ASSESSMENT OF APPLE PACKERS ON FOOD SAFETY PRACTICES AND ATTITUDES ON AND PREPAREDNESS FOR THE FOOD SAFETY MODERNIZATION ACT (FSMA)

By

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ABSTRACT

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On January 6, 2014, Bidart Bros., an apple packing company in Bakersfield, California, voluntarily recalled Granny Smith and Gala apples due to a listeriosis outbreak linked to prepackaged caramel apples from its facility. Around the same time, the final rules for the Food Safety Modernization Act (FSMA), a U.S food safety that places the focus on prevention rather than reaction to foodborne illness outbreaks, were working towards publication. Such a critical event provides the opportunity to assess the current food safety practices, training needs as well as the attitudes and opinions of apple packers on FSMA. For this study, three surveys were administered and a food safety training workshop was held for apple packers. The surveys revealed that the majority of apple packing facilities had critical food safety practices in place, or were working towards incorporating them into their facility, expressed a need for microbial related trainings and FSMA trainings as these were their highest priority for food safety training topics, and the attitudes and opinions of the apple packers showed that there are gaps that need to be addressed by the FDA in terms of current processor practices affecting foodborne outbreaks and the resources provided to educate about FMSA.

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To my heavenly father, I thank you. *Le Seigneur est mon berger…*

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KEY TO ABBREVIATIONS

CDC- U.S Centers for Disease Control and Prevention

cGMP- Current Good Manufacturing Practices

FDA- U.S Food Drug and Administration

FSMA- Food Safety Modernization Act

GAPs- Good Agricultural Practices

GMPs-Good Manufacturing Practices

HACCP- Hazard Analysis Critical Control Point

HARPC- Hazard Analysis and Risk-Based Preventive Controls

NACMF- National Advisory Committee on Microbiological Criteria for Foods

CHAPTER 1

INTRODUCTION

1.1 Motivation for the Study

The apple (*Malus domestica*) is the second leading fruit produced in the world and is also one of the world's oldest fruits (Jackson 2003; Sinha 2012). Whole apples are not typically associated with foodborne illness, although apple cider has been implicated in 17 foodborne illness outbreaks in U.S (CDC 2015a). Thus, the 2014 *Listeria monocytogenes* outbreak linked to caramel apples was rather an unusual occurrence. Even more surprising, the source of the outbreak was determined to be the apple and not the caramel (CDC 2015b). The specific conditions that *L. monocytogenes* needs for growth and survival are not generally the ones provided by apples or caramel. To explain this rare occurrence, Glass and others (2015) hypothesized that inserting a stick into the apple (which is done during caramel-apple processing) releases juice to the interface between the apple and caramel. This could potentially provide an better environment for *L. monocytogenes* growth and survival than either apple or caramel alone (Glass and others 2015).

The above mentioned outbreak impacted 12 states. Thirty-five were infected individuals and seven died. Twenty-eight of the 31 ill individuals reported eating commercially produced, prepackaged caramel apples displaying a strong epidemiological association (FDA 2015a; CDC 2015b). The remaining three individuals recalled eating whole or sliced green apples from an unknown source, but did not remember consuming caramel apples (CDC 2015b). After being traced back to one supplier, a voluntary recall of Granny Smith and Gala caramel apples was issued. Environmental samples from the packing facility revealed *L. monocytogenes* contamination within the facility and, pulsed-field gel electrophoresis (PFGE) analysis of the samples and the outbreak strains further confirmed the contamination (FDA 2015a; CDC 2015b).

The Food Safety Modernization Act (FSMA) is a food safety law that employs science- and risk-based preventative measures from farm-to-table (FDA 2015b). This law has also been referred to as "the most sweeping change in food safety in the past 70 years" (Shinbaum and others 2015). In less than a year from the 2014 *Listeria monocytogenes* outbreak, two specific rules that affect apple packing facilities were published after being in motion since 2011: 1) the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption/ the Produce Safety Rule (FDA 2015c), and 2) the Preventive Controls for Human Food Rule (FDA 2016). FSMA was signed into law in 2011 as a response to the burden of foodborne illness. Approximately 131 produce-related reported outbreaks associated with about 20 different fresh produce commodities occurred from 1996 to 2010, which resulted in 14,350 illnesses, 1,382 hospitalizations and 34 deaths (FDA 2015a).

Although not mandatory, the apple packing industry adheres to Good Agricultural Practice (GAPs) and Good Manufacturing Practices (GMPs), which are prevention-based food production, processing, and marketing systems. These practices are based on the recommendation of the National Advisory Committee on Microbiological Criteria for Foods (NACMF) that GAPs and GMPs should be developed to provide guidance for agricultural and processing steps that can likely reduce pathogen levels on fresh produce in 1995 (De Roever 1999). Both serve as prerequisite programs for the Hazard Analysis Critical Control Point (HACCP) program which is a preventative system of quality control (Pierson and others 1992). HACCP is also not mandatory for the produce industry.

Thus, the apple packing industry is an industry without any in-depth food safety regulations, that has just experienced a major foodborne illness outbreak right around the time of an approaching food safety law aimed to reduce the burden of foodborne illness. This serves as an opportune time to assess that industry in regards to food safety practices, and attitudes on and preparedness for food safety regulations.

1.2 Objectives

1.2.1 Overall Goal

To assess the apple packing industry on food safety and the implementation of FSMA.

1.2.2 Specific Objectives

1. Determine current food safety practices used in the apple packing facilities, identify critical food safety information and training needs for the apple packing industry, and provide food safety and FSMA training during a food safety workshop, with special emphasis on the 2014 *L. monocytogenes* caramel apple outbreak.
2. Follow up on the implementation of FSMA within each facility surveyed and also gauge the attitudes and opinions of the apple packers towards FSMA.

CHAPTER 2

LITERATURE REVIEW

2.1 Foodborne Illness Outbreak in Fresh Produce

Foodborne illness outbreaks linked to fresh produce have increased since the early 1990s, as the consumption of fresh fruits and vegetables have increased (Sivapalasingam and others 2004). In the United States, there has been a significant increase of fresh produce outbreaks with known food vehicles, from <1% in the 1970s to 6% in the 1990s (Lynch and others 2008). This increase may be due to several reasons: increased per capita consumption of fresh produce in the United States, transportation distances to satisfy the desire for fresh produce year round, the close proximity of some produce fields to animal production zones (Lynch and others 2008), as well as the improved surveillance and testing. The consumer shift to 'natural' and 'organically' cultivated produce could result in the increased use of manure, and improperly treated manure may contain pathogens like *Salmonella* spp. and *E. coli* O157:H7 (De Roever 1999). Moreover, good agricultural practices (GAPs) are not practiced by all producers and commodity handlers, which makes produce susceptible to contamination during harvesting and postharvest operations.

Most of the foodborne illness outbreaks associated with fresh produce are linked to sprouted seeds, tomatoes, and leafy greens (Warriner and others 2009), and melons (CDC 2016) (Table 1). Apple cider was implicated in 17 foodborne illness outbreaks from 1998 to 2014 (CDC 2015), and whole apples once between 1973 and 1997(Sivapalasingam and others 2004).

Table 1. Partial listing of 2005-2016 Outbreaks linked to fresh produce (source: Warriner and others 2009; CDC 2016).

Date	Pathogen	Produce	Location
December 2005	*Salmonella*	Mung bean sprouts	Canada
February 2006	*Salmonella*	Alfalfa sprouts	Canada
February 2006	*Salmonella*	Alfalfa sprouts	Australia
June 2006	*E.coli* O121:H19	Lettuce	United states
July 2006	*Salmonella*	Fruit Salad	United States & Canada
August 2006	*Salmonella*	Alfalfa sprouts	United States
September 2006	*E.coli* O157:H7	Spinach	United States
September 2006	*Clostridium Botulinum*	Pasteurized carrot juice	United States & Canada
October 2006	*E.coli* O157:H7	Lettuce	Canada
October 2006	*E.coli* O157:H7	Lettuce	Canada
October 2006	*Salmonella*	Tomatoes	United States
November 2006	*E.coli* O157:H7	Lettuce	United States
November 2006	*E.coli* O157:H7	Lettuce	United States
April 2007	*Salmonella*	Lettuce	UK
August 2007	*Shigella sonnei*	Baby carrots	Canada
April 2008	*Salmonella*	Cantaloupe	Canada
April 2008	*Salmonella*	Alfalfa sprouts	United States & Canada
April 2008	*Salmonella*	Raw produce	United States & Canada
June 2008	*Salmonella*	Tomatoes/peppers	United States & Canada
September 2008	*E.coli* O157:H7	Lettuce	United States & Canada
September 2008	*Salmonella*	Alfalfa sprouts	United States
November 2008	*Salmonella*	Basil	UK
December 2008	*Salmonella*	Alfalfa sprouts	United States
February 2009	*Salmonella*	Alfalfa sprouts	United States
March 2010	*E.coli* O145	Romaine Lettuce	United States
May 2010	*Salmonella*	Alfalfa sprouts	United States
November 2010	*Salmonella*	Alfalfa sprouts	United States
January 2011	*Salmonella*	Papaya	United States
May 2011	*Salmonella*	Cantaloupe	United States
July 2011	*L. monocytogenes*	Cantaloupe	United States
October 2011	*E.coli* O157:H7	Romaine Lettuce	United States
July 2012	*Salmonella*	Mango	United States
July 2012	*Salmonella*	Cantaloupe	United States
October 2012	*E.coli* O157:H7	Spinach &Spring mix	United States
January 2013	*Salmonella*	Cucumbers	United States
October 2013	*E.coli* O157:H7	Salad	United States
May 2014	*E.coli* O121	Clover Sprouts	United States
August 2014	*Salmonella*	Cucumbers	United States
December 2014	*L. monocytogenes*	Caramel Apples	United States & Canada
September 2015	*Salmonella*	Cucumbers	United States
January 2016	*E.coli* O121	Alfalfa Sprouts	United States
January 2016	*Salmonella*	Alfalfa Sprouts	United States

2.1.2 Listeriosis Outbreak Linked to Whole Caramel Apples

On December 18, 2014, there were four illnesses reported to the Minnesota Department of Health, with all four cases purchasing and consuming caramel apples contaminated with Listeria monocytogenes (FDA 2015a). The Public Health Agency of Canada (PHAC) also detected similar pulsed-field gel electrophoresis (PFGE) patterns to the U.S. outbreak in two cases of listeriosis (only one case was genetically related to the U.S outbreak) (FDA 2015a). Ultimately, this outbreak infected 35 people in 12 states with 34 individuals hospitalized (CDC 2015). Three of the seven deaths reported were due to Listeriosis, and eleven illness were pregnancy-related with one illness resulting in a fetal loss (FDA 2015a; CDC 2015). 28 of the 31 ill individuals reported eating commercially produced, prepackaged caramel apples, displaying a strong epidemiological association (FDA 2015a; CDC 2015). The remaining three individuals recalled eating whole or sliced green apples from an unknown source, but did not remember consuming caramel apples (FDA 2015a; CDC 2015). The apples were later traced back to one supplier. This led to a voluntarily recall of Granny Smith and Gala apples from that supplier because testing of environmental samples from the apple-packing facility were found to be contaminated with Listeria monocytogenes (FDA 2015a; CDC 2015). PFGE analysis of the environmental samples and the outbreak strains revealed similar patterns (FDA 2015a; CDC 2015).

According the FDA's Establishment Inspection Report, 110 environmental swabs were collected from food and non-food contact surfaces in the packaging area, common cold storage, and bins stored outside (Clark 2016). Seven swabs were confirmed positive for L. monocytogenes with six of the sites being direct food contact surfaces (Clark 2016). The six direct food contact surfaces were: a black polishing brush, 3 red drying brushes, and the inside area of a non-painted Bidart wooden bin (one of the sites was kept confidential in the report) (Clark 2016).

2.1.2.1 Uncommon Vehicles

Temperatures greater than 50°C are lethal to *L. monocytogenes* with it growing in a suitable medium at temperatures ~ 0 to 45°C (Ryser and others 2007). The optimal temperature for growth is 37°C (Bell and others 2002). Ideal growth for *L. monocytogenes* occurs at neutral to slightly alkaline pH values, but can only grow at pH values from 5.6 to 9.6 (Ryser and others 2007) . *L. monocytogenes* can grow at lower pH values lower than 5.6 under specific conditions; the organism has to be incubated at near-optimum temperatures and given sufficient time to overcome an extended lag phase (Ryser and others 2007). For example, the pathogen multiplied when inoculated into Trypticase Soy broth adjusted to pH 4.4-4.6 with hydrochloric, citric, or malic acid. Lastly, *L. monocytogenes* requires water activity of (a_w) of at least 0.93 for growth (Glass and others 2015). Thus, given these factors, neither caramel nor apples are a food where the pathogenic bacterium *L. monocytogenes* should grow and thrive (Glass and others 2015). Fruits are more acidic than vegetables, favoring the growth of yeasts and molds (Kalia and others 2012). The pH of most apples ranges from 2.9 to 3.3 (Kalia and others 2012) (Table 2). However, somewhat higher pH values for fresh-cut apples were reported by Siddiq and others (2014). For example, 'Empire', 'Jonagold' and 'Mutsu' cultivars were reported to have values of 3.70, 3.82 and 3.85, respectively. Also, the caramel coating used on apples has low water activity <0.80 and is relatively hot at ~95°C (Glass and others 2015). Thus, this is an unlikely environment for *L. monocytogenes* to grow and survive.

