the 1-6 months, and 1-3 years following training completion display the most significant differences between group members (p<0.005) although these differences are less so than their corresponding core HACCP knowledge.
The scores for secondary HACCP knowledge range from 67% to 75% accuracy with those trained over 5 years previously. Probability plots demonstrate that most values lie between expected levels (95% confidence). Multiple means analysis of variance
(ANOVA) with Tukey’s groupings indicates that those with over 5 years since HACCP training have significantly lower values in HACCP and HACCP supporting knowledge such as pre-requisite programs. Overlaying each of the HACCP secondary concepts probability plots below (Figure 5.6) shows the overall distribution of knowledge standard scores (95% confidence).

![Figure 5.6 Combined Probability Plot of Secondary HACCP Knowledge](image)

Figure 5.6 Combined Probability Plot of Secondary HACCP Knowledge

Figure 5.6 above presents a combined view of HACCP secondary knowledge scores where the largest spread of values are presented in those with 1-6 months and 3-5 years of time since training completion (p<0.005), indicating that while some individuals have a high levels of HACCP knowledge, others are far less competent in HACCP knowledge. In contrast, those with over 5 years of a lapse since completing their last HACCP course have the lowest HACCP secondary knowledge scores and are also clustered closer together. Looking closer at HACCP secondary knowledge and the components evaluated under this umbrella; pre-requisite programs/HACCP support programs such as cleaning and sanitation,
allergen management and supplier verification protocols are the main areas in which groups having low scores appear to have trouble with.

**Analysis of Null Hypothesis 2a: There is no relationship between HACCP concepts and their retention.**

To decipher what attributes of post-training knowledge may be impacted by knowledge depletion over time, a select group of HACCP principles knowledge was assessed and scores are presented in the form of pooled percent values based on duration since training. The HACCP concepts knowledge evaluated included chemical hazards (use and storage or chemicals), designating critical control points, and determining critical limits, monitoring activities, corrective actions and pre-requisite programs. Patterns in knowledge trends were observed and are presented in Figure 5.7. Responses to the questions in Table 4.5 a, b and c were used for analysis, the responses were scored as described and the percent accuracy scores were plotted.

**Table 5.5 HACCP Principles Competency Over Time**

<table>
<thead>
<tr>
<th>Duration since HACCP training</th>
<th>&lt;1 month ago (n=24)</th>
<th>1-6 months ago (n=29)</th>
<th>6-12 months ago (n=21)</th>
<th>1-3 years ago (n=45)</th>
<th>3-5 years ago (n=14)</th>
<th>&gt;5 years ago (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Chemical Hazards</td>
<td>93%</td>
<td>83%</td>
<td>90%</td>
<td>93%</td>
<td>90%</td>
<td>87%</td>
</tr>
<tr>
<td>Critical Control Points</td>
<td>93%</td>
<td>76%</td>
<td>78%</td>
<td>78%</td>
<td>79%</td>
<td>85%</td>
</tr>
<tr>
<td>Critical Limits</td>
<td>54%</td>
<td>47%</td>
<td>51%</td>
<td>49%</td>
<td>38%</td>
<td>40%</td>
</tr>
<tr>
<td>Monitoring</td>
<td>88%</td>
<td>63%</td>
<td>97%</td>
<td>81%</td>
<td>48%</td>
<td>61%</td>
</tr>
<tr>
<td>Corrective Actions</td>
<td>76%</td>
<td>72%</td>
<td>80%</td>
<td>75%</td>
<td>59%</td>
<td>84%</td>
</tr>
<tr>
<td>Pre-Requisite Programs</td>
<td>67%</td>
<td>72%</td>
<td>80%</td>
<td>67%</td>
<td>55%</td>
<td>73%</td>
</tr>
</tbody>
</table>
Generally we see lower levels of knowledge comprehension in critical control point designation particularly in terms of meeting, exceeding or staying within the critical temperature limits that are necessary for safety. Similarly monitoring, critical control points knowledge also tends to deplete with time in comparison to some of the other types of HACCP knowledge evaluated here. Overall, the lowest values were observed in critical limits knowledge that relates to factors with competency reducing from a high of 54% to less than 40% within five years. An example of this knowledge includes maintaining foods colder or warmer than the critical limit that is determined for cold food storage and transport or heat steps required for reducing pathogens, respectively. These results indicate that null
hypothesis 2a was found to be false, and indeed there is a relationship between the HACCP concepts knowledge and their retention with statistically significant differences existing between each concepts groupings (p<0.005) using an ANOVA test.
Analysis of Null Hypothesis 2b: There is no relationship between organizational characteristics and retention of HACCP knowledge.

To assess the validity of null hypothesis 2b, factors relating to the characteristics of the business were correlated with knowledge scores. Management support, post training knowledge and the involvement of people in implementing the program requires several factors that were evaluated and the scores are presented below. These summarized scores lie within the range of 64 and 78% in most areas of integration, with most indicating a similar range of support within the business, except the factor of involvement, where the mean level of involvement is 37%.

![Factors Relating to HACCP Integration](image)

*Figure 5.8 Factors Relating to HACCP Integration*
It is important to note that involvement scores were based on a range of involvement factors and no individual may play the role of being involved in all of them unless the business is comprised of a handful of individuals (e.g., 1-5 people). The graphical representation of these scores in Figure 5.8 alludes to the possibility that those playing a more involved role in HACCP activities may retain more knowledge over a longer period of time. Similarly, knowledge of the HACCP process tapers off with time and corresponds with reduction in involvement.

