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The Application of the Food Safety Modernization Act's Produce Safety Rule for Produce Auctions

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THE APPLICATION OF THE FOOD SAFETY MODERNIZATION ACT'S PRODUCE SAFETY RULE FOR PRODUCE AUCTIONS

THESIS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Science in the
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ABSTRACT OF THESIS

THE APPLICATION OF THE FOOD SAFETY MODERNIZATION ACT'S PRODUCE SAFETY RULE FOR PRODUCE AUCTIONS

Produce is a high-risk commodity that is associated with numerous foodborne outbreaks each year. The Food Safety Modernization Act's Produce Safety Rule was designed to address these issues by requiring farms that grow, harvest, package, and/or hold produce to comply with science-based minimum guidelines. However, with the revival of the local food movement there is a subsequent flux in alternative food networks that handle produce but are not covered by this rule. Produce auctions represent only a fraction of these alternative food networks but are the focus of this study because of their interaction with the Plain community whose relationship with food safety is more complex given their way of life without the use of modern technology. Additionally, like other alternative food networks, produce auctions are struggling to understand whether they need to be in compliance with the Produce Safety Rule because they are unsure if their business is holding produce. This is primarily due to the current definition of "holding" that does not specify a minimum amount of time produce must be kept before it considered held. Using survey data, information about the functions and food safety practices yield results that conclude that produce auctions do hold produce and that the Produce Safety Rule is an appropriate and applicable food safety program for these businesses.

KEYWORDS: Food Safety, Produce Auctions, Food Safety Modernization Act, Produce Safety Rule, Policies.

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TABLE OF CONTENTS

ACKNOWLEDGMENTS iii

TABLE OF CONTENTS iv

LIST OF TABLES vi

LIST OF FIGURES vii

Frequently Used Abbreviations ix

CHAPTER 1. INTRODUCTION 1

1.1 Problem Statement 2

1.2 Research Objective 3

CHAPTER 2. LITERATURE REVIEW 4

2.1 Introduction 4

2.2 Alternative Food Networks 4

2.2.1 Produce Auctions 7

2.3 Food Safety 9

2.3.1 Food Security 9

2.3.2 Public Health Burden 10

2.3.3 Economic Burden 14

2.4 Food Safety Modernization Act 16

2.4.1 The Produce Safety Rule 17

2.4.1.1 Holding 23

2.5 Preventive Controls for Human Food 25

CHAPTER 3. MATERIALS AND METHODS 28

3.1 Understanding the Produce Safety Rule 28

3.2 Development of the Survey 28

3.3 Sample Population and Distribution 30

3.4 Institutional Review Board of the University of Kentucky 31

3.5 Statistical Analysis 32

CHAPTER 4. RESULTS 37

4.1 Characteristics of Produce Auctions 37
4.2 Types of Produce and Functions of the Produce Auction 39
4.3 Food Safety Practices at the Produce Auctions 41
4.4 Food Safety Trainings at the Produce Auction 44
CHAPTER 5. Discussion 48
5.1 Introduction 48
5.2 Size of the Produce Auctions 50
5.3 Type of Produce at the Produce Auctions 52
5.4 Functions at the Produce Auctions 54
5.5 Food Safety Practices at the Produce Auction 59
5.6 Food Safety Training at the Produce Auction 67
5.7 Recommendations 77
5.8 Limitations 79
5.9 Future Studies 79
CHAPTER 6. Conclusion 81
REFERENCES 85
VITA 91

LIST OF TABLES

Table 4.1 State the Produce Auction is Located 38
Table 4.2 Number of Years the Produce Auction has been in Operation 38
Table 4.3 Average Number of Growers/Vendors that Participate in the Produce Auction 38
Table 4.4 Average Number of Employees that Work at the Produce Auction 39
Table 4.5 Type of Produce Sold at the Produce Auction 40
Table 4.6 Does the Produce Auction Allow Growers/Vendors to Package Produce? 40
Table 4.7 Functions Performed by the Produce Auction 40
Table 4.8 Average Length of Time Produce is Kept at Produce Auction (from time it is brought in, to the time it is picked up) 41
Table 4.9 Does the Produce Auction Store Produce in Temperature Controlled Room(s)? 41
Table 4.10 Does the Produce Auction have Written Cleaning/Sanitizing Policies? 42
Table 4.11 Designated Areas Covered by the Written Cleaning/Sanitizing Policies at the Produce Auctions 42
Table 4.12 Food Safety Practices the Produce Auction has Implemented in the Last Five Years 43
Table 4.13 Does the Produce Auction Have a Traceability System? 43
Table 4.14 Does the Produce Auction have a Recall Plan? 43
Table 4.15 Has the Produce Auction Ever had a Recall? 43
Table 4.16 Does the Produce Auction have a Designated Food Safety Person? 45
Table 4.17 Has the Designated Food Safety Person or Board Member(s) Completed a Food Safety Training? 45
Table 4.18 Food Safety Trainings the Designated Food Safety Person or Board Member(s) Have Taken 45
Table 4.19 Does the Produce Auction Require its Employees to Complete a Food Safety Training 46
Table 4.20 Food Safety Trainings the Produce Auction Employees Have Completed 46
Table 4.21 Frequency Employees are Trained 46
Table 4.22 Does the Produce Auction Require Growers/Vendors to Complete a Food Safety Training 46
Table 4.23 Food Safety Trainings/Audits Growers/Vendors Have Completed 47