Table 2. Approximate pH values of some fresh fruits (source: Kalia and others 2012).

Fruits	pH Values
Apples	2.9-3.3
Bananas	4.5-4.7
Grape Fruit	3.4-4.5
Watermelons	5.2-5.6
Oranges	3.6-4.3
Limes	1.8-2.0
Melons	6.3-6.7
Figs	4.6
Plums	2.8-4.6

In an attempt to explain this mystery, Glass and others (2015) hypothesized that inserting a stick into the apple (which is done during caramel-apple processing), releases juice to the interface between the apple and caramel. This could potentially provide an optimal environment for L. monocytogenes growth and survival than either apple or caramel alone (Glass and others 2015). This hypothesis was proven to be true, as significant growth was observed within three days at room temperature on caramel apples with sticks inserted (Glass and others 2015). Granny Smith apples were inoculated with L. monocytogenes prior to caramel dipping with some apples having sticks inserted before dipping (Glass and others 2015). The acidic pH of the juice from the apple may have also been neutralized by the caramel during equilibration (Glass and others 2015). Presence of the pathogen on or in the apple after coating with hot caramel, coupled with extended storage at ambient temperature by either the retailer or supplier, would be sufficient for L. monocytogenes to grow to infectious levels (Glass and others). Glass and others (2015) reached an important conclusion: food producers should consider interfaces between components within foods as potential niches for pathogen growth.

This interface or microenvironment which Glass and others (2015) discuss is between the caramel layer and the apple's surface. It was hypothesized that the caramel layer on the apple traps moisture next to the surface of the apple, creating a microenvironment that facilitates the growth of existing L. monocytogenes cells. Furthermore, the insertion of the stick into the apple may accelerate juice traveling to the surface. This then increases water activity in or below the caramel layer (Glass and others 2015). The researchers also stated that caramel-coated apples may be unrefrigerated for 2 to 4 weeks by retailers and consumers, which enhances both moisture migration and bacterial growth (Glass and others).

2.2 Apple Composition

Apples, or Malus domestica, are one of the world's oldest fruits and are primarily grown for the fresh fruit market (Jackson 2003). They are also grown for a number of important processed products, like apple juice, cider, frozen concentrate, applesauce, dried apples, frozen apples, and fresh-cut apples. Apples are the second leading fruit produced in the world, with China and the United States contributing more than 50% of the world apple production (Sinha, 2012). 'Red Delicious' cultivar accounts for two thirds of apple production, followed by 'Golden Delicious', 'Granny Smith', 'Gala', and 'Fuji' (Jackson 2003).

Because of its higher per capita consumption (approximately 7.3 kg), apples promote a greater intake of natural phenolic constituents by humans when compared to other fruits (Sinha 2012). It is suggested that naturally occurring phenolic constituents in produce have antioxidant properties that protect biomolecules (i.e., lipids, proteins, and DNA) within the human body from oxidative stress (Sinha 2012). Apples are also a source of monosaccharides, minerals, dietary fiber, biologically active compounds, and antioxidants (Wu and others 2006). Additionally, the polyphenols and flavonoids in fruits benefit the gut microecology through the inhibition of pathogenic microbes to the gut surface (Kalia 2012).

Apples are composed of approximately 84% water and 16% solids (Smock and others 1950; USDA 2015). However, water percentage (78.9-90.9) varies with apple variety (Smock and others, 1950). The 16% solids consist of approximately 12-14% carbohydrates, 0.3% protein and less than 0.10 % lipids, minerals and vitamins (Sinha 2012). Water content helps determine the weight and eating quality of apples (Smock and others 1950).

2.2.1 Microbiology of Key Apple Parts

To further understand the outbreak associated with apples, one must delve into the key parts of the fruit as unripe, ripe, and unprocessed fruits possess enormous microbial diversity (Kalia and others 2012). This section will focus on the microbiology of the apple's peel, flesh, and core.

2.2.1.1 Peel

The outer covering of a fruit is tough and impervious, as it acts as the first and foremost effective external protective system (Kalia and others 2012). A fruit's surface can harbor diverse types of microbes, which are derived from two sources: the primary microflora (resident population) or the secondary microflora on the fruit (Kalia and others 2012; Doores 1983). The resident population, also referred to as the primary microflora, contains microorganisms that through interactive forces between the plant surface and the cell wall structure of the microorganisms, adhere to the surface of the fruit (Doores 1983). The secondary microflora come from external vectors such as wind, rain, soil, insects, and birds (Doores 1983). Most of these microbes exist as vegetative cells or spores, plant pathogens, opportunistic pathogens, or nonplant pathogenic species, which include bacteria, yeast, and molds. (Kalia and others 2012). The predominant native microflora are nonsporing yeasts (Doores 1983).

There are advantages of the normal microflora to the fruit, as they inhibit the attachment, survival, and multiplication on human pathogens on the fruit's surface (Kalia and others 2012). The native bacterial flora of apples is limited to acidophilic species like acetic and lactic acid bacteria because of the composition and acidic pH of the apple (Doores, 1983). Studies have shown both positive and antagonistic effects of native microflora on the inhibition of L. monocytogenes in fresh-cut melons and normal yeast on molds, respectively (Kalia and others 2012). Another study found that native microflora of minimally processed produce were inhibitory to L. monocytogenes, and some other pathogens (Critizer 2010). Although the mode of action is unknown, antimicrobial peptides were the inhibitory substances to the Gram-positive microorganisms (Critizer 2010).

The surface flora of fruits is representative of pre- and postharvest conditions. Thus, unsafe practices during different processing steps, such as growing, handling, and packaging can inoculate the fruit's surface with human and plant pathogens (Kalia and others 2012). The orchard is the source of the microflora, but the subsequent sorting, handling, flume water, and unclean storage facilities can inoculate incoming fruit (Doores 1983). Additionally, damaged fruit and fallen fruit should be discarded. Fallen fruit can be diseased, insect damaged, or physically injured, which serves as inoculum in storage facilities. The 1991 outbreak of E. coli O157:H7 infections associated with the consumption of apple cider serves as an example. About 90% of the apples used in the cider were apples collected from the ground (De Roever 1999). The outbreak resulted in 23 cases of E. coli O157:H7 infections (De Roever 1999). Therefore, location, the quality of irrigation water, type of compost or manure, insects, and the condition of harvesting and processing equipment are all some of the factors to be considered during production of produce (Kalia and others 2012).

2.2.1.2 Flesh

The flesh of fruit is considered sterile, but during minimal processing of fruits, the fruit's natural cuticle is removed, which creates access for opportunistic microflora (Kalia and others 2012). When this happens, microbes attach to the bruised surfaces of the fruit and enter newer tissue niches (Kalia and others 2012). L. monocytogenes uses this as an opportunity to survive and multiply at low temperatures in fresh-cut fruits, although the environment may not be favorable for proliferation (Kalia and others 2012). Internal colonization of fruits is usually limited to a few species (Doores 1983). Thus, presence of organisms within the tissue indicates the presence of disease (Doores 1983).

Minimally processed fruits contain psychrotrophic microbes like Listeria, and the presence of cut surfaces provides an increased surface area for contamination and growth (Kalia and others 2012). This also allows microbial infiltration of the tissue (Kalia and others 2012).

Pathogens can affect plant tissues by producing one or several kinds of cellulytic or pectionlytic enzymes (i.e., cellulases, pectinases) and other degradative enzymes (i.e. polyphenol oxidase, peroxidase) to overcome the outer covering of fruits (Kalia and others 2012). This causes active invasion and spoilage in fruits (Kalia and others 2012). In contrasts, opportunistic pathogens lack the degradative enzymes (Kalia and others 2012). This serves as a burden to these microorganisms, as they can only gain access when the normal plant defense system weakens. An opportunity may arise from damaged fruit during harvest or postharvest and allow opportunistic pathogens to invade the internal tissue and cause spoilage (Kalia and others 2012). The pathogen enters through the damage on the produce and moves through natural pathways like the lenticels, stomata, hyathrodes, or other pores/lesion caused by insect infestation or invasion by true pathogens (Kalia and others 2012).

2.2.1.3 Core

Microorganisms can enter the core of apples through transfer from the skin. This was demonstrated by a decline in E. coli O157:H7 in the inner core when the pathogen was eliminated on the surface, but present in the core (Buchanan and others 1998). This also shows that surface disinfectants are not effective on internalized enteric pathogens (Critzer and other 2010). This is one of the challenges in developing effective methods to kill human pathogens on fresh produce; pathogens infiltrate tissue, which gives them protection against chemical sanitizers and physical methods of removal (Burnett and others 2000).

In apple varieties, the core region pH may be 0.06 to 0.08 units higher than that in the apple flesh (Glass and others 2015). This is important to note because Glass and others (2015) also hypothesized that the other parts of the apple (core or seeds), also hosted L. monocytogenes growth. The pathogenic cells in the stem area might have also been pushed into the core (when the stick was inserted), where bacterial cells would be protected from the heat of the caramel (Glass and others 2015).

The uptake of water through irrigation or washing procedures can also introduce human pathogenic bacteria and viruses to the flesh of the fruit (Kalia and others 2012; Burnett 2000) and eventually the core. Buchanan and others (1999) conducted a study to characterize the extent and location of contamination when intact apples were exposed to an aqueous environment contaminated heavily with E. coli O157:H7. This is similar to the environment in dump tanks or flume water not hygienically maintained (Buchanan and others 1999). The study showed that the frequency and the degree of internalization was less when cold apples were immersed in cold peptone water as opposed to warm apples in cold water (Buchanan and others 1999). Ideally, the temperature of wash water should be greater than that of the produce (De Roever 1999). If not, the pressure differential will result in the aspiration of bacteria into the plant material (De Roever 1999). The uptake of E. coli O157:H7 was not uniform, as the greatest site of contamination was the outer core region (Buchanan and others 1999). This uptake will take place if chlorination of water where the apples are immersed is insufficient to prevent cross contamination, as the uncontaminated apples can be expected to take up E. coli O157:H7 (Buchanan and others 1999). Open channels in the apple's blossom end lead right into the inner core region of the apples, which explains the presence of high levels of the pathogen in the core (Buchanan and others 1999). Burnett and others (2000) explain this through the general gas law: as the temperature of produce decreases, gases in their tissues exert a reduced pressure. This causes the combined atmospheric and hydrostatic forces on the produce to equilibrate with internal pressure and facilitate the entry of water (Burnett and others 2000).

2.3 Factors Influencing Microbial Growth

Commercial apple production uses science-based technologies to allow for prolonged storage (Jackson 2003). 'Granny Smith' cultivars are an excellent example as they have been shown to store for eleven months under appropriate conditions (Jackson 2003). The processing, storage conditions, and contamination load of fruits can easily be determined by the microbiological profile of the fruit's surface and internal tissue (if there is surface bruising) (Kalia and others 2012). If not effectively eliminated through interventions during crop development, as well as GAPs during harvesting, these microbes can lead to spoilage and foodborne diseases (Barth and others 2009). Fungi is the dominant microorganism in many fruits and includes both spoilage and innocuous types (Roberts and others 2005). Specific niches, or microenvironments, can harbor human pathogenic microbes which can be created through the help of spoilage pathogens (Montville and others 2001). This section will focus on certain intrinsic and extrinsic factors which contribute to the microbiological profile of produce as spoilage.

2.3.1 Available Nutrients

Like all living organisms, microorganisms have varied nutrient requirements. These requirements are influenced by temperature, pH and redox (Eh) values (Wareing and others 2011). At ideal temperatures, nutrients control microbial growth; the opposite happens at reduced temperatures (Kalia and others 2012). As a result, pectionlytic bacteria (Pectobacterium carotovora, Pseudomonas spp.), or pectinolytic molds grow best on produce (Kalia and others 2012). The nitrogen requirements of this microorganism is usually met by proteolysis of protein present in substrates, use of amino acids, nucleotides, certain polysaccharides, and fats under usual microbe-specific conditions (Sinha 2012).

Gram-positive and Gram-negative bacteria grow on fruits under the influence of unusually low pH and positive Eh values (Barth and others 2009). These two group of microbes grow abundantly on foods relatively low in B-complex vitamins (Kalia and others 2012). Vitamins are to be furnished by substrate because microorganisms are not able to synthesize essential vitamins (Kalia and others 2012). Unlike Gram-negative bacteria, Gram-positive bacteria require a supply of certain vitamins before growth and are least synthetic (Sinha 2012). Thus, gram-negative bacteria and molds can synthesize most of the vitamins and are relatively independent (Sinha 2012).