Table 5.6 HACCP Principles Knowledge- Factors Relating to HACCP Integration

<table>
<thead>
<tr>
<th>Duration Since HACCP Training</th>
<th>% Involvement</th>
<th>Percent HACCP Knowledge</th>
<th>Management Support</th>
<th>Proactive Participation</th>
<th>Cultural Support for HACCP</th>
<th>HACCP Process</th>
<th>Mean Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month (n=29)</td>
<td>39%</td>
<td>71%</td>
<td>68%</td>
<td>78%</td>
<td>74%</td>
<td>61%</td>
<td>65%</td>
</tr>
<tr>
<td>1-6 months (n=35)</td>
<td>26%</td>
<td>64%</td>
<td>70%</td>
<td>75%</td>
<td>72%</td>
<td>65%</td>
<td>62%</td>
</tr>
<tr>
<td>6-12 months (n=24)</td>
<td>49%</td>
<td>70%</td>
<td>70%</td>
<td>79%</td>
<td>76%</td>
<td>70%</td>
<td>69%</td>
</tr>
<tr>
<td>1-3 years (n=52)</td>
<td>39%</td>
<td>68%</td>
<td>69%</td>
<td>80%</td>
<td>77%</td>
<td>65%</td>
<td>66%</td>
</tr>
<tr>
<td>3-5 years (n=15)</td>
<td>29%</td>
<td>68%</td>
<td>65%</td>
<td>67%</td>
<td>67%</td>
<td>64%</td>
<td>60%</td>
</tr>
<tr>
<td>&gt;5 years (n=25)</td>
<td>38%</td>
<td>70%</td>
<td>63%</td>
<td>69%</td>
<td>69%</td>
<td>57%</td>
<td>61%</td>
</tr>
<tr>
<td>Mean of Total Scores</td>
<td>37%</td>
<td>69%</td>
<td>68%</td>
<td>75%</td>
<td>73%</td>
<td>64%</td>
<td>64%</td>
</tr>
</tbody>
</table>

7 Involvement scores (100%) with 11 points total and based on a positive response to each of the following: 1) I am involved in Hazard Analysis, 2) Determining Critical Control Points, 3) Establishing Critical Limits, 4) I am involved in performing the daily Monitoring functions, 5) I am involved in Record Keeping, 6) Developing Verification Procedures, 7) I am involved in Developing Corrective Actions, 8) Auditing the HACCP plan, 9) I am not involved in HACCP, 10) Don’t know, 11) Other (input box provided for any other factors)
Taking a closer look at the dynamics of involvement in HACCP processes, plots of low to no involvement, moderate involvement and high involvement with corresponding scores for each of these groups are presented in Table 5.7 and graphically in Figure 5.9. Management support for HACCP was measured by management personnel providing the tools and training as well as supporting the time requirements of administering a HACCP program and its related activities. Cultural support for HACCP included supervisor support, environmental conditions, business priorities for safety, and the ability and confidence level of workers in reporting process deviations or unsafe conditions. Additionally, proactive participation was a designation given to the likelihood of action taken in response to a food safety or safety related issue. While most study participants felt they were likely to report process deviations and safety issues, this self-driven need to achieve high levels of food safety is an indication of the internal drive and can be compared with the external or business factors that support and allow workers to function optimally or poorly. These results clearly indicate (with statistical significance at p<0.005 using paired t-tests) that the greatest levels of involvement achieved before 12 months following completion of HACCP training delivers the highest HACCP knowledge scores.

<table>
<thead>
<tr>
<th>Level of Involvement in HACCP</th>
<th>Minimum involvement (n=101)</th>
<th>Moderate involvement (n=34)</th>
<th>Maximum involvement (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical use and storage</td>
<td>51% 68%</td>
<td>89% 82%</td>
<td>87%</td>
</tr>
<tr>
<td>Critical Control Points</td>
<td>44% 67%</td>
<td>77% 68%</td>
<td>87%</td>
</tr>
<tr>
<td>Traceability</td>
<td>38% 46%</td>
<td>63% 50%</td>
<td>50%</td>
</tr>
<tr>
<td>Critical Limits</td>
<td>25% 39%</td>
<td>49% 40%</td>
<td>48%</td>
</tr>
<tr>
<td>Management Support</td>
<td>36% 71%</td>
<td>79% 84%</td>
<td>80%</td>
</tr>
<tr>
<td>Operational HACCP</td>
<td>28% 53%</td>
<td>63% 66%</td>
<td>65%</td>
</tr>
<tr>
<td>Monitoring</td>
<td>21% 71%</td>
<td>85% 70%</td>
<td>92%</td>
</tr>
<tr>
<td>Corrective Actions</td>
<td>28% 65%</td>
<td>80% 75%</td>
<td>79%</td>
</tr>
<tr>
<td>Safety Culture</td>
<td>31% 68%</td>
<td>75% 76%</td>
<td>74%</td>
</tr>
</tbody>
</table>
The success of HACCP program implementation was measured by operational factors relating to an actively managed HACCP program. These operational factors included corrective actions, updates to the HACCP plan, as well as monitoring and record keeping activities that need to be in effect for a functional HACCP system. These applied principles
were measured using questions in Table 4.5(b) and listed under operational HACCP. Additionally a value for the adequacy of HACCP training was obtained (Table 5.8, 4.5 (c) listed “training adequacy”). Appropriately grouped pooled values are listed below in Table 5.8 and graphically presented in Figure 5.10.