LIST OF FIGURES

Figure 2.1 Comparison of the non-commercial food supply chain and the commercial food supply (The Multiple Ontologies of Surplus Food, 2019) 5
Figure 2.2 Contribution of Different Food Categories to Estimated Domestically Acquired Illnesses and Deaths, 1998-208 (Painter et al., 2009). 12
Figure 2.3 Total number of Hepatitis A outbreak from 2000-2017 (Hepatitis A Outbreaks, 2019) 14
Figure 2.4 Chipotle's Stock After CDC Links Restaurants in Six States to *E. coli* 0157:H7 Outbreak (Chipotle's Reputation, 2015) 16
Figure 2.5 Perception of Chipotle after *E. coli* Outbreak compared to the overall perception of restaurant chains (Garcia, 2015). 16
Figure 2.6 Flowchart for covered, not covered, exempt and qualified exempt farms in the Produce Safety Rule (Food and Drug Administration, 2018) 20
Figure 3.1 Produce Auction Survey 36
Figure 5.1 State the Produce Auction is Located 49
Figure 5.2 Number of Years the Produce Auction has been in Operation 49
Figure 5.3 Average Number of Growers/Vendors that Participate in the Produce Auction 51
Figure 5.4 Average Number of Employees that Work at the Produce Auction (Full/Part-Time) 51
Figure 5.5 FDA Outbreaks Linked to Produce Contamination Likely Prior to Retail: 1996-2014 (Bihn et al., 2017) 53
Figure 5.6 Types of Produce Sold at the Produce Auction 54
Figure 5.7 Functions Performed by the Produce Auction 55
Figure 5.8 Average Length of Time Produce is Kept at the Produce Auction 56
Figure 5.9 Does the Produce Auction Store Produce in Temperature Controlled Room(s)? 58
Figure 5.10 Does the Produce Auction Allow Growers/Vendors to Package Produce? .. 59
Figure 5.11 Does the Produce Auction have Written Cleaning/Sanitizing Policies? 61
Figure 5.12 Designated Areas Covered by the Written Cleaning/Sanitizing Policies at the Produce Auctions 62
Figure 5.13 Food Safety Practices the Produce Auction has Implemented in the Last Five Years 63
Figure 5.14 Has the Produce Auction Ever had a Recall? 65
Figure 5.15 Does the Produce Auction have a Traceability System? 66
Figure 5.16 Does the Produce Auction have a Recall Plan? 67
Figure 5.17 Does the Produce Auction Have a Designated Food Safety Person? 70
Figure 5.18 Does the Produce Auction Require the Designated Food Safety Person or Board Members to Complete a Food Safety Training? 71
Figure 5.19 Trainings the Produce Auction Requires the Designated Food Safety Person or Board Members to Complete 71

Figure 5.20 Does the Produce Auction Require Its Employees to Complete a Food Safety Training? 73
Figure 5.21 Food Safety Trainings the Produce Auction Employees Have Completed ... 73
Figure 5.22 Frequency of Employee Food Safety Trainings 74
Figure 5.23 Does the Produce Auction Require Growers/Vendors to Complete a Food Safety Training? 76
Figure 5.24 Food Safety Trainings the Growers/Vendors Completed 76

FREQUENTLY USED ABBREVIATIONS

AFN = Alternative Food Networks

CDC = Centers for Disease Control

FDA = Food and Drug Administration

FSMA = Food Safety Modernization Act

GAP = Good Agricultural Practices

HACCP = Hazard Analysis Critical Control Points

PA = Produce Auction

PBPT = Produce Best Practices Training

PSA = Produce Safety Alliance

PSR = Produce Safety Rule

USDA =United Sates Department of Agriculture

CHAPTER 1. **INTRODUCTION**

Food safety is constantly threatened by over 250 foodborne pathogens and, as such, is viewed as a top priority among public health officials (Centers for Disease Control and Prevention, 2019; World Health Organization, 2019). In the United States alone, approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths are attributed to foodborne diseases each year (Centers for Disease Control and Prevention, 2019). The most susceptible populations for foodborne diseases are children under the age of 5, adults over the age of 65, pregnant women, and people who are immunocompromised (Food and Drug Administration, 2014). In addition to foodborne diseases being a public health burden, the diseases carry a financial consequence and contribute to an economic burden of over $77.7 billion (Scharff, 2012). As the public becomes more aware of the implications of foodborne diseases, due to extensive media reporting covering foodborne outbreaks, there has been a greater push for the improvement in food safety at both an industrial and federal level (Newkirk et al., 2012).