2.3.2 Antimicrobial Factors

Antimicrobial factors, or compounds, can be present in food, added, or developed by associated microbial growth or by processing methods (Jung and others 2016). These compounds improve the safety of the food product and subsequently increase shelf life. Plants have a wide range of volatile compounds. Some are important flavor quality factors in fruits and vegetables (Lanciotti and others 2003). These volatile compounds have been credited as a main contributor to the defense system of fresh produce (Lanciotti and others 2003). For example, the presence of aroma precursor hexanal readily gets converted to aroma volatiles in vivo by fresh-cut apple slices (Song and others 1996). Hexanal acts as an antibrowning agent (Corbo and others 2000). It also inhibits the growth of molds, yeasts, mesophilic and psychrotropic bacteria (Corbo and others 2000). Because of these properties, hexanal and (E)-hexenal are used in modified atmosphere packaging (MAP) of sliced apples to reduce spoilage microbe populations (Corbo and others 2000). Siroli and others (2015) conducted a study which found that 2-(E)-hexenal/hexanal and 2-(E)-hexenal/citral combined with strains of Lactobacillus plantarum increased the shelf life and safety characteristics of minimally processed apples. When hexanal, hexyl acetate, and (E)-2-hexenal are used at 150, 150, and 20 ppm, respectively, they display a bactericidal effect on L. monocytogenes (Lanciotti and others 2003).

Furthermore, some antifungal compounds added to fruits are benomyl, biphenyl and other phenylic compounds (Sinha 2012). These compounds must exist in small quantities as by-product of phenol synthesis pathways (Sinha 2012). Benzoic acid has both antibacterial and antifungal activities and is present in most plant products including fruits like cranberries (Sinha 2012).

2.3.3 Relative Humidity

The relative humidity (RH) of an environment affects the storage temperature of the food stored in that environment (Kalia and others 2012). RH also affects aw within a processed food and microbial growth at the surface (Kalia and others 2012). When excessively high, RH provides conditions for the development of fungal disease and physiological disorders (Anese and others 2015). When RH is excessively low, there is high mass loss and wilting (Anese and others 2015). A low aw food kept at high RH value will usually absorb moisture until an equilibrium is reached while foods with high aw lose moisture in a low-humidity environment (Kalia and others 2012). Anese and others (2015) found that after storage, mass loss induced by low RH increased gas diffusion in the flesh of ‘Royal Gala’ and ‘Galaxy’ apples. It also reduced fruit flesh cracking flesh breakdown and mealiness during controlled atmosphere (CA) storage (Anese and others 2015). However, produce is susceptible to spoilage during storage at low RH conditions due to the variety of surface growth from yeasts, molds, and bacteria (Kalia and others 2012).

2.4 Listeria monocytogenes

The genus Listeria is oxidase-negative, microaerophilic, aerobic, catalase-positive, and facultatively anaerobic (Ryser and others 2007). These Gram-positive bacteria are psychrotrophic, and also reproduce at temperatures between 1 and 45° C (Ryser and others 2007). Their uncanny ability to reproduce at low temperatures poses a risk to refrigerated foods, with growth at refrigeration temperatures being dependent on the interaction between pH and temperature (De Roever 1999). Another challenge for the food industry is L. monocytogenes’ resistance since this pathogen can survive under adverse environmental conditions unlike many other non-spore-forming bacteria (Ryser and others 2007). For example, it can tolerate high (up to 20%) salt concentrations, as well as adapt and survive acid stress (Ryser and others 2007). This allows the pathogen to persist on processing equipment as well as colonize and multiply (Ryser and others 2007).

2.4.1 Source of Pathogen

The natural habitats of L. monocytogenes are soil, water, sewage, and animal feeds (Ryser and others 2007). L. monocytogenes has also been isolated from farm environments and food –processing environments (Ryser and others 2007; Beuchat 1996) as they can be contaminated by soil, water, sewage, and animal feeds. This section will focus on soil, silage and water as sources of the pathogen (Brandl 2006; Brooks and Brashears 2008). Kader and Siddiq (2012) reported that the emphasis of ongoing research on produce safety is on developing reliable and quick detection methods for human pathogens, improved efficacy of water disinfection methods, and develop methods for reducing microbial load on intact and fresh-cut fruits.

2.4.1.1 Soil

Soil is a source for *Listeria* contamination. Survival of *L. monocytogenes* depends on soil type and moisture content; however, soil does not appear to be a natural reservoir where the pathogen multiplies (Ryser and others 2007). Decaying plant material, animal waste, and sewage sludge, all well-documented sources of *L. monocytogenes*, are usually deposited in soil and can account for the widespread presence of the pathogen (Ryser and others 2007). The damp soil's surface provides a cool, moist environment, and the decaying vegetation serves as the substrate enabling the pathogen to survive (Ryser and others 2007).

2.4.1.2 Silage

Silage, or fermented fodder, is a favorable environment for high numbers of *L. monocytogenes* (Ryser and others 2007; Goldline and Others 2007). One study conducted isolated *L. monocytogenes* from the soil collected from fields where cattle, or sheep-fed silage diets had been kept, but not from soil samples associated with vegetable crops (Oliver and others 2007). This highlights the role that animals play as sources of *L. monocytogenes* in soil and plants. Listeriosis, an infection caused by contamination of *L. monocytogenes*, was first observed in animals and most of the reported cases in animals have occurred in farm ruminants (Oliver and others 2007). Although prevalence of the pathogen varies in ruminants or ruminant farms, it is usually the highest in animals fed silage (Oliver and others 2007). The transmission of *L. monocytogenes* is greatly impacted by the presence of *L. monocytogenes* in silage (Oliver and others 2007). Further dispersal through fecal shedding in ruminant-associated agricultural environments, within animal populations as well as from animal populations, and farm environments to humans also play a major role in transmission (Oliver and others 2007).

2.4.1.3 Water

True to its ubiquitous nature, *L. monocytogenes* is present in varying numbers in water (Ryser and others 2007). The pathogen is also present in a wide range of surface waters – lakes, rivers, and streams (Ryser and others 2007). This can be explained through the use of surface waterways as discharge of sewage effluents (Ryser and others 2007). Studies have shown isolation of *L. monocytogenes* from shrimp caught off the U.S. Gulf Coast and also that some strains associated with shrimp can persist in processing plants and enter the final product (Ryser and others 2007). Therefore, *L. monocytogenes* can be present in both marine and fresh waters.

Fortunately, no epidemiological evidence has yet been presented to show the occurrence of *L. monocytogenes* infection of humans through contaminated water (Ryser and others 2007).

2.4.2 Classification

L. monocytogenes is rod-shaped and forms single short chains (Jones 2010). Gram-positive bacteria have a cell wall comprised of several layers of peptidoglycan or polymers of sugar and amino acid (Todar 2012). The cell wall is a vital component of the cell especially since *L. monocytogenes* is non-spore forming. This component protects the cell protoplast from mechanical damage and from osmotic rupture (Todar 2012). The particularly rigid cell wall of *L. monocytogenes* can also be credited for this bacterium's ability to survive a wide range of environments (Pucciarelli and others 2007).

Teichoic acid are polymers of polyglycerol bounded to the peptidoglycan of *L. monocytogenes,* which also contribute to the bacteria's viability (Todar 2012). Lipoteichoic acids are another polyanionic polymer found in the cell wall. These polymers are specifically entrenched in the plasma membrane by a diacylglycerolipid (Bierne 2007). Teichoic and Lipoteichoic acids are the main contributing factors of surface immunogenicity. Their functions include: attaching virulence proteins, stimulating a large variety of responses in the host and transporting ions, nutrients and proteins (Bierne 2007). Once ingested, the bacteria are actively internalized by host cells and incorporated into phagolysosomes (Dabiri and others 1990). With the aid of hemolysin, the bacteria seeps from the phagolysosome and enters the cytoplasm where it spreads from cell to cell. In the peripheral membrane, it promotes the growth of cytoplasmic projections that are immediately engulfed by neighboring cells (Dabiri and others 1990).

2.4.3 Listeriosis

According to the Centers for Disease Control and Prevention (CDC) (2014), approximately 1600 illnesses and 260 deaths occur annually in the U.S. from listeriosis. Listeriosis is an infection caused by ingesting food contaminated with *L. monocytogenes*. Foods most susceptible to *L. monocytogenes* contamination are uncooked meats and vegetables, unpasteurized milk and cheeses, cooked or processed foods, which include certain soft cheeses, ready -to-eat meats, and smoked seafood (CDC 2014). Besides being ingested, *L. monocytogenes* can also be transmitted transplacentally from mother to child during pregnancy and via the birth canal during birth, from direct contact with diseased animals to farmer, nosocomial infections and person-to-person transmission (Pucciarelli and others 2007). Thus, *L. monocytogenes* can be disseminated through reservoirs as well as zoonosis (Bell and others 2002).

Temperature abuse during storage and preparation, along with improper hygiene, are major contributors to the proliferation of foodborne illness. Bell and others (2005) listed additional factors of foods linked to outbreaks of listeriosis as use of raw ingredients not subjected to a listericidal process, products susceptible to post-process contamination, refrigerated storage, production formulation allowing growth of *L. monocytogenes,* extended shelf life (>10 days), ready-to-eat foods, and consumption by vulnerable groups. To avoid being infected with *L. monocytogenes,* it is highly recommended to thoroughly cook animal sourced food, thoroughly wash raw vegetables, avoid unpasteurized milk, wash hands, utensils and cutting boards used with uncooked food, and keep ready-to eat foods cold (CDC 2014). *L. monocytogenes* has an infectious dose of about 10^5 to 10^7 CFU (Farber and others 1991). The individuals most at risk are pregnant women, the elderly and those who are immunocompromised (CDC 2014). Listeriosis in pregnancy happens most commonly during the third trimester where the onset symptoms are described as "flu like" symptoms. This includes fever, chills, back pain and diarrhea (CDC 2014). These conditions can potentially lead to miscarriage, stillbirth, premature delivery, or life threatening infection of the newborn (CDC 2014). In the elderly and the immunocompromised, the infection may present itself as headaches, stiff neck, confusion, septicemia and meningitis. Therefore, listeriosis most commonly takes the form of an infection of the uterus, bloodstream or central nervous system (Bell and others 2002)

"Healthy People 2010" goals for the United States addressed listeriosis by proposing a 50% reduction of foodborne listeriosis by the end of 2005 (U.S. Department of Health and Human Services, 2010) It is noted that a significant reduction was observed by 2004 (U.S. Department of Health and Human Services, 2010). The Food and Drug Administration (FDA), CDC, and the U.S. Department of Agriculture (USDA) established and released a national *Listeria* Action Plan in 2001 and 2003 (Ryser and others 2007). The purpose of this plan was to help guide control efforts by industry, regulators, and public health officials (Ryser and others 2007). Additionally, the plan identified eight key areas and called for multiple points of action which included increased regulatory guidance over the manufacture of ready-to-eat foods (Ryser and others 2007; Bell and others 2005).