<table>
<thead>
<tr>
<th>Duration Since HACCP Training</th>
<th>Operational HACCP</th>
<th>Training Adequacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 month (n=29)</td>
<td>67%</td>
<td>58%</td>
</tr>
<tr>
<td>1-6 months (n=35)</td>
<td>70%</td>
<td>53%</td>
</tr>
<tr>
<td>6-12 months (n=24)</td>
<td>73%</td>
<td>50%</td>
</tr>
<tr>
<td>1-3 years (n=52)</td>
<td>65%</td>
<td>56%</td>
</tr>
<tr>
<td>3-5 years (n=15)</td>
<td>56%</td>
<td>43%</td>
</tr>
<tr>
<td>&gt;5 years (n=20)</td>
<td>62%</td>
<td>51%</td>
</tr>
</tbody>
</table>

It is of interest to note that while immediately following training completion, trainees are confident that the HACCP training they received is adequate to fulfill their program development/engagement needs, this level of confidence drops shows are decrease over time. Survey respondents completing a HACCP program within 3-5 years previously believed they had not received sufficient training and only 43% consistently indicated they had received sufficient training to be confident in developing a HACCP program. Similarly this same group indicated a lower level of success of maintaining a HACCP program and in HACCP pre-requisite, critical control points, monitoring and corrective action knowledge as illustrated in Figure 5.10 where the operational HACCP (blue) curve corresponds with adequacy of training, meaning that those perceiving they had received adequate HACCP training, were also linked to operations with functional HACCP principles being maintained.
A probability plot of training adequacy (Figure 5.11) shows significant differences between groups based on the adequacy of training received to complete developing a HACCP plan. While all groups included individuals with high confidence levels in their HACCP training knowledge, the majority of trainees with more than 5 years lapse since training demonstrated the largest distribution of values.
Additional Analysis on Who Should be Trained

It has been proposed that HACCP training for employees not involved in food processing, and training of food regulatory officials is a condition that success relies upon (Ehiri, Morris & McEwen, 1995). The following results of this study reveal the perception of HACCP trainees about the usefulness of their own HACCP training and their opinion about the relevance of HACCP training for others in their organization.

- 96% agree that HACCP training helped them contribute to the HACCP team.
- 73% agree that HACCP training provided the knowledge needed to successfully prepare a HACCP plan.
- 18% agree that HACCP training was insufficient to contribute to developing the HACCP system at their organization.
• 74% agree that HACCP training is necessary for all employees.
• 82% disagree that HACCP training is only needed for those involved in quality assurance.
• 82% disagree that HACCP is only needed for those involved in production and processing.
• 79% disagree that HACCP training is not necessary for those in sourcing or distribution.
• 99% agree that HACCP training can minimize the risks of a product recall.

Most respondents in this study had a clear sense of who does and does not require HACCP training and 74% believed that all employees should be HACCP trained. While all agreed that production, quality and sanitation workers require HACCP training, most also believed that finance and sourcing should be required to complete HACCP training.
Analysis Summary

Overall, both hypotheses were successfully tested using the methods set forth in this study. The results of these tests are summarized below:

1. What is the durability of HACCP knowledge?
Null hypothesis 1: There is no relationship between time since HACCP training and knowledge retained.

   Results of hypothesis test: False
   Basic HACCP knowledge is durable five years past the training event. However, HACCP pre-requisites and secondary HACCP knowledge requires intervention in the 3-5 years following the previous HACCP training event. i.e. HACCP refresher training is recommended within three years.

2. What factors influence the durability of HACCP knowledge?
Null hypothesis 2a: There is no relationship between HACCP concepts and their retention.

   Results of hypothesis test: False
   Some HACCP concepts are retained less stringently over time than others.

Null hypothesis 2b: There is no relationship between socio-demographic characteristics of trainees and retention of HACCP knowledge.

   Results of hypothesis test: True
   The responses obtained in this study do not provide sufficient information to draw conclusions about relationships between the socio-demographic characteristics of trainees and retention of HACCP knowledge.
CHAPTER SIX

Summary and Conclusions

Summary

A broad survey of HACCP knowledge was conducted using a web-based survey to evaluate the durability of HACCP knowledge among workers in the food industry that had previously completed a HACCP training program. The responses were gathered on a one-time basis rather than through a longitudinal study over a period of time with the same subject. It was found that HACCP training knowledge can be retained up to and beyond 5 years at above 60% competency in most HACCP principles areas. While competency of some HACCP principles (e.g., sanitation, critical control points) is strong over time, other knowledge areas (e.g., critical limits, pre-requisite programs, monitoring) rapidly decline over time and are likely linked to low levels of concept knowledge usage or involvement in HACCP activities. Knowledge about pre-requisite programs such as cleaning and sanitation holds strong over time with over 80% competency. While overall HACCP knowledge depletion occurs in the area of critical control point designation, pre-requisite programs, validation and critical limits, some recovery does occur and is likely due to exercising the knowledge in a team environment with experience or more knowledgeable team members compensating for overall team knowledge and playing a role in raising overall team knowledge. It is important to note that while teams do play an important role in mentorship and team decision making, HACCP teams have been found not to perform consistently better in teams (Wallace et al., 2012) and further inquiry is needed to uncover if knowledge recovery occurs because of team practices, or from continued education and improvement of the individual HACCP team member is responsible for that knowledge recovery.