The Food Safety Modernization Act (FSMA) was created to address ongoing food safety issues from a preventative approach rather than a reactive approach (Food and Drug Administration, 2019). There are seven rules that make up FSMA and spread the responsibility of food safety throughout the supply chain (Food and Drug Administration 2019). The Produce Safety Rule (PSR) is one of the rules and uses minimum science-based guidelines to prevent microbial risks for farms that grow, harvest, package, and/or hold produce (Food and Drug Administration, 2019). The Preventive Controls for Human Food (PCHF) is also a rule under FSMA and has guidelines for produce that is

manufactured, processed, packaged, or held. Produce is of particular concern because it contributes to nearly half of foodborne illnesses (Painter et al., 2013). This is because fresh fruits and vegetables are typically eaten raw and do not undergo a kill step such as heating, acidifying, or irradiating to eliminate harmful pathogens (Painter et al., 2013).

Unfortunately, the PSR and PCHF are not all inclusive and do not extend to cover alternative food networks (AFNs) that are links in the supply chain and may handle fresh fruits and vegetables. AFNs include, but are not limited to, food hubs, farmer's markets, and produce auctions (PAs). PAs are of particular interest because, in addition to handling fresh produce, they are primarily owned, operated, and utilized by the Plain community (Stoltzfus, 2019). Since the Plain community does not use modern technology, education and practices in food safety need to be adapted in a way that maintains food safety standards while being able to be delivered in a manner that respects their religion. However, these adaptations prove to be difficult because there is a lack of published information about PAs.

1.1 Problem Statement

PAs are not specifically covered by the current food safety regulations. This is a concern because these businesses handle high-risk commodities in buildings and with activities that can generate food safety risks and introduce pathogens into the food supply chain. The PSR and PCHF are two food safety regulations that make up FSMA and have been designed to help businesses that handle fresh fruits and vegetables mitigate food safety risks. However, because the PAs are not classified as a farm or a facility, types of

businesses that are explicitly addressed by these regulations, it is unclear which regulation is most appropriate for the PAs.

1.2 Research Objective

The overall goal of this study was to collect information about the risks associated with PAs in order to determine which regulation would be most applicable for the PAs. This determination is important because it will help PAs mitigate food safety risks and prevent pathogens from entering the supply chain while also protecting the PAs from the devastating consequences a foodborne outbreak could impose on their businesses.

To achieve this goal, this study focused on two objectives. The first objective was to collect data about the PAs that included their functions and current knowledge and attitude towards food safety practices and food safety trainings. The second objective was to apply the data in the context of FSMA and determine if the PSR or the PCHF would be the most applicable food safety regulation for the PAs.

CHAPTER 2. **LITERATURE REVIEW**

2.1 Introduction

Despite the many advances in food safety along the food supply chain, there continues only to be a focus on the conventional supply chain. This has created a concern because there are outlets that deviate from this conventional route that have been neglected by regulations and; therefore, are not receiving the proper guidance on how to mitigate food safety risks for their business. This lack of oversight has not only created a blatant gap in food safety, but it also hinders these businesses' ability to best protect themselves from the consequences associated with a foodborne outbreak.

To address these concerns, the following section reviews relevant literature that will aid in understanding how current food safety regulations can be appropriately applied to AFNs, such as PAs. This section will begin with a discussion of AFNs and their role in the food supply chain and then shift the focus to PAs, whose unique structure needs calls for special consideration of how the food safety regulations can be applied to their business operation. The following section will then review the components of FSMA's PSR and PCHF and highlight the key distinctions between these two rules. Lastly, these key distinctions will be used to discuss the relevance of each rule to the application of PAs.

2.2 Alternative Food Networks

As the food supply chain has becoming more complex with the advancement of technology and transportation, there has been an increased awareness by consumers of the

origin of their food (Brinkley, 2018). This awareness has led to the local food movement that encourages consumers to support the direct sales from local growers and businesses. In turn, this local food movement paved the way for AFNs.

AFNs differ from the conventional food supply chain because they have been designed to shorten the route from farm to fork. Figure 2.1 highlights these differences by showing that the supply chain from farm-to-fork is shorter using AFNs than by conventional means (The Multiple Ontologies of Surplus Food, 2019).