2.5 Apple Packing Process

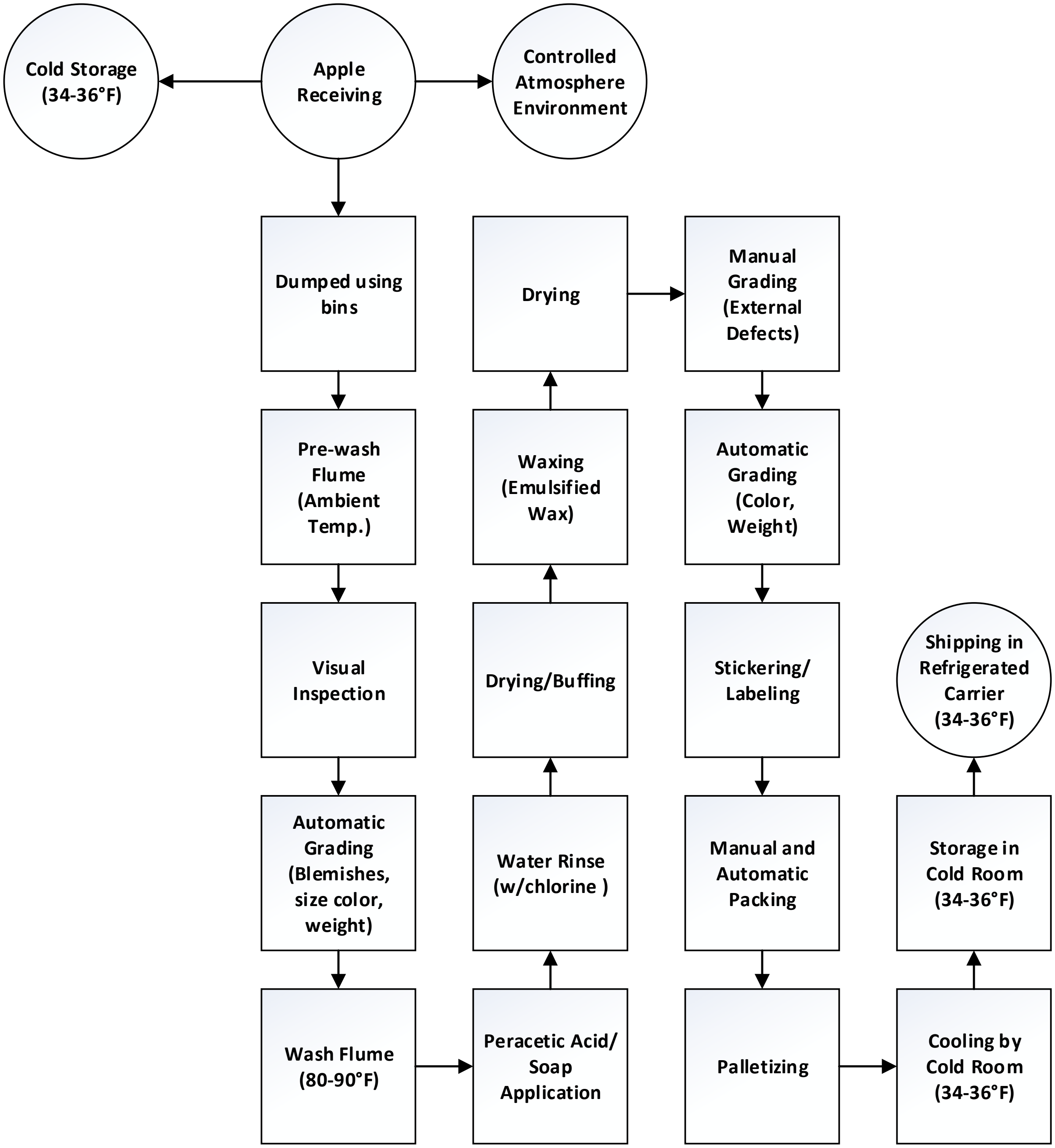
A general apple packing process in a commercial packinghouse is detailed in Figure 1. Although minimally processed, the processing steps listed address opportunities for pathogen growth and cross-contamination as processing of fresh produce increases the risk of bacterial contamination and growth (De Roever 1999). Every attempt should be made to reduce the possibility of the presence of pathogenic microorganisms on produce at all points in the value-chain from growing, processing, and storage to distribution channels (Beuchat 1996; Al-Zenki and others 2012)

The apple packing process contains several wash steps; from drying to pre-waxing (Figure 1). When it comes to temperature, prewashing should be conducted at 10°C above the temperature of the fruit to minimize the temperature differential, and cold water for subsequent washing to remove field heat and maintain quality (Buchanan and others 1999; Al-Zenki and others 2012). When produce arrive at the packinghouse, they contain populations of 10^4 to 10^6 microorganisms/g (Beuchat 1996). Thus, although water can effectively remove sand, soil, and other debris from produce, additional chemicals may be needed as water can only achieve a 1 to 2 log reduction in microbial load (Beucaht 1996). Using 200 to 300 µg/ml of chorine is recommended for produce as chlorination of wash water reduces the microbial load on produce (Beuchat 1996). Residual chlorine should then be rinsed with potable water as only a residual concentration of 2-7 ppm of chlorine is accepted in fruits (Al-Zenki and others 2012). For fresh-cut and whole apples, peroxyacetic acid, hydrogen peroxide, and *N*-acetyl-L-cysteine have been suggested as potential disinfectants for the fresh fruit industry (Al-Zenki and others 2012). Hot water sanitation is also another option and has been investigated for fruits such as apples, lemons, and mangoes (Al-Zenki and others 2012). One caveat is that the FDA does not consider thermally treated produce as "fresh" as outlined in FDA rule 21 CFR part 101.95 (Al-Zenki and others 2012).

Additional postharvest steps for apples are hydrocooling, sorting, grading, testing, waxing, and packing (Sinha 2012). Traceability is an important part of the process as apples may be received from different orchards and may have different destinations. Therefore, lot codes, universal product codes (UPCs), and bar codes are used for traceability and contain the source of the raw material used, or the processing date of the finished product (Siddiq and others 2012). The apples also usually have stickers with pertinent information and can be bagged or placed in cartons and then boxes with additional labeling.

The last steps are storage and transport. Minimally processed fruits are usually stored at lower temperatures, with temperatures between 1°C and 3°C recognized as a hurdle to pathogen growth (Al-Zenki and others 2012). Apples are stored at 0°C to –1°C, with 92-95% relative humidity (RH) in cold storage (Sinha 2012). Temperature abuse is fairly common as an effect of mishandling during storage and transport thus, temperature management is critical at these points (Al-Zenki and others 2012). Kader (2003) recommended maintenance of cold-chain throughout the postharvest operations.

Figure 1. Flowchart of typical apple packing process



2.6 Fresh Produce Guidance Documents Prior to FSMA

According to De Roever (1999), regulation of fresh produce is relatively difficult. This is primarily because fruits and vegetables are simultaneously raw agricultural commodities, and ready-to-eat foods (De Roever 1999). Since food safety is so complex, it is important to understand the mechanisms of food contamination (Siddiq and others 2012). This section will focus on guidance documents that have improved the food safety of fresh produce prior to the Food Safety Modernization Act (FSMA) by focusing on the key areas of food contamination.

2.6.1 Industry Guide to Minimize Microbiological Food Safety Hazards for Fresh Fruits and Vegetables

Developed by the FDA and USDA in collaboration with the food industry after President Clinton's produce safety initiative, the Industry "Guide to Minimize Microbiological Food Safety Hazards for Fresh Fruits and Vegetables" identifies the principal areas of concern and provides a generic guidance for growers (FDA 1998). The guidance document is voluntary and science based, and is encouraged for domestic and foreign fresh producers' use (FDA 1998). It also focuses on primarily risk reduction and not risk elimination (FDA 1998), as it is impossible to completely avoid the risk of microbial contamination (Siddiq and others 2012). There are eight basic principles provided that serve as the foundation for GAPs (FDA 1998). These principles of food safety focus in the areas of growing, and harvesting and transporting that will minimize microbial food safety hazards (Tapia and others 2009).

2.6.2 GAP & GMP

GAP'S and GMPs are prevention-based food systems. Generic GMPs were introduced into the fresh produce industry in the late 1990s and GAPs have become a model for focusing on the key areas of presumptive risk potential for fruit and vegetable production and handling (Tapia and others 2009). In 1995, the National Advisory Committee on Microbiological Criteria for Foods (NACMF) recommended that GAPs and GMPs should be developed to provide guidance for agricultural and processing steps that can likely reduce pathogen levels on fresh produce (De Roever 1999). Additionally, GAPs and GMPs are prerequisite programs for the hazard analysis and critical control point (HACCP) system. Bihn and Reiners (2010) reported that since microbial contamination is difficult to remove once attached, the focus of GAPs is prevention.

GMPs, which serve as one basis for FDA inspections, describe the methods, equipment, facilities and controls for producing processed foods (FDA 2014). Enforced by the FDA, they contain the requirements and guidelines for manufacturing food in a sanitary environment (Keener 2007). Lastly, GMPs make reference to FDA action levels, which are for a defect that is natural or unavoidable even when foods are produced when all eight categories are acceptable (FDA 2014). According to the FDA (2014), these defects are not hazardous to health at low levels and include rodent filth, insects, or mold.

GAPs are voluntary and are used for the production, packing, handling, and storage of produce (USDA 2015). They ensure the safety of fruits and vegetables and minimize the risks of microbial food safety hazards (USDA 2015). As the safety of produce begins with practices followed at the farm or orchards (Siiddiq and others 2012), GAPs' focus on water use, soil amendments, animals and land use on the farm as well as aspects within field harvest and field packing, house packing facility, and storage and transportations (USDA 2015). The USDA implemented the GAP & good handling practices (GHP) voluntary audit verification program in for operations interested in verifying their microbial risk and contamination activities (USDA 2015).

2.6.3 HACCP

The HACCP system is a preventive system of quality control (Pierson and others 1992) which focuses on building food safety in the manufacture of a product (Siddiq and others 2012). It is also a management system that uses the analysis and control of biological, chemical, and physical hazards from raw material production to the consumption of the finished product (FDA 2015). This system is recognized by the NACMCF as the most effective and flexible system for assuring the microbiological safety of a variety of foods (De Roever 1999). This systematic approach is based on seven principles: 1) Conduct a hazard analysis, 2) Determine the critical control points (CCPs), 3) Establish critical limits, 4) Establish monitoring procedures, 5) Establish corrective actions, 6) Establish verification procedures and, 7) Establish record-keeping and documentation procedures (FDA 2015). According to the USDA (2016), in the U.S, HACCP is mandatory by law for manufacturers of meat and poultry, seafood, and juice products with guidance documents for all three. It has also been incorporated into the low acid canned food industry (Siddiq and others 2012). Although HACCP is voluntary for all other manufacturers, there are guidance documents for dairy grade A voluntary HACCP and retail and food service HACCP (FDA 2015).

HACCP programs have been encouraged by the fresh-cut produce industry and many segments have adopted the principles (Tapia and others 2009). The NACMCF also surmises that HACCP plans would be equally useful for fresh produce (De Roever 1999). But when it comes to produce operations, HACCP systems have limited applications (Tapia and others 2009). A 'farm-to-table' HACCP approach which includes the production and processing of fresh produce has been attempted a few times (De Roever 1999). The International Fresh-cut Produce Association (IFPA) developed a model HACCP system for the fresh-cut produce industry (Beuchat 1996). A model HACCP for sprouted seeds, shredded lettuce, and tomatoes was developed by two trade associations: Clemson University, The CDC, and The University of Georgia (De Roever 1999). Unfortunately, the models for sprouted seeds, shredded lettuce and tomatoes were not validated (De Roever 1990). According to Tapia and others (2009), specific critical limits cannot be established and monitored to ensure the hazard is reduced to acceptable levels. De Roever (1999) supports this by adding that there is insufficient data to support the development of validated HACCP plans for fresh produce. Conclusively, further research is needed to establish CCPs, critical limits, and types of monitoring procedures to apply HACCP to fresh produce (Soon and others 2012).

2.7 The Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act is intended to be proactive rather than reactive, focusing on the likelihood of risks and employing measures to mitigate those risks. FSMA is also described as a "modern mandate and tool kit to improve the safety of the country's food supply" (Taylor 2011). Pouliot (2014) argues that food producers are rarely accountable for the food safety incidents that they cause often escape without reprimand and explore opportunistic behaviors in producing and handling safe food. He adds that these behaviors have been the motivation for food safety laws within the United States. Although there is not much research on the impact that commercial food processing employees have on foodborne illnesses, one can look at the parallels in the research conducted on food service employees (Shinbaum and others

2015). According to Shinbaum and others (2015), food service employees play a defining role in a majority of their customers' illnesses and 97% of all foodservice related illnesses can be traced back to employees improperly handling food. Shinbaum and others also add that "FSMA places the responsibility for food safety where the liability resides, with the food processors and producers." Not only are foodborne illnesses a substantial burden, but they can also reduce the consumer's confidence in the food supply and subsequently cause major economic disruptions for the food system (Taylor 2011).

The Food Safety Modernization Act, signed by President Obama on January 4th, 2011 gives the FDA the authority to issue a recall when a company fails to voluntarily recall unsafe food (FDA 2015b). Prior to this act, food companies would use their own discretion on when to issue a recall. The FDA only had the jurisdiction to issue recalls on infant formula and infant food related products. The FSMA is to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply (FDA 2014) and places focus on preventing food safety issues rather than responding to them after the fact (FDA 2015b). Drew and others (2015) stated, "FSMA aims to prevent or reduce large-scale foodborne illness outbreaks through stricter facility registration and record standards, mandatory prevention based controls, increased facility inspection in the United States and internationally, mandatory recall authority, import controls and increased consumer communication."

Approximately 131 produce-related reported outbreaks associated with about 20 different fresh produce commodities occurred from 1996 to 2010 (FDA 2015b). This resulted in 14,350 outbreak-related illnesses, 1,382 hospitalizations and 34 deaths (FDA 2015b). Under the FSMA, the FDA has two rules to address produce: "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" and "Preventive Controls for Human Foods."