Those with over three years of time since the completion of HACCP training overall were the least likely to take proactive measures to mitigate or report an incident. They were
also less confident of management’s support for HACCP, scored relatively lower on HACCP knowledge and support programs (pre-requisites) suggesting they experienced the least support for HACCP in their company culture. We may infer that there may be some relationship with their experience level and therefore, level in the company hierarchy that impacts their outlook. It is also possible that many of these individuals (especially those with > 5 years since training) may play a role in HACCP leadership (and are thus the recipients of incident reports), or the financial gatekeepers making the decisions about HACCP, and this perspective may reflect on the relatively lower scores.

**Limitations of the study**

Participants in this study included a large proportion of food manufacturing workers, retail HACCP trainees, HACCP team members, HACCP leaders, peer trainers that coach and mentor fellow HACCP team members and a few HACCP trainers. While responses in this study are highly valuable and indicative of several trends in HACCP knowledge, it is possible that these respondents represent a higher level of HACCP knowledge, training and experience than an average HACCP team member. It is therefore likely that the HACCP knowledge of most HACCP workers is likely to be either equivalent or less proficient than the knowledge and competency levels evaluated and presented in this study. Additionally self selection of individuals into this study may in fact have led to a specialized population of HACCP team members and leadership responding to this study. Self selection bias in the context of HACCP knowledge could have led to extraction of the best-case for HACCP knowledge. i.e., the most knowledgeable individuals working in HACCP may have participated in this study.

This variance (coefficient of variance) has not been estimated for this study, as this data is considered part of a pilot study in which further data is currently being obtained. Additionally, calculating a meaningful sampling error would require that a larger subset of HACCP trainees be polled, and thus confidence intervals have not been presented in this
study. The 90% of individuals that chose not to participate in this study by themselves may contribute to a valuable portion of the observations gained through this research and is an important group for consideration in further investigations related to this study. Non-response rate tracking is known to be difficult (Andrews et al., 2003), and a challenge which we have attempted to address by offering a lottery option to win an iPad®. Self-selection bias, or the tendency of some individuals to respond to online surveys while others tend to ignore online surveys may also be a concern (Thompson et al., 2003). While it is not possible to estimate the non-response rate, it is possible to estimate that approximately 10% responded and 8% provided complete responses. This non-probability survey (does not include all possible HACCP trainees) further does not provide sufficient information to calculate the sampling error for non-responders. It may be proposed that organizational factors including the availability of time, resources, access to the internet or computers, lack of management support, fear, management unwillingness to allow workers to participate in this study, low level of support for HACCP or process related activities within the organization may have contributed to this non-response bias.

**Implications**

The results presented in this study, are inclusive of the broad spectrum of food processing businesses, number of employees in each organization, number of members on each HACCP team, respondent’s age, and types of products being processed and include businesses operating under the purview of the major regulatory bodies (FDA and USDA). Results of this study indicate that while HACCP training successfully prepares over 60% of food industry professionals to actively participate in food safety activities and program development, approximately 18% of those trained require more training. Much of the knowledge depletion occurs rapidly following training, particularly when new trainees are not swiftly integrated into HACCP related activities. This preliminary data can be used to develop a framework for evaluating HACCP program administration competency, which then may be developed into a tool for evaluating the integrity of a process or processor. More
importantly it is an important tool for the food processor to use in understanding their own processes. Data such as this may be used to study trends in processes vs. outcomes (productivity, yields etc.) as well as when and if it is necessary to use monitoring data to make food safety decisions with large financial implications such as releasing, holding, reprocessing, or destroying product. In all cases monitoring and recordkeeping are one way inputs that require every piece of data to be entered in a timely manner and that corrections or additions are done so with complete transparency. As uncovered in this study, monitoring and record keeping activities are often not carried out in a timely manner or may be completed only to appease an auditor or inspector.

**Recommendations**

Future HACCP trainees could benefit greatly by the inclusion of training modules specific to pre-requisite programs, best practices for using monitoring equipment and record keeping, allergen education and control techniques as well as traceability at both the supplier end and distribution end. The content of training materials should also include best practices of how to plan, develop, administer and manage a HACCP program. Trainees may gain incremental knowledge and refresher training through several training instances that are delivered progressively. To support additional training, a train the trainer approach for in-house HACCP training for small businesses may be developed which includes access to more evaluation tools such as an expanded version of the survey instrument used in this study.

Although it is not required that an employee of a food business be trained in HACCP, it is recommended here that once an individual is trained in HACCP, they should be required to maintain an active HACCP training registration that requires continuous HACCP knowledge development on a regular basis (every 2-3 years). To facilitate continuous education standards, organizations should also develop and maintain current information about available training activities and a database of trained individuals. Trainer
credentialing should also require evaluation and re-calibration or re-education when necessary to ensure consistency of training programs.

It is recommended that businesses with HACCP programs use multi-member teams and begin the process by including workers involved in production/processing, quality, sourcing and distribution and whenever possible including all workers in HACCP training and activities. Businesses could also benefit greatly by swiftly involving those trained in HACCP in process improvement activities immediately following the training activity. Developing a culture of openness, honesty and respect can enhance HACCP program effectiveness by allowing possible issues to surface and be addressed before they lead to a food safety emergency or recall. Retraining HACCP team members should be done every 3 years at a minimum. Developing a positive safety culture may also lead to effective HACCP programs by allowing employees to contribute proactively to minimizing food safety incidents. Maximizing the value of HACCP training may be achieved by increasing involvement, expanding training to more individuals in more functional areas of the organization and by retraining HACCP team members on a rotating basis so that no member of the HACCP team spends more than 3 years between training events. Furthermore, the HACCP team should include at least one individual that has been trained less than 6 months previously.