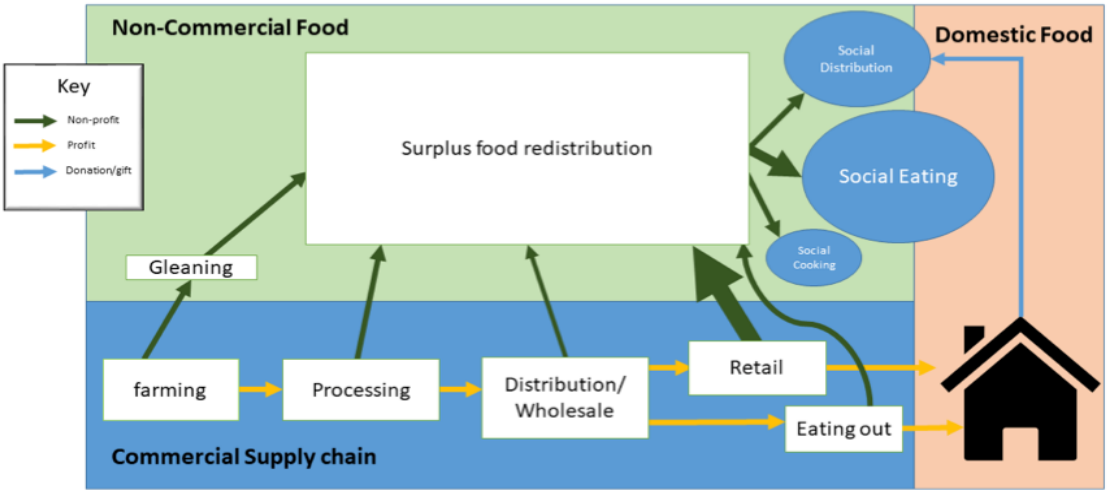

Figure 2.1 Comparison of the non-commercial food supply chain and the commercial food supply (The Multiple Ontologies of Surplus Food, 2019)

In addition to wanting products that were grown locally, consumers support the local food movement to stimulate the local economy. It is estimated that locally produced food accounts for up to $12 billion in annual food sales (Johnson, 2016). Therefore, support for local food has been addressed at the national and state level, through various programs that have been created to increase awareness of the benefits of buying local products and

providing these entities with the resources and funding that they need to be successful (Grants, Loans and Other Support, 2019).

The Know Your Farmer Know Your Food Compass initiative, launched in 2009 by the U.S. Department of Agriculture (USDA), is one of the government programs that continue to expand the movement into the digital world by creating a website that consists of pictures, videos, stories, and an interactive map of regional and local food activities in all 50 states to promote participation (Vilsack et al. 2018). Additionally, the 2014 United States Farm Bill awarded $50 million in grants and loans to reauthorized programs that provided low-income seniors vouchers to use at local produce markets and healthy snacks to children in low-income areas (Agricultural Act of 2014, 2014). The bill also tripled the mandatory funding of the Farmer's Market and Local Food Promotion Program to $30 million and made further legislative and regulatory changes to strengthen the sustainability of the movement (Agricultural Act of 2014, 2014). The 2018 Farm Bill created a new program that streamlines the Farmers Market and Local Food Promotion Program and Value-Added Producers Grant Program and is known as the Local Agriculture Market Program (LAMP) (A Closer Look at the 2018 Farm Bill, 2019).

There are many different types of AFNs that are able to satisfy the various buyers and seller groups logistically. For instance, farmer's markets, community-supported agriculture, programs, and roadside stands have been developed to provide food from the farmer to consumer directly, while food hubs and produce auctions allow small scale growers to sell their products at a wholesale level with only one middleman (Perrett and Jackson, 2015; Navin, 2015; Reid and Newbold, 2018).

2.2.1 Produce Auctions

PAs have existed in the United States as early as 1827 and served as an important market channel for fruits and vegetables (McEhelny, 1916; Miller and Hauck, 1925). Historically, these PAs primarily functioned between 'country assemblers,' distributors, and retailers in large cities as an intermediary (McEhelny, 1916). The majority of the PAs did not accept 'direct consignments from the farmers themselves and functioned with little to no control from producers (McEhelny, 1916).

Today, PAs continue to be an important intermediate market channel for fruits and vegetables and allow small-scale farms to participate in wholesale economies while increasing the supply of local produce (Johnson et al., 2016). Specifically, these auctions act as physical aggregation points where fruits and vegetables from various farmers are sold to the highest bidder. In addition to helping small-scale farmers participate in wholesale markets, the PAs provide the service of attracting buyers, collecting payment and providing a weekly income for the farmers that allows the farmers to focus more on production and packing (Pena, 1996). The PA receives a commission from the farmer to cover the auction's operating expenses (Bergefurd, 2011).

Even though PAs have been an outlet for produce sales for nearly two centuries, they have not been addressed by any food safety regulations. This is a concern because many of the PAs are typically owned and operated by members of the Plain community (Amish and Mennonite) and are the main outlet for farmers of the Plain community (Stoltzfus, 2019; Vekaufhause, 2003). The Plain community is of special interest in the food safety community because their self-restricting use of modern technology may present additional food safety risks (Reid et al., 2018). For example, although horses can introduce

foodborne diseases into the food system; they are still used by the Plain community as working animals because they cannot use machinery, such as tractors or trucks (Bergefurd, 2011).

The self-restricting use of modern technology also presents a challenge because most food safety information is published online. A study about Ohio PAs revealed that 97.1% of the Amish and Mennonite produce farmers did not use the Internet as a source of farming information and 83.3% did not belong to a formal farm organization (Bergefurd, 2011). The authors concluded that food safety education needed to be tailored to this particular population (Bergefurd, 2011).