2.7.1 Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption/Produce Safety Rule

The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Rule (hereafter referred to as the Produce Safety Rule) has six key requirements which produce businesses must fulfil on designated compliance dates based on business size (FDA defines size in terms of sales). These six requirements address areas of potential food safety concerns. The key requirements focus on agricultural water, biological soil amendments, sprouts, domesticated and wild animals, worker training and health hygiene and equipment, tools and buildings (FDA 2015c). This rule does not apply to produce that is not a raw agricultural commodity, food grains, produced used for person or on-farm consumption and produce rarely consumed raw (FDA 2015c). For example, asparagus, black beans, eggplants, sweet potatoes and winter squash are listed as produce rarely consumed raw (FDA 2015c). Produce that receives commercial processing that adequately reduces specific microorganisms as well as certain farms that meet specific qualifications are also exempt (FDA 2015c).

The agricultural water requirement focuses on microbial water quality and testing. There are two sets of criteria for microbial water quality: "No detectable generic *E.coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact" (FDA 2015c) and "The geometric mean (GM) of samples is 126 or less CFU of generic *E.coli* per 100 mL of water and the statistical threshold (STV) number is 410 CFU or less of generic *E.coli* in 100 mL of water" (FDA 2015c). The criteria given are based on the presence of generic *E.coli* as it indicates the presences of fecal contamination (FDA 2015c). Corrective actions are to be employed as soon as possible but no later than the following year if the criteria are not met. Flexibility is given to farmers who do not meet the microbial criteria and specific options are outlined for them. The testing portion specifies testing frequency based on the type of water source. However, agricultural water received from public water systems do not have to be tested. The farm must have the public water system's results if this is the case.

The biological soil amendments requirement outlines standards for the use of raw manure and stabilized compost. For the use of raw manure, the FDA allows farmers to comply with the USDA's National Organic Program's standards (FDA 2015c). The FDA is currently conducting research on the appropriate number of days needed between the applications of raw manure and harvesting as there is concern for contamination (FDA 2015c). The USDA's National Organic Program standards detail the interval needed to avoid contamination with crops. The FDA does note that precaution must be taken when applying untreated biological soil amendments of animal origin so it does not contact covered produce during or after the application (FDA 2015c). Stabilized compost section has microbial limits set for *L. monocytogenes, Salmonella* spp., fecal coliforms and *E. coli* O157:H7 for processes used to treat biological soil amendments (FDA 2015c). The FDA provides examples of two scientifically valid composting methods (FDA 2015c).

The sprouts requirement is pertinent because of their frequent association with foodborne illness outbreaks; according to the FDA (2015c), there have been 43 outbreaks and 2,405 illnesses. This requirement will help prevent the contamination of sprouts through measures like testing of spent sprout irrigation water, testing the holding environment for *L. monocytogenes,* and taking corrective actions if environmental samples test positive. Unlike the other requirements, the sprout requirement gives sprout operations less time to comply with the rule than farms growing other produce (FDA 2015c).

The domesticated and wild animals' requirement takes into consideration produce contamination from both grazing animals (i.e., livestock) and wild animals. Farmers are to visually inspect the growing area and all produce to be harvested as well perform additional assessments during the growing season under certain circumstances (FDA 2015c). Waiting periods between grazing and harvesting are not provided, but farmers are encouraged to consider to adopt the practice (FDA 2015c). It is also stated that this rule does not support destroying animal habitats or any similar behaviors as this is not the FDA's intention (FDA 2015c).

Worker training, health and hygiene is the fifth requirement. Here, the focus is on preventing produce contamination by individuals who handle produce. Hygienic practices, training and education for workers and their supervisors are listed. Additionally, measures for visitors are also included as they can be a source of contamination.

Equipment, tools and buildings is the last requirement. These sources need to be adequately cleaned, maintained and stored to prevent produce contamination (FDA 2015c). This also covers greenhouses, germination chambers and also hand-washing facilities (FDA 2015c).

2.7.2 Preventive Controls for Human Foods Rule

The Preventive Controls for Human Foods rule has four key requirements. According to the FDA (2016), the four key requirements are: facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls, clarification of the definition of 'farm', a more flexible supply-chain program, updated and clarified current good manufacturing practices (CGMPs).

The required food safety plan under this rule is very similar to HACCP, which requires a hazard analysis, preventive controls, monitoring, corrective actions and corrections, and verification. Unlike HACCP, the food safety plan is a U.S standard and only applies internationally to facilities exporting to the U.S. There are no preliminary tasks required with the food safety plan (i.e. assembling a team, describing product, identifying intended use, etc.) as it requires an individual qualified by training or experience. This qualified individual is responsible for preparing the plan, validating the controls, reviewing the records and conducting a re-analysis. HACCP has Critical Control Points (CCPs) while the food safety plan has preventive controls. CCPs are steps in a process where control can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Preventive controls are procedures and practices used to significantly minimize or prevent hazards. They include process, food allergen, sanitation, and supply-chain controls, and also a recall plan (FDA 2016).

The definition of 'farm' is also clarified. There are two types of farm operations and those that fall under the definitions are not subject to this rule (FDA 2016). The two types of farm operations are primary production farm and secondary activities farm. The FDA (2016) describes primary production farms as "an operation under one management in one general, but not necessarily contiguous, location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or any combination of these activities." These farms package, label, and hold commodities as well as perform some manufacturing/processing activities (FDA 2016). An example of manufacturing/processing activities would be dehydrating raw agricultural commodities to create a distinct commodity as in drying/dehydrating grapes to produce raisins (FDA 2016). A farm may also use treatment to manipulate the ripening of raw agricultural commodities as in treating produce with ethylene gas (FDA 2016). The definition also covers companies that only harvest crops from farms (FDA 2016). Secondary activities farm is defined as operation not located on the primary production farm, but harvests, packs and hold raw agricultural commodities (FDA 2016). The farm must be majority owned by the primary production farm that supplies the majority of the raw agricultural commodities (FDA 2016). The additional activities allowed on a primary production farm are also allowed on a secondary activities farm (FDA 2016).

Under this rule, manufacturing/processing facilities requiring a supply-chain applied control are required to have a risk-based supply chain program (FDA 2016). These facilities have identified a hazard for raw material and other ingredients that need a supply-chain applied control (FDA 2016). However, if the manufacturing/processing facility that controls the hazard uses preventive controls, they are not required to have a supply-chain program for that hazard. (FDA 2016). Facilities that follow requirements applicable when relying on a customer to control hazards are also exempt for that hazard, but they must disclose that the food is "not processed to control" and have written assurance from the customer about the actions that the customer agrees to take. (FDA 2016). This arrangement gives the supply-chain program a little more flexibility.

Lastly, the CGMPs of this rule are updated are reflect most of the similar requirements as the preventive controls (FDA 2016). Education and training provisions are also now binding with employers required to certify that employees who manufacture, process, pack or hold food are qualified to perform their assigned duties (FDA 2016). These employees should be qualified in terms of education, training and/or experience (FDA 2016). Additionally, employers must provide training in the principles of food hygiene, food safety, and employee health and hygiene (FDA 2016).

2.8 Food Processor Beliefs and Attitudes

When it comes to beliefs and attitudes of safe food, consumer food safety attitudes, knowledge and practices have been surveyed and results indicate that there are unsafe handling practices despite acceptable food safety knowledge (Meysenbur and others 2014). There is not as much research on processor beliefs and attitudes as there are for consumers and even less on processors and food safety regulations.

Kaplowitz and others (2006) address this gap in research by focusing on the distribution of attitudes towards safety regulations among business in the food industry, as there was no prior research conducted on the attitudes of the food industry towards regulation. The researchers also decided to learn what characteristics of the business and of the individual respondent influence these attitudes and also learn the effects of the September 11th, terrorist attacks on these attitudes. According to Kaplowitz and others (2006), regulations disproportionately affect businesses in the industry being regulated, thus the regulating body must be seen as legitimate to the business being regulated. Kaplowitz and others (2006) continue by noting businesses comply with safety regulations to the extent that they see them as legitimate. This highlights that the attitudes of business owners play a role in compliance to safety regulations. Additionally, education and sex are factors, as better educated people are more likely to engage in health enhancing behaviors and women are more worried about food safety than men (Kaplowitz and other 2006). Kaplowitz and others' (2006) research found that most food industry managers thought the amount of regulation was "about right", and that producers and processors were more opposed to regulation than other businesses. The researchers also discovered that the greatest predictor of a manager's attitude towards regulation is how safe they perceived the food supply to be which is also indirectly influenced by the belief that their customers are concerned about safety.

In America, business owners have a negative attitude towards government regulation primarily because of the cost involved with compliance (Kaplowitz and others 2006). This is important to dissect as strong attitudes have greater resistance to change and a greater impact on behavior (Kaplowitz and other 2006). Loader and others (1999) argue that when there are changes in food safety legislation, businesses will respond in different ways depending on their corporate strategies and objectives. Ten Eyck and others (2006) found that some cider processers in Michigan felt HACCP would lead to undue government oversight and financial burden. However, Young and others (2010) found that dairy producers in Canada have positive attitudes towards food safety. Despite the incentive, businesses respond quickly to food safety issues as that has a direct bearing on the marketability of their product (Loader and others 1999).

Management's enthusiasm, as well as knowledge and persistence, can help in changing habits and standards especially with 'lower level' employees who lack motivation (Jacobs 1989). Food handler's attitudes play an important role, as the right attitude can help reduce outbreaks of foodborne illnesses (Sani and others 2013).

2.9 Food Processor Food Safety Training

Educating food-handlers in safe practices is one of the most effective preventive measures to deal with foodborne illness (Jacob 1989), as training leads to changes in behavior, attitudes, and practices model (Egan and others 2007). Sani and others (2013) presented research that highlighted that lack of food safety training for food service operations led to poor knowledge of pathogens associated with disease causing agents, as well as critical temperatures for storage of ready-to-eat foods. Improper temperatures during processing can lead to bacterial growth and possibly foodborne illness. It is imperative that food handlers have adequate food safety knowledge, which can be acquired through proper food safety training programs. Research conducted by Soon and others (2012), showed that food safety training not only increased knowledge about hand hygiene practices, but also improved the food handler's attitude about the practice. Adesokan and others (2014) also showed improved knowledge and behaviors of food service workers after receiving food safety training, and also recommended shorter training durations for improved performance.

Food handler training offers long-term benefits to the industry by increasing food safety (Smith 1994), and also by aiding in effective implementation of new food safety programs like HACCP, for example (Walker and others 2002). More than 1/3 of all food recalls between 1999 and 2003, were attributed to ineffective employee training (Shinbaum and others 2015). The FDA recognizes the importance of training and makes it mandatory under FSMA. As specifically stated in the Produce Safety Rule, a combination of training, education, and experience is required for farm workers who handle covered produce and/or food contact surfaces, as well as their supervisors (FDA 2015c). These individuals must also be trained on the importance of health and hygiene, among other topics (FDA 2015c). Similar requirements are listed under the Preventive Controls for Human Food Rule for facility personnel, but it also includes specific trainings for persons deemed a ‘qualified individual’ who are responsible for the facility’s food safety plan. (FDA 2016).

CHAPTER 3

METHODS AND PROCEDURES

As a part of the present research, three surveys were disseminated and a food safety training workshop was prepared for the apple packers. The apple packers surveyed were from Michigan, New York, Pennsylvania, California, Illinois, and Missouri. The first survey of three focused on assessing commercial apple packers' training needs and current practices following the 2014 *L .monocytogenes* outbreak linked to caramel apples. The second of the three surveys was a post-workshop questionnaire distributed after a food safety workshop held in April 2015 to evaluate the workshop, provide commentary, as well as to express comprehension of the topics presented. The third and final survey focused on gauging the attitudes and opinions of the apple packers on FSMA as well as their progress towards implementation about ten months after the food safety workshop.

3.1 Assessing Commercial Apple Packer's Training Needs and Current Practices

The first survey of three focused on assessing commercial apple packers' training needs and current practices following the 2014 *L .monocytogenes* outbreak linked to caramel apples. The objectives of this survey was to: 1) determine current food safety practices by apple packing facilities and 2) to identify critical food safety information and training needs for the industry. This information would not only fulfill a gap in the industry regarding common practices as well as training needs for this specific group of individuals, but it would also help prepare a workshop to address the outbreak, prevent future occurrences and prepare for the implementation of

FSMA. This outbreak also presented the opportunity to assess the industry's response to food safety questions following a food safety issue of that magnitude.

3.1.1 Instrument

Email surveys consisting of eight demographic questions, as well as 39 common practices questions divided into six sections, were emailed to the participants in March 2015 (Appendix A). The demographic questions were yes and no questions with one open-ended question. The current-practice questions had options of yes, no, or in progress to indicate if these practices were or were not in place and operating, or if they were in progress. The six sections for the common practice portion were: shipping/receiving, facility design and equipment, cleaning and sanitation of facility, pest control, food safety management and HACCP, and environmental monitoring. The apple packers were also given a list of food safety topics and asked to rate the topics as a low, medium or high training need for their facility. The accompanying email detailed the purpose of the survey, and a consent form was sent with the survey questionnaire. The participants were given options on how to return the survey. They were instructed to return the completed survey by email or via postal mail, whatever was most convenient for them.