Further research about pre-requisite program knowledge and their practical application is needed to elucidate specific necessary training criteria that need to be addressed through standard HACCP training programs. Based on this research, it may be inferred that differences in trainer beliefs about critical control point designation and their relationship with good manufacturing practices may exist and requires further investigation. Expanding this research could yield valuable information on how and when to provide interventions to manufacturing organizations and trainer development resources for peer trainers. Further study in this area may also include a sampling of individuals who have received refresher
training to compare cohorts of retrained vs. one-time trained HACCP team members to evaluate knowledge retention and the practical use of this knowledge.

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APPENDIX A

Initial Review

Approval Ends
April 25, 2013

IRB Number
12-0343-P4S

TO:
Marianne Angela Anandappa
Animal Sciences
440 Charles E Barnhart Bldg
0276
Phone #: (859) 257-7272 ext. 286

FROM:
Chairperson/Vice Chairperson
Non-medical Institutional Review Board (IRB)

SUBJECT:
Approval of Protocol Number 12-0343-P4S

DATE:
April 27, 2012

On April 26, 2012, the Non-medical Institutional Review Board approved your protocol entitled:

Evaluating Food Safety Training Effectiveness Through Post Training Assessments Utilizing an Online Survey Methodology

Approval is effective from April 26, 2012 until April 25, 2013 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigators responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol’s status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity’s Guidance and Policy Documents web page [http://www.research.uky.edu/ori/human/guidance.html#PIresp]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI’s web site [http://www.research.uky.edu/ori/]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

Chairperson/Vice Chairperson

An Equal Opportunity University

98
Online Tool for HACCP Training Assessment

Dear Survey Participant:

Hazard Analysis Critical Control Point (HACCP) training is a vital part of ensuring the safety of our food supply. Researchers at the University of Kentucky are performing a study to assess a web based tool for its capabilities at measuring various aspects of HACCP training courses. You are receiving this invitation to participate in this research study because you are registered with the International HACCP Alliance as someone who has participated in HACCP training or because you are a professional in the food processing and manufacturing industry. Participation in this study is completely voluntary and you are not obligated to participate in it. Although you will not get personal benefit from taking part in this research study, your responses may help us understand more about the endurance of training following the participation in one of these training programs. This information will assist us in further developing this online tool that may then be used by all in the food industry. It is important to have as many responses as possible and our hope is to have 1000 individuals participate. And so, your answers and willingness to participate in this study are very important and appreciated.

The survey/questionnaire will only take about 15-20 minutes to complete.

This is a confidential survey in which information specifically pertaining to you will not be used for the purpose of completing the study. No names will appear or be used in research documents, or be used in presentations or publications. The research team will not know specific information about you or the organization you are affiliated with unless you choose to provide this information. To encourage your participation in this study, you may optionally choose to receive the report of our findings. Any contact information you provide will be used solely for the purposes of providing you with a report. If you do not participate or provide your contact information, there are no alternatives for receiving the report.

Please be aware, while we make every effort to safeguard your data once received from the online survey/data gathering company, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still on the survey/data gathering company’s servers, or while en route to either them or us. It is also possible the raw data collected for research purposes may be used for marketing or reporting purposes by the survey/data gathering company after the research is concluded, depending on the company’s Terms of Service and Privacy policies.

If you have questions about the study, please feel free to ask; my contact information is given below.

If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-403-9428.

Thank you in advance for your assistance with this important project. To ensure your responses/opinions will be included, please complete this online survey by ____________.

Sincerely,

Angela Anandappa, Ph.D. Candidate
Department of Animal and Food Sciences
College of Agriculture, University of Kentucky
PHONE: (859) 257-7272 ext 286
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Melissa C. Newman Ph.D.
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University of Kentucky

Survey/Questionnaire Cover Letter Template
QUESTION CATEGORY 1: HACCP TRAINING
Please choose the most accurate response to the following questions.

1) Have you participated in a HACCP course?
   Yes/No

For responses of “no” survey logic will direct participant to the final page.
“Thank you for agreeing to participate in this study. Participating in a HACCP training activity is a pre-requisite for participating. We thank you for your time.”

2) What type of HACCP Course was it?
   o Introductory HACCP
   o HACCP Certification for food processors
   o Seafood HACCP
   o Juice HACCP
   o HACCP for restaurants
   o Advanced HACCP
   o HACCP for Medical Devices
   o HACCP Refresher Course
   o Dairy HACCP
   o Retail and Food Service HACCP
   o School/Day Care HACCP
   o Other (please specify)

3) What was the duration of the course?
   o 1 day
   o 2 days
   o 3 days
   o 4 days
   o 5 days
   o Don’t Recall
4) **When did you complete the training?**
   - Less than 1 week ago
   - 1-2 weeks ago
   - 2-3 weeks ago
   - 3-4 weeks ago
   - 1-2 months ago
   - 2-3 months ago
   - 3-6 months ago
   - 6-12 months ago
   - 1-2 years ago
   - 2-3 years ago
   - 3-4 years ago
   - 4-5 years ago
   - More than 5 years ago

5) **What country was this course held in?**
   - U.S.A.
   - Other (box will be provided for input).