In addition to wanting to prevent consumers from becoming sick, PAs are concerned with food safety risks because they recognize that if an outbreak were to happen the repercussions could tarnish their image and dissuade buyers from using them as a source for produce. Unfortunately, because there are not any food safety regulations for PAs, resources for helping these entities mitigate food safety risks are limited. By finding a regulation that would be appropriate for their operation, PAs would be provided with clear guidelines that would help them protect their business from a foodborne outbreak.

Currently there are two regulations, the Produce Safety Rule (PSR), and the Preventive Controls for Human Food (PCHF), which are components of the Food Safety Modernization Act (FSMA) and will be discussed at length in the following section. To date, these regulations only apply to farms and facilities, which are businesses along the conventional supply chain. However, these regulations do encompass mitigation strategies for food safety risks pertaining to produce, which is handled by the PAs. Understanding

how the regulations differ from one another, and how those differences would impact the PAs is key to determining if one is more suitable for the PAs than the other.

2.3 Food Safety

Before discussing the nuances of FSMA and the PSR and PCHF, it is important to take a step back and understand why and how mitigating food safety risks is a topic of concern. Food safety is necessary to increase food security as well as to reduce the public health and economic burden due to food related illnesses (National Institute of Food and Agriculture, 2019). However, food safety has not been prioritized until the early 1990s when the implementation and advancement of surveillance systems highlighted the consequences that inadequate food safety practices yielded (Soon et al., 2020). During this time, tremendous efforts have been made to strengthen food safety practices along the food supply chain including the Food Safety Modernization Act (FSMA) (Grover et al., 2019).

2.3.1 Food Security

Food security, as stated by the Food and Agriculture Organization (FAO) of the United Nations (UN), "exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life" (World Food Summit, 1996). Food safety impacts food security by reducing available food supplies that are safe for consumption (King, 2017). Foodborne outbreaks create food waste because recalls force suspected products to be pulled from shelves and thrown away (Hall, 2009). Furthermore, these outbreaks may create hysteria around the implicated products and lead to more food waste

as it is no longer being used by the consumer (Helmer, 2019). For example, Dole did not have to recall any of its products during the 2018 *E. coli* outbreak in romaine lettuce, but after the CDC advised against eating any romaine lettuce, Dole released a statement that they had stopped harvesting and shipping romaine lettuce (Dole, 2018). In order to increase food security, food safety needs to be addressed to prevent food supplies from becoming waste.

After terrorist attacks in 2001, the term food security expanded to encompass the prevention of intentional contamination (Walter et al., 2005). Although the food supply chain was not compromised during these atrocities, it did reveal its vulnerabilities to future attacks (Grover et al., 2016). Chemical, physical, and biological attacks are hazards that continuously threaten to contaminate the food supply chain through various entry points (James et al., 2010). These hazards become prominent as the food supply chain becomes more complex with the ability to transport products around the globe, advancement in technology, and the demand for new products to be developed (Adams, 2000).

2.3.2 Public Health Burden

Foodborne diseases are a top concern for public health officials as they are a common occurrence and impede the health and well-being of the public (Tucker et al., 2011). It was estimated that foodborne diseases attribute to 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths in the United States each year (Centers for Disease Control, 2019). Many of these foodborne diseases can be associated with an outbreak, which demonstrates the large-scale effect a single source of contamination can have and creates a greater concern for food safety efforts due to the extensive media coverage they

attract (Newkirk et al., 2012). For instance, the outbreak in 1993 caused by contaminated meat from Jack in the Box is still regarded as one of the most devastating foodborne outbreaks in United States history (Seo et al., 2014). Over 500 people became ill and three died because the meat was not cooked to the proper 155°F in order to avoid its patties from becoming "too tough" (Centers for Disease Control and Prevention, 1993, Seo et al, 2014). Although the company suffered tremendous losses, it was able to survive and regain its credibility by instituting the fast-food industry's first comprehensive food safety program, the Hazard Analysis and Critical Control Points (HACCP) system (Harris et al., 2002).

The lack of regulatory monitoring to protect the public health was emphasized in 2010 when a Salmonella outbreak from contaminated eggs led to 1,500 reported illnesses and a recall of more than 550 million eggs that had been sold in 22 states (Centers for Disease Control and Prevention, 2010). Neither of the two egg operations that were involved with this outbreak, and produced billions of eggs each year, had an inspection history (Martin, 2010). The outbreak served to highlight flaws of the regulatory process and further prompted the need to increase food safety regulations (Martin, 2010).

The consequences of foodborne diseases extend beyond the period of experienced symptoms and are measured in units called disability-adjusted life years (National Institute of Mental Health, 2019). Disability-adjusted life years represent the total number of years lost from illnesses, disabilities, or premature deaths within a given population (Havelaar et al., 2015). It is estimated that the seven leading foodborne pathogens in the United States cost the public 112,000 disability-adjusted life years annually (Scallan et al., 2015**)**. This number is likely to increase as research continues to uncover correlations between

foodborne diseases and long-term health outcomes such as neurological, kidney, and liver disorders, and autoimmune diseases (Batz et al., 2013).