3.1.2 Duration

The email informed the participants that a response to the survey would be appreciated within 7 days as the results of the survey would be used to design a food safety workshop in April 2015. After 7 days, a reminder email was sent to participants who had not responded yet, followed by phone calls if needed. As a result of the delay in responses, survey collection lasted a little over a month.

3.1.3 Participants

The list of survey participants (n=49) and their contact info were provided by the Michigan Apple organization. The participants were apple packers from Michigan, New York, California, and Pennsylvania.

3.2 Food Safety Workshop for Commercial Apple Packers

The second of the three surveys was a post-workshop questionnaire distributed after the food safety workshop help in April 2015 to evaluate the workshop, provide commentary as well as express comprehension of the topics presented. The food safety workshop was prepared for commercial apple packers with the information received for the survey discussed in Section 3.1. The workshop was tailored to the training needs indicated by the packers and took into account the current practices shared. The objective of the workshop was to address the caramel apple outbreak, prevent future occurrences and prepare for the implementation of FSMA which would help in reducing foodborne illness outbreaks.

3.2.1 Instrument

The food safety workshop was held in Grand Rapids, Michigan and presented expert speakers on the following topics: the caramel apple outbreak and related incidents, characteristics and control of *Listeria* in food facilities, practical aspects of *Listeria* control in the food facilities by cleaning and sanitation programs, the new FDA produce safety regulation and regulatory requirements, and sanitary design in food facilities. The expert speakers were representatives from academia, food safety companies, and government agencies. A post-workshop questionnaire along with a consent form was given to the participants and collected on the spot (Appendix B). The questionnaire provided multiple choice, open-ended questions as well as questions using a Likert scale (strongly agree, agree, strongly disagree, and disagree) to evaluate the workshop. Participants were also encouraged to provide additional comments, if they had any.

3.2.2 Duration

The food safety workshop lasted one day and the questionnaire was filled out during the last hour of the workshop.

3.2.3 Participants

The participants who filled out the questionnaire and attended the workshop were from the same group of individuals who were sent Survey 1, as well as others who were interested (n=53). Most of the attendees were of managerial positions or positions of impact within their facilities.

3.3 Opinions and Attitudes of Commercial Apple Packers on FSMA

The third and final survey focused on gauging the attitudes and opinions of the apple packers on FSMA as well as their progress towards implementation about ten months after the food safety workshop.

3.3.1 Instrument

An online survey tool, SurveyMonkey, was used to collect responses to Survey 3 (Appendix 3). This tool was used with an objective to increase the response rate with respect to the first survey. The participants were emailed a link that would direct them to the survey. The email contained the purpose of the survey and the time it would take to complete the survey. The survey was estimated to take only 10 minutes. A consent form prefaced the survey questions.

The survey contained demographic questions, follow-up questions as well as attitude questions using a 4-point Likert scale (strongly agree, agree, strongly disagree, and disagree). Space was also provided for commentary.

3.3.2 Participants

The survey participants targeted were the same individuals from the food safety workshop as a follow-up on training and implementation were to be evaluated (n=16). The participants were from Michigan, New York, Illinois, Pennsylvania, and Missouri.

3.3.3 Duration

The participants were given instructions to complete the survey within 12 days. After 12 days, a follow-up email was sent which garnered more responses.

3.4 Statistical Analysis

All responses were coded and descriptive statistics (mean) was generated using Microsoft Excel.

3.5 Limitations

The sample sizes used for this study were rather small. Despite that limitation, the information is still valuable as these individuals are representing companies which vary in size. These individuals hold positions of impact within these companies, so there is a greater chance of the information being received.

CHAPTER 4

RESULTS AND DISCUSSION

4.1 Assessing Commercial Apple Packers’ Training Needs and Current Practices

The overall response rate was 45% (n=22). The response rates from Michigan were 65%, New York 14%, California 17%, and Pennsylvania 100%.

4.1.1 Apple Packers’ Characteristics

The characteristics of the apple packers responding to the survey are detailed in Table 3. The majority of the respondents were from Michigan (59%) and made $1,000,001 - 10,000,000 (64%) in sales meaning that they were larger facilities. The FDA determines size from sales, so under the FSMA Produce Safety Rule, very small businesses are those with more than $25,000, but no more than $250,000 in average annual produce sales during the previous three-year period, and small businesses are those with more than $250,000, but no more than $500,000 in average annual produce sales during the previous three-year period (FDA 2015). Under the FSMA Preventive Controls for Human Food Rule, very small businesses average less than $1 million per year (adjusted for inflation) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, and a small business is a business with fewer than 500 full-time equivalent employees (FDA 2016).

Table 3. Characteristics of apple packers responding to training needs and current practices survey (n=22)

Characteristic of survey respondents	Percent and number of survey respondents %(n)
Business State	
Michigan	59 (13)
New York	18 (4)
California	9(2)
Pennsylvania	14(3)
Size ($)	
25,000 or less	0
25,001 - 500,000	5(1)
500,001 - 1,000,000	0
1,000,001 - 10,000,000	64(14)
10,000,001 - 50,000,000	23(5)
>50,000,000, but < 500 employees	5(1)
>500 employees	0
Customer	
Domestic	38(8)
Foreign	0
Both	62(13)
Customer Food Safety Audits/Certifications	
No	18(4)
Yes	82(18)
Government Regulator Inspection	
No	50(11)
Yes	50(11)
Equipment Dedicated to Apples	
No	5(1)
Yes	95(21)
Percentage of Apples for Further Processing	
0-20	32(7)
21-40	59(13)
41-60	5(1)
Unknown/depends	5(1)

Both of the definitions under the Produce Safety Rule and Preventive Controls for Human Food Rule are used as apple packing facilities may fall under either of the rules. Also, the majority of the respondents (62%) had both foreign and domestic (restaurants, institutional food services, and food hubs) customers, equipment dedicated to apples (95%) and 21-40 % of their apples are used for further processing (59%). Half of the facilities had government regulator inspections within the last 12 months (surveyed in May 2015) which included FDA, USDA, USDA GAPs, Michigan Department of Agriculture & Rural Development (MDARD), New York State Department of Agriculture & Markets (NY AG & MKTS), and Pennsylvania Department of Agriculture. So most of these facilities were familiar with government inspections and standards.

4.1.1 Apple Packers' Current Practices

It is important to dissect the apple packers' current practices to further understand their training needs. As Egan and others (2006) state, in order to be effective, food hygiene training needs to target behaviors most likely to result in foodborne illness and focus on changing them. Common practices question about shipping/receiving, facility design and equipment, cleaning and sanitation, pest control, food safety management and HACCP, and environmental monitoring programs were asked to isolate what each packing facility has in place or is currently working on establishing (Table 4). The apple packers were asked to answer either 'no', 'yes', or 'in progress' to 39 common practices divided into six food safety categories. Seventeen practices were chosen because of their relevancy to the outbreak and highlighted in table 4. The responses were ranked with scores of 1 through 3, with 1 representing a practice not in place, 2 for a practice in place, and 3 for a practice in progress.

Table 4. Reported current practices of survey respondents (n=22)

Current Practices	Response Ranking
Our suppliers have a traceability process	2.1
There is a supplier approval program in place	2.0
The facility currently swabs for Listeria monocytogenes	2.0
The water in the flumes are changed on a routine basis	2.0
Sanitizer chemicals such as chlorine are used in the flume system	2.0
There is a written sanitation standard operating procedure for the facility	2.0
The facility has designated food safety program leader	2.0
Our employees receive regular training on food safety practices	2.0
The facility has HACCP plan or a written food safety program	2.0
The water used in the facility is tested on a regular basis	2.0
Records are kept of all E.M swab results and corrective actions	2.0
Environmental monitoring (E.M) swabs/tests are conducted	2.0
E.M program has set microbiological criteria	2.0
The pH of the water in the flumes system is regulated	1.9
Effective cleaning of food contact surfaces are monitored using validation tests	1.9
There is a sanitation standard operating procedure in place for fruit bins and containers	1.6
Food contact surfaces are either stainless steel or food-grade plastic	1.5

The apple packers were asked to answer either ‘no’, ‘yes’, or ‘in progress’ to each common practice given. Answers were coded as following: no=1, yes=2, and in progress =3. The ranking represents the mean of the responses.

Current practices for the industry generally follow GAPs, GMPs, and HACCP although they are not mandatory for produce. Overall, the respondents had a high baseline for the common practices given. The majority of the food safety common practices ranked above 1 and below 3 meaning that they were already in place or in progress. For example, all facilities had a HACCP plan or a written food safety plan (ranking of 2.0), although this is not mandatory for this industry. HACCP builds on prerequisite programs, so if HACCP plan is in place, food safety issues under several categories are being addressed. The majority of these respondents (86%) follow the written food safety protocol or HACCP at all times (results not shown).

This high baseline may be because 82% of the facilities have customer food safety audits and certifications that went beyond the legal requirements in the U.S. PrimusGFS, USDA

Harmonized, and USDA GMP/GAP/GHP were noted as some of the customer food safety audits and certifications for the apple packing facilities. PrimusGFS audits alone can include Food Safety Management Systems (FSMS), GAPs, GMPs and HACCP (PrimusGFS 2016). Customer standards seem to be one of the reasons for existing food safety practices for this industry which lacks regulations. However, 91% of the facilities had passed a food safety audit (not including inspections by government authorities) within the past 12 months and 9% were waiting on their results. Since not all of these audits were customer driven, there certainly seems to be an awareness of critical food safety practices and follow-through with implemented practices.

4.1.2 Apple Packers' Training Needs

The apple packers were also given a list of food safety topics and asked to rate the topics as a low, medium or high training need for their facility (Table 5). The ratings were coded (low=1, medium=2, high=3), and the average rating was assigned as that topic's rank.

The topics which received the highest rankings and were deemed of higher priority for the facilities were: 1) *Listeria,* 2) Cleaning and Sanitization of Facility, Equipment, Bins etc., 3) Other Microbial Pathogens and 4) FSMA Produce Safety Rule and Preventive Controls Rule. These topics ranked from 2.5 to 2.1, respectively. Three of these topics focus on reducing and eliminating microbial loads and the other on a new and fast approaching food safety law. It is understandable that these topics are ranked the highest as there was a major outbreak involving *Listeria* and FSMA focuses on preventing such outbreaks.

Table 5. Food safety topics in ranking of priority for trainings for apple packers (n=22)

Topics	Response Ranking
Listeria	2.5
Cleaning and Sanitization of Facility, Equipment, Bins etc.	2.2
Other Microbial Pathogens	2.1
FSMA Produce Safety Rule and Preventive Controls Rule	2.1
Washing and Sanitization of Received Fruit	2.0
Environmental Monitoring	1.9
Food Safety Management Systems	1.8
Characteristics of Food Safety in General	1.8
Private Food Safety Standards	1.7
Worker Health and Hygiene	1.7
Facility Design and Appropriate Construction	1.6

The apple packers were asked to rate the topics as a 'low', 'medium', or 'high' need for their facility. Answers were coded as following: low=1, medium=2, and high =3. The ranking represents the mean of the responses.

With the *Listeria* topic ranked the highest food safety topic, the need seems to be influenced by the outbreak in some capacity. However, it is difficult to determine the influence of the outbreak on the apple packer's training needs because a survey assessing training needs before the outbreak was not administered. That survey would have served as a baseline and help in determining the shift in training needs before and after the outbreak. For example, Kaplowitz and others (2006) conducted a study and observed that managers of businesses that sell and produce food who completed a survey after the terrorist attacks of September 11, 2001, were less opposed to regulation than those who completed the survey prior to the attacks. This shows that catastrophic events of public importance may play a role in the decision making of individuals. The lowest ranking topics, those determined to be a lower priority were: 1) Facility Design and Appropriate Construction, 2) Worker Health and Hygiene, and 3) Private Food Safety Standards with rankings of 1.6, 1.7,1.7 respectively. These topics are less relevant to the outbreak when compared to the three which ranked the highest.

4.2 Food Safety Workshop for Commercial Apple Packers

Egan and others (2006) express that the primary aims of food safety training is to a bring about change in behavior towards less risky food handling practices, as well as an improvement in knowledge about food safety practices. A Likert scale was used to measure the participant's attitude toward the workshop and 92.68% either strongly agreed or agreed that participating in the workshop helped improve their knowledge of appropriate food safety practices (Table 6.). The response rate for the post-workshop questionnaire was 77.4% (53 individuals attended the workshop and 41 completed a questionnaire).

One participant commented: "I was glad to see the industry being proactive. I would like to see some testing being done in apple packing facilities to help illustrate whether or not *Listeria* is a major issue or may become more of an issue. Swabbing results, cleaning programs." Another noted: "It would be beneficial to have "current event" programs like this related to food safety on a regular basis geared specifically for fresh apple a related program. The food safety topics presented at the GR [Grand Rapids] Expo are often at a level below that of most commercial packers."