6) **What state was this course held in?**
   Drop down list of states will be provided

7) **What organization was responsible for conducting the course?**
   - Drop down list of organizations affiliated with the International HACCP Alliance will be provided
   - Other (Fill in box for responses of “other” to the previous question.)
QUESTION CATEGORY 2: PARTICIPANT CLASSIFICATION

Please choose the most appropriate response for each of the following questions.

1) **What is the highest level of education you have received?**
   - Less than high school
   - High school graduate
   - Two year degree
   - Four year college degree
   - Masters degree
   - Doctoral degree

2) **Please indicate which trainings/certifications you have completed to date.**
   - ServSafe Food Handler
   - ServSafe Food Safety Manager
   - Sanitation Certification
   - HACCP Course
   - HACCP Certification
   - HACCP Certification, Meat and Poultry HACCP
   - HACCP Certification, Seafood HACCP
   - HACCP Certification, Juice HACCP
   - ISO 9000 Standards Training
   - ISO 9000 Auditor
   - ISO 22000:2005 Standards Training
   - ISO 22000:2005 Auditor
   - ASQ Certified HACCP Auditor
   - ASQ certified Quality Improvement Associate
   - SQF Safe Quality Food Standard Practitioner
   - SQF Safe Quality Food Standard Auditor Level
   - BRC British Retail Consortium Standard
   - BRC British Retail Consortium Standard Auditor
   - Better Process Control School
   - Food Defense Coordinator
   - Food Defense Coordinator
   - ECOLAB: Sanitation Food Safety Workshop
   - Six Sigma
   - Lean Manufacturing
   - Other (Fill in box will be provided)
3) What is your age
   - Less than 18
   - 18-22
   - 23-27
   - 28-32
   - 33-37
   - 38-42
   - 43-47
   - 48-52
   - 53-57
   - 58-62
   - 63-67
   - >68

4) Gender
   - Male
   - Female

5) Race
   - White
   - Black
   - Hispanic
   - Asian
   - Other (box will be provided for input)
   - Multi Racial

6) For how long have you worked in the food industry?
   - 0-12 months
   - 13-24 months
   - 25-36 months
   - 37-48 months
   - 49-60 months
   - 5-7 years
   - 8-10 years
   - Over 10 years

7) How would you best identify your job function?
   - Production
   - Manufacturing
   - Quality Assurance
   - Sanitation
   - Research and Development
   - Marketing
   - Packaging
   - Shipping
   - Auditor
   - Other (input box will be provided)
8) Please check all that apply (multiple responses allowed)
   o Team Member
   o Team Leader
   o Team Manager
   o Multi-team Manager
   o Site Manager

9) Please select the most accurate descriptor of your wage structure.
   o Owner
   o Salaried Employee
   o Hourly Employee

10) What has your involvement been in HACCP at your workplace? Please check all that apply.
    (Multiple responses)
    o I am involved in Hazard Analysis
    o Determining Critical Control Points
    o Establishing Critical Limits
    o I am involved in performing the daily Monitoring functions
    o I am involved in Record Keeping
    o Developing Verification Procedures
    o I am involved in Developing Corrective Actions
    o Auditing the HACCP plan
    o I am not involved in HACCP
    o Don’t know
    o Other (input box will be provided)
QUESTION CATEGORY 3: HACCP PRINCIPLES

Please choose if the following statements are True or False.

- Initial validation of the HACCP plan should be completed by a team of individuals from manufacturing.
- Chemicals used for cleaning and sanitation purposes should be stored close to the area where they will be used.
- Chemicals are not considered a source of contaminations in food products.
- It is important to include as many critical control points as possible in a HACCP plan.
- Trace forward and Trace back procedures are related to HACCP.
- Customer complaints are not considered a pre-requisite program for food safety.
- A HACCP plan can be skillfully developed through process mapping that accounts for all steps in the operation.
- Utilizing Good Manufacturing Practices and sanitation can minimize the number of critical control points.
- All control points should be designated as critical control points in a HACCP plan.
- The critical limits must be set for the process before operational limits are determined.
- For a product that must be cooled to ensure its safety, critical control points must be higher than operational temperatures.
- Customer complaints are not considered an indicator of issues with food safety.
- Initial validation of a HACCP plan must be conducted by independent experts.
- Chemicals should be stored away from food processing areas.
- Maintaining a cold chain is an effective method for controlling the growth of pathogens.
- For a product that must be heated to ensure safety, operational temperatures must meet or exceed the critical temperature that is set at a Critical Control Point.
QUESTION CATEGORY 4: Training Translation.

A grid with the 7 point Hedonic scale below will be used to gather responses from the following questions:

- Strongly Agree
- Agree
- Somewhat Agree
- Neither Agree nor disagree
- Somewhat disagree
- Disagree
- Strongly Disagree