Produce is a high-risk commodity because it is usually consumed raw, meaning that there is not a kill step to reduce cross contamination and growth of foodborne pathogens (Buck et al., 2003). Additionally, the increase in production, distribution, and consumption of fresh fruits and vegetables in congruence with inconsistent agricultural practices may increase the likelihood of produce being the source of foodborne outbreaks (Badrinath and Vijayakumar, 2019). In 2008, after a 10-year study, the CDC estimated that 46% of the total foodborne illnesses and 23% of total foodborne illnesses that resulted in death were attributed to contaminated produce (Figure 2.4) (Painter et al., 2013).

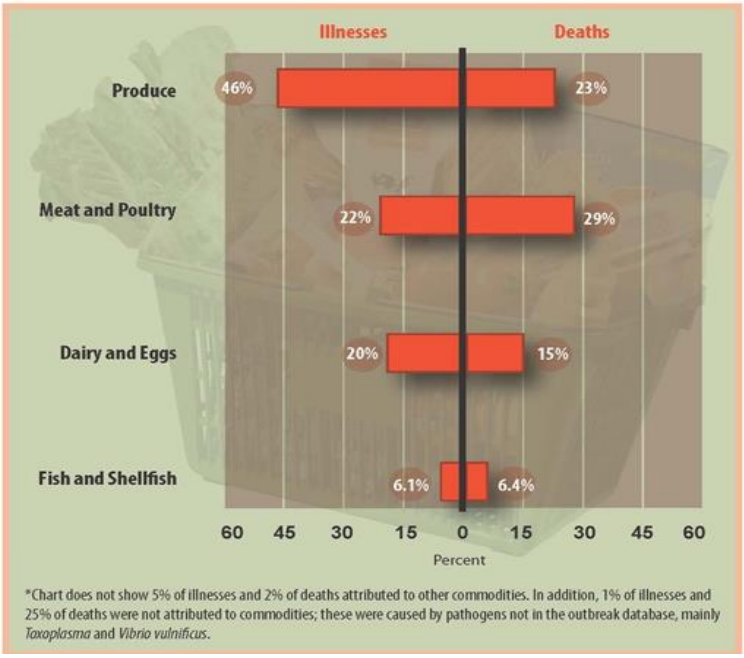

Figure 2.2 Contribution of Different Food Categories to Estimated Domestically Acquired Illnesses and Deaths, 1998-208 (Painter et al., 2009).

Recently, there have been numerous recalls associated with produce such as the Romaine lettuce outbreak in 2018 that infected at least 62 people and hospitalized 25 of

them across 16 states as a result of *E.coli* O157:H7 (Outbreak Investigation of *E. coli* Infections Linked to Romaine Lettuce, 2019). Furthermore, a recall related to pre-cut melons, announced on April 12, 2019, has resulted in 117 reported illnesses and 32 hospitalizations across 10 states due to *Salmonella* Carrau (Outbreak of Salmonella Infections Linked to Pre-Cut Melons, 2019). The 2011 outbreak of *Listeriosis* in cantaloupes serves as a reminder of the devastation that improper food safety protocols can create (Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado, 2012). Because equipment had not been appropriately utilized or sanitized, 147 cases were reported, 143 afflicted were hospitalized, and 33 had died across 28 states (Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado, 2012).

In addition to outbreaks caused by bacteria, viruses are also a culprit of illness. The number of Hepatitis A Virus (HAV) cases have been increasing in the last few years (Figure 2.5) and is considered one of the most highly contagious diseases in the United States (Hepatitis A Outbreaks in the United States, 2019). Chancellor et al. (2006) examined the largest documented HAV outbreak in the United States that occurred. The primary source of the outbreak was contaminated green onions, which were imported from Mexico and infected 601 people and killed three. Through extensive research, it was determined that the raw onions were contaminated at the point of cultivation and were subsequently chopped and stored in bulk, which indirectly led to the further spread of the virus (Chancellor et al., 2006).

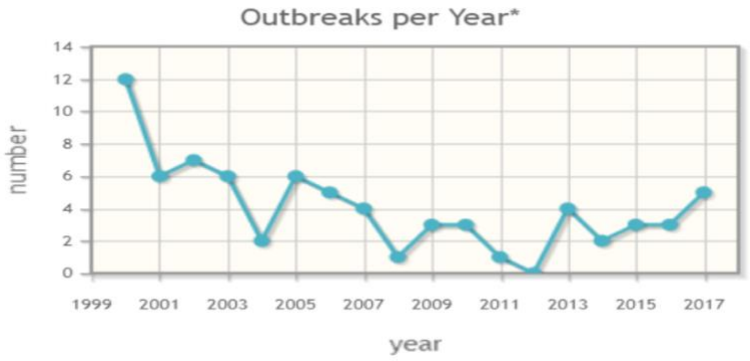

Figure 2.3 Total number of Hepatitis A outbreak from 2000-2017 (Hepatitis A Outbreaks, 2019)