Table 6. Level of agreement of commercial apple packers after the food safety workshop (n=41)

Statement	Strongly Agree	Agree	Disagree	Strongly Disagree
	Response (%)			
Participating in this workshop helped improve my knowledge of appropriate food safety practices.	39	61	0	0
The knowledge I gained in this workshop will help me implement practices in my operation to ensure the production of safe products.	43	54	3	0
Participating in this workshop improved my understanding of the following topics:				
Occurrence of *Listeria* and other microbial pathogens on fresh and minimally processed produce.	50	50	0	0
Characteristics of *Listeria* and its control in food facilities	47	53	0	0
Appropriate cleaning and sanitation programs for control of *Listeria* and other microbial pathogens	39	61	0	0
Appropriate sanitary design for food facilities	41	57	3	0
Requirements under the upcoming FDA produce safety and preventive controls regulations	26	68	5	0

Although the post-workshop questionnaire did not ask for demographic information, a majority of the attendees were individuals of managerial positions. According to Egan and others (2006), training managers is more cost-effective, as they can self-inspect and subsequently, train employees. Thirty-six participants answered ‘yes’ to the question, “Will you use the information from this workshop to train others from your organization?” and 31 provided the number of individuals that they would train. The willingness to train others is important to implement critical food safety practices in the workplace. Egan and others (2006) states that effective training depends on both attitude and willingness on the part of the manager to provide the resources and systems for food handlers to implement good practice. Studies have also identified a correlation between management attitude towards training, levels of food hygiene knowledge and standards of food handling practice (Walker and others 2002). Additionally, food handler training increases food safety and consequently offers long-term benefits to the food industry (Egan and others 2006). More than one-third of all food recalls between 1999 and 2003 were related to ineffective employee training (Shibaum and others 2015). The FDA recognizes the importance and impact of employee training and made this mandatory under FSMA. Companies not in compliance can face civil and criminal penalties (Shibaum and others 2015)

4.3 Opinions and Attitudes of Commercial Apple Packers on FSMA

According to Egan and others (2006), attitude is a cognitive element that may influence food safety behavior and practice. Bas and others (2006) agreed and stated that attitudes ensure a downward trend of foodborne illness and are an important factor besides knowledge and enforcement. With the introduction of FSMA, which Shinbaum and others (2015) referred to as “the most sweeping change in food safety in the past 70 years,” a food safety law created to reduce outbreaks of foodborne illness, and an industry recently impacted by an outbreak, attitudes can be seen as a key player in the implementation process of this new law. The response rate for Survey 3 was 52%, 31 companies were emailed and 16 companies responded.

4.3.1 Apple Packers’ Characteristics

The respondents of this survey were from Michigan, New York, Illinois, Pennsylvania, and Missouri with the majority of the respondents from Michigan (73%) and male (69%) (Table 7). Most (87%) of the facilities were relatively larger facilities making $1,000,001 - 10,000,000 in sales. The respondents were also well-educated with 31% having a 4-year college degree and 19% having a graduate level degree.

Table 7. Characteristics of apple packers responding to FSMA preparation, and opinions and attitudes survey (n=16)

Characteristic of survey respondents	**Percent and number of survey respondents %(n)**
Business State	
Michigan	73(11)
New York	7(1)
Illinois	7(1)
Pennsylvania	7(1)
Missouri	7(1)
Size ($)	
25,000 or less	0
25,001 - 500,000	0
500,001 - 1,000,000	13(2)
1,000,001 - 10,000,000	87(13)
10,000,001 - 50,000,000	0
>50,000,000, but < 500 employees	0
>500 employees	0
Gender	
Female	31(5)
Male	69(11)
Education	
Some high school, but no diploma	0
High school diploma (or GED)	6(1)
Some college or technical school	31(5)
2-year college degree	13(2)
4-year college degree	31(5)
Graduate level degree	19(3)
None of the above	0

Note: One respondent skipped demographic questions resulting in 15 respondents competing this section

4.3.2 FSMA Preparation

The apple packers were asked two questions about their FSMA preparation (Tables 8 and 9). The first question (Table 8), focused on the apple packers taking initiative and attending other training programs discussing FSMA-related food safety requirements other than the one presented in Section 4.2. The results showed 69% of the respondents being proactive and attending more training programs on FSMA after the Food Safety Workshop in April. Empire State Training Global GAP workshop, USDA'S Webinar on the Final Ruling of FSMA, Train the Trainers Seminar for FSMA in Kalamazoo, Produce Safety Rule Train the Trainer, and the 2015 Food Safety Summit were some training programs listed among others.

Table 8. Survey question #4

Q4. Besides the Food Safety Workshop you attended in Grand Rapids on April 22, 2015, have you personally participated in any other training programs for FSMA-related food safety requirements?	
Percent and number of survey respondents %(n)	
No	**Yes**
31(5)	69(11)

Table 9. Survey Question #5

Q5. In the past year, have you made changes to your company's food safety program in response to new regulatory requirements associated with FSMA?		
Percent and number of survey respondents %(n)		
No	**Yes**	**Not yet, but plan to**
38(6)	31(5)	31(5)

The second question concentrated on changes that the facilities made in response to FSMA and its new regulatory requirements (Table 9). Almost a third (31%) of the responds had already made changes and another third (31%) had not yet made changes, but planned to in the future. Some of the changes that the 31% who answered yes had made were: implementing a crisis management team, having environmental testing completed by an outside vendor, doing in-house adenosine triphosphate (ATP) tests, increasing water testing, completing a HACCP plan, revamping cleaning and sanitizing standards of procedures, adding a food fraud program, and water testing for farms. Once facility planned to develop a water management team.

Following up on the apple packers from the Food Safety Workshop in April 2015 illustrated that the majority of these facilities were continuing to educate themselves on FSMA and also making changes to be compliant with the new requirements.

4.3.3 Apple Packers' Opinions and Attitudes on FSMA

Table 10 displays the opinions and attitudes of commercial apple packers on FSMA (n=16). A majority (63%) of the packers admitted to not fully understanding the requirements for FSMA and 67% disagreed or strongly disagreed that the FDA has provided enough tools and information to help their company prepare for FSMA. Over half (56%) of the respondents disagreed with the statement that FSMA requirements address all current processor practices which may contribute to a foodborne outbreak. Additionally, 60% agreed that FSMA requirements will give the FDA too much control over their facility.

This highlights that there is a gap with what the FDA believes and what the packers actually do. Ten Eyck and others (2005) call this a "disjoint constitution." The researchers describe similar scenario in the apple cider industry with HACCP, the processors and the inspectors. The processors did not believe the inspectors to be knowledgeable about the business and saw the inspectors as outsiders (Ten Eyck and others 2005). The researchers added that a disjoint constitution would affect the implementation of HACCP, making it difficult since the processors will question its legitimacy.

More than half (69 %) of the apple packers agreed or strongly agreed that FMSA requirements will help reduce instances of foodborne outbreaks, but only 56% agreed FSMA requirements will improve food safety for the apple packing industry. Along that line, 53 % disagreed with the statement that this is the right time for the implementation of FSMA requirements despite the impact of the caramel apple outbreak and FSMA's purpose to reduce such outbreaks. One can argue that these respondents may believe that the implementation is in fact too late, and has been long awaited by the industry.

Table 10. The Opinions/Attitudes of Commercial Apple Packers on FSMA (n=16)

Opinion/Attitude	**Strongly Agree**	**Agree**	**Disagree**	**Strongly Disagree**
	Response (%)			
FSMA requirements are necessary for food safety within my facility	0	63	31	6
The FDA has provided enough tools and information to help my company prepare for FSMA	0	33	60	7
FMSA requirements will help reduce instances of foodborne outbreaks	6	63	31	0
Implementing FSMA requirements is too expensive	13	56	31	0
The implementation of FSMA requirements in my facility will have a positive impact on the relationships with my customers	13	50	38	0
My facility is currently ready for the implementation of FSMA requirements	13	63	25	0
FSMA requirements will improve food safety for the apple packing industry	0	56	38	6
FSMA requirements address all current processor practices which may contribute to a foodborne outbreak	0	44	56	0
I fully understand the requirements for FSMA	6	31	63	0
FSMA requirements will cause too many changes within my facility	0	25	75	0
FSMA requirements will give the FDA too much control over my facility	0	60	40	0
Government regulations are necessary for food safety	13	47	40	0
This is the right time for the implementation of FSMA requirements	0	47	53	0

Cost is noted as an issue, as 69% either strongly agreed or agreed that implementing the FSMA requirements is too expensive. It is unclear if these individuals had already spent a great amount making their facility FSMA-compliant, as 75% either strongly agreed or agreed that their facility is currently ready for the implementation of FSMA requirements, or if they are in the planning stage and foresee major costs. Despite the cost and timing, over half (60%) of the packers agreed that government regulations are necessary for food safety and 63% agreed that FSMA requirements are necessary for food safety within their facility.

The apple packers shared additional comments to further explain their opinions of the FSMA. One packer commented, “FSMA seems to be a wide- ranging set of regulations that are going to be enforced on facilities which are mostly complying with similar requirements (or higher standards) through currently required food safety programs which have been customer-driven by market demand. Smaller operations, which pose greater risks, are not currently practicing a food safety plan in most cases and will not be required to change under FSMA. In addition, customers are not aware of this and are under the false assumption that FSMA will treat everyone equally and therefore make all food equally safe.” Another commented,

> “Many of my answers came from the point of view that our customer base has required 3rd party audits which in most sections of coverage are more stringent than FSMA. Years ago maybe our attitude was more to create a system to pass but we have long passed beyond that into doing it because it's the right thing to do and we do not want to put anyone at risk with our product. Are we perfect - no but we continue to educate ourselves and improve our practices. We didn't need a FSMA to encourage us to do this. However, I do feel it is necessary and feel they missed the boat from requiring all levels of farms to comply. If the practices are good to stop/reduce an outbreak, then is it

OK to put at risk a few people because of being a smaller operation? I just wish that the FDA would work or approve USDA and other 3rd party audits as OFFICAL means of proof to compliance with FSMA."

The apple packers appear to agree with the food safety aspect of the FSMA, but not its timing, cost, or the control that the FDA will have. Additionally, they do not agree that they have been given enough tools and information from the regulating body to implement the FSMA requirements and believe that their understanding of the law is lacking. Despite that, the packers do think that FSMA will not cause too many changes within their facility and that their facility is currently prepared for the implementation. They also agree that implementation of FSMA requirements in their facility will have a positive impact on the relationships with their customers. Also, contrary to their attitude towards the FSMA, the apple packers were still preparing for the implementation.

CHAPTER 5

CONCLUSION

The apple packing industry was impacted by a *L. monocyotgenes* outbreak linked to caramel apples right before the introduction of new food safety regulations promulgated under FSMA, which aimed to prevent foodborne illness. This opportunity was ideal to learn about the industry's current practices, provide training and also assess the opinions and attitudes of the industry on FSMA as it may play a role in implementation.

Despite the lack of formal regulations, the majority of apple packing facilities had critical food safety practices in place or were working towards incorporating them into their facility. This industry also expressed a need for microbial-related trainings and FSMA trainings as these were their highest priority for food safety training topics. When provided food safety training, 97% of the apple packers agreed that the information received would help implement practices in their operation to ensure the production of safe products and 88% were also willing to train others in their companies. Additionally, the apple packers responded to the importance of FSMA by attending more FSMA-related training and by making the necessary changes within their facility. The attitudes and opinions of the apple packers revealed that there are gaps that need to be addressed by the FDA in terms of current processor practices affecting foodborne outbreaks and the resources provided to educate about FMSA.

This research helped compile is a list of training topics that this industry needs. This list can be used to provide future trainings for this industry. Future work can also focus on the changes made in current practices after the implementation of FSMA.

APPENDICES

APPENDIX A

Email and Instrument for Survey 1

To Whom It May Concern in the Fresh Apple Packing Industry:

Attached is a survey that is being conducted to determine current food safety practices by apple packing facilities and to identify critical food safety information and training needs for the industry. Our records show that we sent this surveys to you on March 6th, but we have not received a response from you. We apologize if you are receiving this email in error and if this is the case, please disregard this reminder. If you have not had the opportunity to respond to this survey, we hope that you will find a few moments to complete the survey for us. Your accurate and thoughtful responses to this survey are important to us and essential to the design of effective education and training efforts for apple packers in 2015. As the results of this survey will be used to design a training program to be held in April 2015, we would appreciate your response to this survey within 7 days if possible. Please limit one survey per facility.

We recognize the survey instrument is relatively detailed, but we are particularly interested in determining current industry practices as well as immediate and future training needs. The survey has been developed in partnership with the Michigan Apple Committee and has been endorsed by the California Apple Commission and the New York Apple Association.