1. I am given time by my supervisor to participate in food safety training activities.
2. I participate in the HACCP team/committee or activities during the year.
3. Company Management (Production Mgr, Supervisors) visibly demonstrates a commitment to food safety.
4. My immediate supervisor actively encourages the reporting of all unsafe conditions.
5. I feel comfortable reporting quality and safety issues to my immediate supervisor or a member of the operations/leadership team.
6. When I observe a food safety concern, I report it.
7. When improper environmental and/or safety conditions are reported, they are prioritized and addressed in a timely manner.
8. When time/temperature readings do not fall within critical limits, immediate action is not taken to correct the issue.
9. I am given time by my supervisor to participate in process improvement activities.
10. I am encouraged to report early, any signs of pain or discomfort (ergonomic) as soon as I first notice it, even if it is just a small pain.
11. Appropriate corrective actions are implemented after accidents or near misses to prevent re-occurrence.
12. I am comfortable to perform my job function.
13. My work team pays special attention to review paperwork and make the necessary changes to adjust temperature and time chart values when a food safety audit is due.
14. When new ingredients or vendors are chosen a member of the HACCP team is involved in those decisions.
15. My supervisor has provided me with information on how my job function relates to food safety.
16. I spend additional time preparing for a food safety inspection or audit.
17. The HACCP team re-evaluates the company HACCP plan whenever a new product is being developed for production.
18. I receive the results of food safety audits performed in my work area.
19. The costs of maintaining a HACCP plan are too great for the benefits it offers.
20. My supervisor has provided me the necessary tools and information on how to perform my job safely.
21. I am satisfied with my contribution to food safety at my organization.
QUESTION CATEGORY 4, Part 2:
Please choose the most accurate response to the following questions.

1) The HACCP team at my workplace is comprised of how many individuals?
   - Don’t Know
   - Zero Individuals
   - 1
   - 2
   - 3
   - 4
   - 5
   - More than 5

2) Please choose all job categories that are included in the HACCP team at your organization. Multiple responses allowed.
   - Production
   - Quality
   - Sanitation
   - Research and Development
   - Management
   - Finance
   - No formal HACCP team has been assembled
   - Other (Box will be provided for additional comments)

3) My organization has an in-house HACCP training team.
   - Yes
   - No

4) Please indicate the main product manufactured by your organization:
   - Meat and Poultry Processing
   - Beverages
   - Ready-to-eat Refrigerated Foods
   - Ready-to-eat Frozen Foods
   - Shelf Stable Food Items
   - Fresh Produce
   - Poultry Products
   - Prepared Fresh Fruit and Vegetables
   - Other (box will be provided for input)

5) What regulatory Agency(ies) does your work place get inspected by?
   - USDA
   - FDA
     - Local Health Department
   - Other (please specify)
QUESTION CATEGORY 5: POST TRAINING ACTIVITIES

- HACCP training provided me the information and knowledge needed to successfully prepare a HACCP plan at my organization.
- HACCP training provided me the knowledge to effectively contribute to the HACCP team.
- HACCP training was insufficient to complete a HACCP plan for my organization.
- It was important for my organization to have a HACCP consultant work with us to verify our HACCP plan.
- HACCP training is a necessity for all employees of a food business.
- HACCP training is only needed for those who are involved in quality assurance.
- HACCP training is only needed for those who are involved in production and processing.
- HACCP training has helped my organization to produce a higher quality product.

Please provide some feedback about HACCP training in general

- What additional information would have been useful to you during your HACCP training experience? (box will be provided for feedback)

QUESTION CATEGORY 6: QUESTIONNAIRE UTILITY

Please respond with a Yes or No to the following questions.

Did you find this online survey easy to access?
  ○ Yes ○ No

Do you prefer online training for HACCP to in-class training?
  ○ Yes ○ No

Would you be willing to participate in future studies relating to HACCP training?
  ○ Yes ○ No

Do you wish to receive the report that will be generated through this study?
  ○ Yes ○ No

Please provide your contact information to receive this report.
  ○ Yes ○ No
Name (Box will be provided for input)
Email Address or mailing Address (Box will be provided for input)
Modification Request Form  
University of Kentucky Institutional Review Board (IRB) 

Date: 07/17/2012  
IRB #: 12-0343-P4S

Pl Name: Marilene Anandappa  
Pl Signature: 

1. Address Change for Protocol Correspondence?  
   □ Yes  X No

   If yes, indicate new address: __________________________

2. Study Title: Evaluating Food Safety Training Effectiveness Through Post-Training Assessments Utilizing an Online Survey 
   Methodology

   Title change?  
   □ Yes  X No

   If yes, indicate new title: __________________________

3. Is this a one-time request for a deviation from the currently approved protocol or an exception to the currently approved enrollment criteria?  
   X Yes  □ No

   If yes, be sure changes are reflected in all your revised consent/assent documents, including VA versions, and any applicable HIPAA documents.

4. Consent/Assent Form Change?  
   X Yes  □ No

   If yes, this modification does not increase risk to study participants.

   □ This modification may or will increase risk to study participants.

5. Check One:  
   X This modification does not increase risk to study participants.

   □ This modification may or will increase risk to study participants.

6. Is this modification request due to an Unexpected Problem or Adverse Event?  
   □ Yes  X No

7. In your professional opinion, does this modification involve information that might relate to a subject’s willingness to continue to take part in the research?  
   □ Yes  X No

   If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.): Letter

8. Changes Made To: (check all that apply and attach appropriate documents)

   Form A: General Information Sheet
   □ Anticipated Project End Date
   □ Estimated # of Subjects
   □ Subject Population
   □ Vulnerable Subject Population
   □ Impaired Consent Capacity (Form T)
   □ Children age 17 or less (Form W)
   □ Pregnant Women (Form U)
   □ Prisoners (Form V)
   □ Other vulnerable population
   □ Off-site Facility (Form L)
   □ Study Personnel (SP List Template)

   Other - Describe: __________________________

   Form B: Research Description & Appendices
   □ Objectives
   □ Inclusion/Exclusion Criteria
   X Subject Recruitment
   □ Procedures/Materials
   □ Research Procedures
   □ Grant Application
   □ Sponsor Protocol: Investigator Brochure

   Forms C-F
   □ Consent Form (Form C-Medical; Nonmedical)
   □ Assent Form (Form D-Medical; Nonmedical)
   □ Waiver of Informed Consent (Form E)
   □ Waiver of Documentation of Informed Consent (Form F)

   Forms I-K
   □ HIPAA De-Identification Certification (Form I)
Modification Request Form
University of Kentucky Institutional Review Board (IRB)

PI Name: ____________________________ IRB #: ____________________________

[ ] HPAA Authorization (Form J)
[ ] HPAA Waiver of Authorization (Form K)

REQUIRED: For each proposed modification, describe the currently approved procedures, forms, etc. and then summarize the proposed change, addition, etc. Include a justification for the modification request. Add additional sheets if necessary.