2.3.3 Economic Burden

The physical burden from foodborne outbreaks has its own rippling effect and extends financially. It has been estimated that illnesses, hospitalizations, and deaths from foodborne illnesses carry a burden of $77.7 billion (Scharff, 2012). This estimate is conservative, as it does not include the financial losses companies would have experienced after an outbreak (Scharff, 2012). For example, not only was the 1993 Jack-in-the-Box outbreak an eye-opener for the necessity of food safety regulations, but it also cost the company $160 million and its reputation (Knight et al., 2007; Desk, 2017). 2008 was another devastating year for companies involved in the outbreak of *Salmonella* that derived from contaminated Serrano peppers (Behravesh et al., 2008). Although the outbreak was eventually traced back to contaminated irrigation water in Mexico, initially it was suspected that peppers and tomatoes from southern states such as Florida and Georgia, who faced an economic burden of $100 million and $14 million respectively, were to blame (Taylor, 2010).

It is important to note that these costs are only associated with the outbreak investigation and do not calculate future costs the company may lose in terms of investments and loss of sales from a damaged reputation. Chipotle is a recent example, and the graphs below clearly illustrate how their investments and reputation has significantly declined since their 2015 *E. coli* outbreak (Chipotle Reputation, 2015). The graph below (Figure 2.2) shows Chipotle's steady decline in stocks after the investigation for the source of the contamination began in October. There is then a sharp decrease in stocks after the CDC announced that restaurants across six states were linked to the *E.coli* outbreak(Garcia, 2015). Figure 2.3 further emphasizes the impact of the outbreak by comparing Chipotle's reputation to other restaurants after the report of the outbreak (Chipotle's Reputation Badly Hurt by *E. coli* Drama, 2015). Together, these two figures demonstrate the direct impact that foodborne outbreaks have on companies both financially and on their reputation among customers.

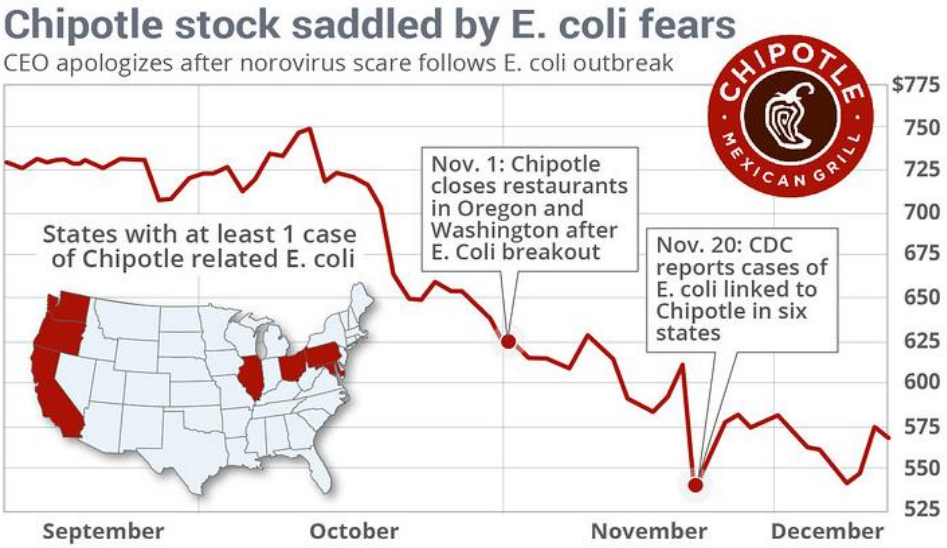

Figure 2.4 Chipotle's Stock After CDC Links Restaurants in Six States to *E. coli* O157:H7 Outbreak (Chipotle's Reputation, 2015)

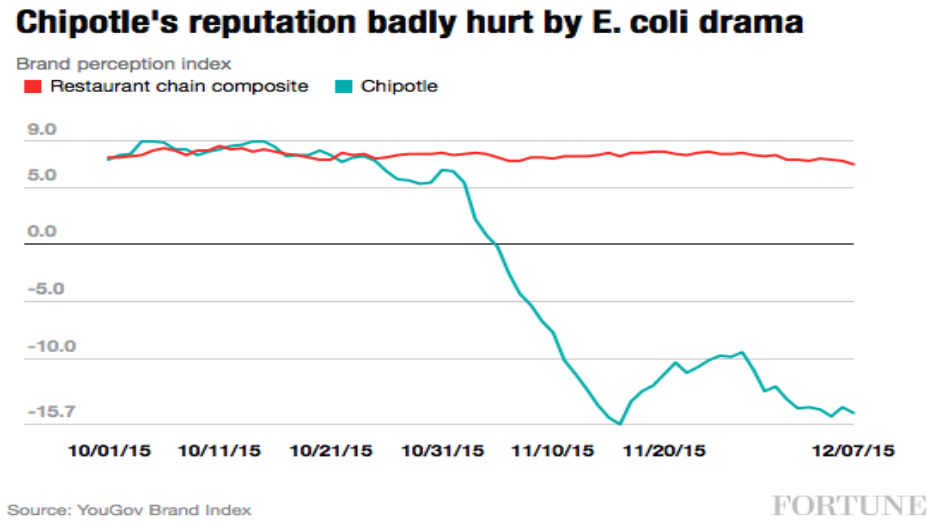

Figure 2.5 Perception of Chipotle after *E. coli* Outbreak compared to the overall perception of restaurant chains (Garcia, 2015).