To preserve confidentiality of respondents to this survey, all responses will be coded prior to analysis and only aggregate data will be shared or published. Comments, when shared, will not be identifiable to any individual or facility.

Attached is the survey and consent form. Please return the signed consent form and the completed survey instrument through either email or post to:

Lordwige Atis
Department of Food Science and Human Nutrition
Michigan State University
139A G. M. Trout Bldg.
469 Wilson Road
East Lansing, MI 48824-1224
Email: atislord@msu.edu

If you have any questions about this survey, please contact:

Leslie D. Bourquin
Professor and Food Safety Specialist
Department of Food Science and Human Nutrition
Michigan State University
139A G. Malcolm Trout FSHN Building
469 Wilson Road
East Lansing, MI 48824-1224 USA
Voice: +1-517-353-3329
Email: bourqui1@msu.edu

DEMOGRAPHICS

First, please tell us a bit about your company.

1) Please indicate your business name and location, your name and job title, and your contact information. PLEASE NOTE THAT THIS INFORMATION WILL ONLY BE SEEN BY MSU RESEARCHERS AND WILL NOT BE SHARED WITH ANY OUTSIDE PARTIES.

Business Name:

Business Location (address):

Your Name:

Your Job Title:

Your Contact Information:

Phone Number:

Email address:

2) In terms of sales, what is the size of your operation? Please select the closest option from the following:

☐$25,000 or less

☐$25,001 - $500,000

☐$500,001 - $1,000,000

☐$1,000,001 - $10,000,000

☐$10,000,001 - $50,000,000

☐>$50,000,000, but < 500 employees

☐>500 employees

3) Who are your customers? Please check all that apply.

☐Domestic customers (e.g. retailers, brokers, etc.)

☐Retailers

☐Brokers

☐Restaurants

☐Institutional Food Service

☐Direct to consumer

☐Food Hubs

☐Other:________________________

☐Foreign customers

4) Do any of your customers require food safety audits/certifications that go beyond legal requirements in the U.S.? (e.g. certifications against the SQF, BRC, Primus GFS or FSSC 22000 food safety programs; USDA GAPs/GHPs Audit Verification Program). If yes, please list the food safety audit(s)/certification(s).

☐No

☐Yes: ___________________________________

5) Has your facility passed a food safety audit in the past 12 months? (Not including inspections by government authorities) (e.g. certifications against the SQF, BRC, Primus GFS or FSSC 22000 food safety programs; USDA GAPs/GHPs Audit Verification Program) If yes, please list the food safety audit(s).

☐No

☐Yes: ___________________________________

6) Has your facility been inspected by government regulators in the past 12 months (e.g. State Department of Agriculture, FDA)? If yes, please list inspector(s).

☐No

☐Yes: ___________________________________

7) Is your equipment dedicated to apples, or are other products run on the same lines/equipment? If no, please list products.

☐No: ____________________________________

☐Yes

8) What percentage of your apples will be further processed into something other than whole uncut apples before reaching the consumer (i.e. apple slices, caramel apples, apple cider, etc.)Please write percentage on the line below.

____

CURRENT PRACTICES

The following questions pertain to existing food safety practices at your facility.

The table below lists a number of common practices that might be used in food packing or processing facilities. For each, please indicate if your facility currently has these practices in place and operating. If you are currently developing procedures, please indicate by checking the "in progress" box.

Shipping/Receiving	Yes	No	In Progress
1. My facility has a supplier approval program that includes elements of food safety and quality.			
2. My facility has a system for buying from unapproved suppliers when growing conditions require it.			
3. My suppliers have a traceability process.			
4. Incoming goods must meet specifications prior to acceptance into my facility.			
5. Does your facility have written specifications for incoming apples (or other fruit)?			
6. If you have written specifications for incoming fruit, do these specifications include food safety parameters (e.g. microbiological criteria)?			
7. Dedicated trucks are used to transport goods to and from my facility (only one type of item per truck).			
8. My facility has sanitation requirements for incoming and outgoing transportation vehicles (general cleanliness, appropriate cleaning schedules, prevention of cross-contamination, etc.)			
9. There is a sanitation check for incoming and outgoing transportation vehicles.			
10. Loads from incoming trucks are rejected if sanitation requirements are not followed.			
11. The condition and cleanliness of fruit bins/containers are monitored for incoming shipments.			
12. Fruit in damaged or filthy bins/containers are rejected for incoming shipments.			
Facility Design and Equipment			

1. My packing facility is fully enclosed with effective barriers to pest entry operating at all times (e.g. air curtains, dock seals, etc.)			
2. My facility has a sanitary design procedure/program in place and my facility is following this program.			
3. Are washer/brusher units are used in the facility to clean fruit? If yes, what is the composition of the units? (e.g. stiff bristles, foam?)___________			
4. The water in the flumes are changed on a routine basis? If yes, what is the frequency of flume water changes? ________________________			
5. Sanitizer chemicals such as chlorine are used in flume systems. If yes, what is the sanitizer used and concentration? ________________________________			
6. The pH of the water in the flumes system is regulated? If yes, what pH is maintained? _____________			
7. A sanitation standard operating procedure is in place for fruit bins and containers.			
8. Fruit bins/containers are cleaned and sanitized on a regular basis? If yes, what method of sanitization and what frequency? _____________________________			
9. Damaged in-house fruit bins/containers are discarded.			
10. Food contact surfaces in my facility are all stainless steel or food-grade plastic? If no, what other food contact surfaces are present in the facility? (e.g. wood) ______________________________________			
Cleaning and Sanitation of Facility			
1. My facility has written sanitation standard operating procedures.			

2. If yes to number 1, are these procedures followed as written?			
3. Are Cleaning and sanitation procedures and corrective actions routinely recorded?			
4. Effective cleaning of food contact surfaces in my facility is monitored using validation tests (for example, ATP swabs).			
Pest Control			
1. Are there regularly scheduled visits and checks with a pest control service provider?			
2. We keep a visible chart for employees to list any possible pest or animal sightings.			
3. We have a written plan to address animal presence in the facility (e.g. birds in the facility).			
Food Safety Management and HACCP			
1. Does your facility have a designated food safety program leader?			
2. Do employees at your facility receive regular training on appropriate food safety practices?			
3. Does your facility have a HACCP plan or a written food safety program?			
4. If you have a written HACCP plan, is your facility following it at all times?			
Environmental Monitoring			
1. We currently swab our facility for *Listeria monocytogenes*.			
2. My facility is familiar with and uses hygienic zoning plans and monitoring procedures.			
3. Are environmental monitoring swabs/tests are conducted in the facility on a routine basis? If yes, what is the frequency of testing? _______________________________			
4. We keep records of all environmental monitoring swab results and corrective actions.			
5. Testing of water used in my facility is conducted on a regular basis. If yes, what is the frequency of water testing? ________________________________			
6. Microbiological criteria have been established in my facility for environmental monitoring results. If yes, what are the current criteria you use in your facility?			

Listeria:___________________________ *Salmonella*:_______________________ Coliforms: ________________________ Other:_____________________________ Other:_____________________________			

TRAINING NEEDS

We would like to know what you believe are your greatest needs for training related to food safety practices in your facility. Please rate the following topics based on your current needs.

Training Topic	Training Need		
	Low	Medium	High
1. Characteristics of food safety hazards in general			
2. Listeria – characteristics and its control			
3. Other microbial pathogens – characteristics and control			
4. Facility design and appropriate construction			
5. Cleaning and sanitization of facility, equipment, bins, containers, etc.			
6. Washing and sanitization of received fruit			
7. Environmental monitoring			
8. Worker health and hygiene			
9. Food safety management systems			
10. Private food safety standards			
11. FSMA Produce Safety Rule and Preventive Controls Rule			
12. Other: ________________________________			
13. Other: ________________________________			
14. Other: ________________________________			

THANK YOU FOR YOUR COOPERATION IN COMPLETING THIS SURVEY

Please email the completed survey instrument to:

Lordwige Atis

Email: atislord@anr.msu.edu

APPENDIX B

Instrument for Survey 2

Post-Workshop Assessment Questionnaire
Food Safety Workshop for Apple Packing Facilities
Grand Rapids, MI

Name ______________________________

NOTE: We are collecting information from you to evaluate this workshop, offer suggestions for future training programs, and to understand your perceived benefits from participating in this workshop. Aggregate results from this assessment instrument may be used in published manuscripts or reports on this project.

Any information obtained that could be identified with you will be kept confidential and your privacy will be protected to the maximum extent provided by the law. All data analyzed will be reported in an aggregate format that will not permit associating subjects with specific responses or findings.

WORKSHOP EVALUATION QUESTIONS

For each question, please mark the answer that is most reflects your opinion of the workshop.

1) What is your overall rating for this workshop?
_________Excellent
_________Very Good
_________Good
_________Fair
_________Poor

2) How do you evaluate the level of detail of the material covered in the workshop?
_________Too Simple
_________About Right
_________Too Detailed

3) Please rate your familiarity with the concepts covered prior to the workshop?
_________Mostly familiar
_________Somewhat familiar
_________Somewhat new
_________Mostly new

4) Will you use the information from this workshop be used to train others from your organization?
_________Yes; If so, how many?_______

__________No

5) Which aspects of the workshop were the most helpful?

____
____
____

6) Which aspects of the workshop need improvement?

____
____
____

7) What suggestions do you have to make this workshop more useful in the future? Do you have any other suggestions to improve the workshop?

____
____
____

8) Please add any additional comments you would like to make about this program.

____
____
____

For the following statements, please indicate your level of agreement with the statement by placing an X in the appropriate box to the right of the statement.

Statement	**Strongly Agree**	**Agree**	**Disagree**	**Strongly Disagree**
1. Participating in this workshop helped improve my knowledge of appropriate food safety practices.				
2. The knowledge I gained in this workshop will help me implement practices in my operation to ensure the production of safe products.				
3. Participating in this workshop improved my understanding of the following topics:				
a. Occurrence of *Listeria* and other microbial pathogens on fresh and minimally processed produce.				
b. Characteristics of *Listeria* and its control in food facilities				
c. Appropriate cleaning and sanitation programs for control of *Listeria* and other microbial pathogens				
d. Appropriate sanitary design for food facilities				
e. Requirements under the upcoming FDA produce safety and preventive controls regulations				

APPENDIX C

Instrument for Survey 3

First, please tell us a bit about your company.
1) Please indicate your business name and location, your name and job title, and your contact information. PLEASE NOTE THAT THIS INFORMATION WILL ONLY BE SEEN BY MSU RESEARCHERS AND WILL NOT BE SHARED WITH ANY OUTSIDE PARTIES.

Business Name:
Business Location (address):
Your Name:
Your Job Title: Your Contact Information:
Phone Number:
Email address:

2) Please check one of the following:
Gender:
☐ Male
☐Female

Education:
☐Some high school
☐High school graduate
☐Some college or technical school
☐College graduate
☐Post college graduate

3) In terms of sales, what is the size of your operation? Please select the closest option from the following:

☐$25,000 or less
☐$25,001 - $500,000
☐$500,001 - $1,000,000
☐$1,000,001 - $10,000,000
☐$10,000,001 - $50,000,000
☐>$50,000,000, but < 500 employees
☐>500 employees

4) Besides the Food Safety Workshop you attended in Grand Rapids on April 22, 2015, have you personally participated in any other training programs related to FSMA-related food safety requirements?

☐No ☐Yes

If yes, please list training programs:_________________________________

<u>5) In the past year, have you made changes to your company's food safety program in response to new regulatory requirements associated with FSMA. (Y/N/Not yet, but plan to) (if Yes, what changes?)</u>

☐No

☐Yes

Not yet, but plan to

If yes, please list changes :____

The following questions ask your opinions/attitudes regarding several issues surrounding new food safety requirements associated with the Food Safety Modernization Act of 2011 (FSMA). In the following questions, "FSMA Requirements" refers to new requirements your company may be subject to under the Preventive Controls for Human Foods Regulation and Produce Safety Regulation. Please choose the option which best reflects your opinion/attitude.

	Strongly Agree	Agree	Disagree	Strongly disagree
FSMA requirements are necessary for food safety within my facility				
The FDA has provided enough tools and information to help my company prepare for FSMA				
FMSA requirements will help reduce instances of foodborne outbreaks				
Implementing FSMA requirements is too expensive				
The implementation of FSMA requirements in my facility will have a positive impact on the relationships with my customers				
My facility is currently ready for the implementation of FSMA requirements				
My facility will be ready for to implement FSMA requirements by the deadline for my facility				
FSMA requirements will improve food safety for the apple packing industry				
FSMA requirements address all current processor practices which may contribute to a foodborne outbreak				
I fully understand the requirements for FSMA				
FSMA requirements will cause too many changes within my facility				
FSMA requirements will give the FDA too much control over my facility				

Government regulations are necessary for food safety				
This is the right time for the implementation of FSMA requirements				

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