Example:

Currently Approved: study staff as listed on attached SP List Template

Proposed Revision: add Jane Doe, MD, as co-investigator, Dr. Doe has completed human subject protections training, Dr. Doe is a new faculty member who will be working with subjects on this protocol and she is authorized to obtain consent.

1. Currently Approved: No incentive to participate.

Proposed Revision: Add option of registering to win an iPad.

2. Currently Approved: ____________________________

Proposed Revision: ____________________________

3. Currently Approved: ____________________________

Proposed Revision: ____________________________
Dear HACCP Training Participant

You are receiving this request to participate in a research study to test an online tool for assessing HACCP training that is being developed by researchers at the University of Kentucky. Please click here to access and participate in this important survey. For more information about this research, please see below.

Dear Survey Participant:

Hazard Analysis Critical Control Point (HACCP) training is a vital part of ensuring the safety of our food supply. Researchers at the University of Kentucky are performing a study to assess a web based tool for its capabilities at measuring various aspects of HACCP training courses. You are receiving this invitation to participate in this research study because you are registered with the International HACCP Alliance as someone who has participated in HACCP training or because you are a professional in the food processing and manufacturing industry. Participation in this study is completely voluntary and you are not obligated to participate in it. Although you will not get personal benefit from taking part in this research study, your responses may help us understand more about the endurance of training following the participation in one of these training programs. This information will assist us in further developing this online tool that may then be used by all in the food industry. It is important to have as many responses as possible and our hope is to have 1000 individuals participate. And so, your answers and willingness to participate in this study are very important and appreciated.

The survey/questionnaire will take about 15-20 minutes to complete.

This is a confidential survey in which information specifically pertaining to you will not be used for the purpose of completing the study. No names will appear or be used in research documents, or be used in presentations or publications. The research team will not know specific information about you or the organization you are affiliated with unless you choose to provide this information. To encourage your participation in this study, you may optionally choose to enter into a drawing to win an iPad 3 ($550 value) or receive the report of our findings. Any contact information you provide will be used solely for the purposes of providing you with a report. If you do not participate or provide your contact information, there are no alternatives to receiving the report.

Please be aware, while we make every effort to safeguard your data once received from the online survey/data gathering company, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still on the survey/data gathering company servers, or while en route to either them or us. It is also possible the raw data collected for research purposes may be used for marketing or reporting purposes by the survey/data gathering company after the research is concluded, depending on the company’s Terms of Service and Privacy policies.
If you have questions about the study, please feel free to ask; my contact information is given below.

If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the staff in the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-400-9428.

Thank you in advance for your assistance with this important project. To ensure your responses/opinions will be included, please completed this online survey by ____________

Sincerely,

Angela Anandappa Ph.D. Candidate
Department of Animal and Food Sciences
College of Agriculture, University of Kentucky
PHONE: (859) 257-7272 ext. 286
E-MAIL: AnandaAnandappa@uky.edu

Melissa C. Newman Ph.D.
Department of Animal and Food Sciences
College of Agriculture, University of Kentucky
PHONE: (859) 257-5891
E-MAIL: mnewman@email.uky.edu

Please click here to access the survey.
APPENDIX E

Recruitment, Procedures/Materials, Research Description, Consent

Modification Review

<table>
<thead>
<tr>
<th>Approval Ends</th>
<th>IRB Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 25, 2013</td>
<td>12-0343-P4S</td>
</tr>
</tbody>
</table>

TO: Marianne Angela Anandappa
Animal Sciences
440 Charles E Barnhart Bldg
0276
PI phone #: (859)257-7272 ext. 286

FROM: Chairperson/Vice Chairperson
Institutional Review Board (IRB)

SUBJECT: Approval of Modification Request for Protocol 12-0343-P4S

DATE: July 23, 2012

On July 20, 2012, the Institutional Review Board approved your request for modifications in your protocol entitled:

Evaluating Food Safety Training Effectiveness Through Post Training Assessments Utilizing an Online Survey Methodology

If your modification request necessitated a change in your approved informed consent/assent form(s), attached is the new IRB approved consent/assent form(s) to be used when enrolling subjects. [Note, subjects can only be enrolled using informed consent/assent forms which have a valid "IRB Approval" stamp, unless waiver from this requirement was granted by the IRB.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's Guidance and Policy Documents web page [http://www.research.uky.edu/ori/human/guidance.html?frmsnp]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [http://www.research.uky.edu/ori]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

[Signature]
Chairperson/Vice Chairperson
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Please click here to access the survey.
Bibliography


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WHO/SDE/PHE/FOS/99.7
VITA

Marienne Angela Anandappa was born in Sri Lanka where she completed her elementary and secondary education. She attended the University of Kentucky from 1995-2000 earning a Bachelor’s Degree in Biology (1997) and a Masters Degree in Food Microbiology (2000).