2.4 Food Safety Modernization Act

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011, in response to food security threats and the public health and economic burdens that stem from food related illnesses. It is considered the first major overhaul since the 1930s in the United States' regulatory system for food safety (Hassanein, 2011). The goal of FSMA is to prevent foodborne diseases from reaching the consumer rather than responding after people become ill. To reach this goal, FSMA grants new authority to the Food and Drug Administration (FDA) to implement and monitor the food safety standards and issue recalls if necessary (Food and Drug Administration, 2019). It also grants the FDA the authority to hold imported foods accountable to the same standards as domestic foods and enables the

FDA to partner with state and local authorities to create an integrated national food safety system (Food and Drug Administration, 2019).

The seven rules/programs that make up FSMA and divide food safety responsibility to major points in the food supply chain where foodborne pathogens are likely to gain entry. These include: 1.) the Produce Safety Rule, 2.) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food (PCHF), 3.) Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Animal Food, 4.) Foreign Supplier Verification Programs, 5.) Mitigation Strategies to Protect Food Against Intentional Adulteration, 6.) Sanitary Transportation of Human and Animal Food, and 7.) Accredited Third-party Certifications (Food and Drug Administration, 2019).

As previously stated, the two regulations under specific consideration for this study are the PSR and the PCHF. This is because both of these regulations encompass standard guidelines for the handling of fruits and vegetables, commodities that the PAs handle. In the following section, there will be a discussion on the reasoning for the development of the key requirement for each regulation, how those requirements differ from one another, and why those differences are essential in determining which regulation is most appropriate for PAs.

2.4.1 The Produce Safety Rule

To address the specific risks associated with raw fruits and vegetables, the PSR was included in FSMA. The final rule went into effect January 26, 2016 with its first major compliance date two years later on January 26, 2018 (Food and Drug Administration,

2019). Currently, the PSR is written for those businesses that fall under the definition of a farm. According to the FDA, farms fall into two different classes, a primary production farm and secondary activities farm, but are both covered under the PSR. They are defined below:

> A **Primary Production Farm** is an operation:
>
> 1. Under one management;
> 2. In one general physical location (that may include multiple non-contiguous parcels); and
> 3. With the **principal focus** of growing or harvesting crops or raising livestock.
>
> In addition, a primary production farm may:
>
> - Pack and hold Raw Agricultural Commodities (RACs, *defined as a food crop in its raw or natural state*), including RACs grown on your farm and RACs from other farms;
> - Dry/dehydrate RACs to create a distinct product with no other processing (e.g., drying grapes to make raisins); and
> - Artificially ripen RACs (e.g., tomatoes in controlled storage).
>
> A **Secondary Activities Farm** is an operation:
>
> 1. Not located on a primary production farm;
> 2. Majority-owned by the operator of a primary production farm, or by multiple primary production farm operators together;
> 3. Where the primary production farm (or farms) of the majority-owner (or owners) also provide the majority of the RACs handled by the secondary activities farm; and
> 4. The operation does no more than harvest, pack, hold, package, and label RACs, and/or artificially ripen and/or dry/dehydrate RACs to create a distinct product (e.g., dried herbs, or grapes into raisins) with no additional processing (Food and Drug Administration 2019).

Due to limited resources, not all farms who met the definitions outlined above will be subject to the PSR; such as farms that average less than $25,000 in produce sales over the previous three years (Bihn et al., 2017). These farms are not covered under the PSR,

because if an outbreak were to occur, the severity of that outbreak would be relatively small.

Furthermore, produce that is rarely consumed raw is not covered by the PSR, as it will likely be cooked, reducing risk of foodborne illnesses (Rogers, 2018). The rarely consumed raw list was created by the FDA and includes: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts (21 CFR Part 112). Additionally, produce that will be sold with the intent to go through a commercial kill-step are eligible for an exemption given that the farm provides certain documentation and written assurances (Bihn et al., 2017).

Farms can also be qualified exempt and will not be subject to federal inspection if they average less than $500,000 in annual food sales over the previous three years and sell the majority of their products to a qualified end-user (Bihn et al., 2017). A qualified end-user is defined as "the consumer of the food or a restaurant or retail food establishment that is located in the same State or the same Indian reservation as the farm that produced the food; or not more than 275 miles from such farm" (21 CFR Part 112) These farms are qualified exempt because the severity of an outbreak, if one to occur, would be lessened due to the increased ability to trace the contaminated products back to the source (Rogers, 2018). A summary of farms that are not covered, exempt, or qualified exempt are summarized in a flowchart that the FDA has created (Figure 2.6).

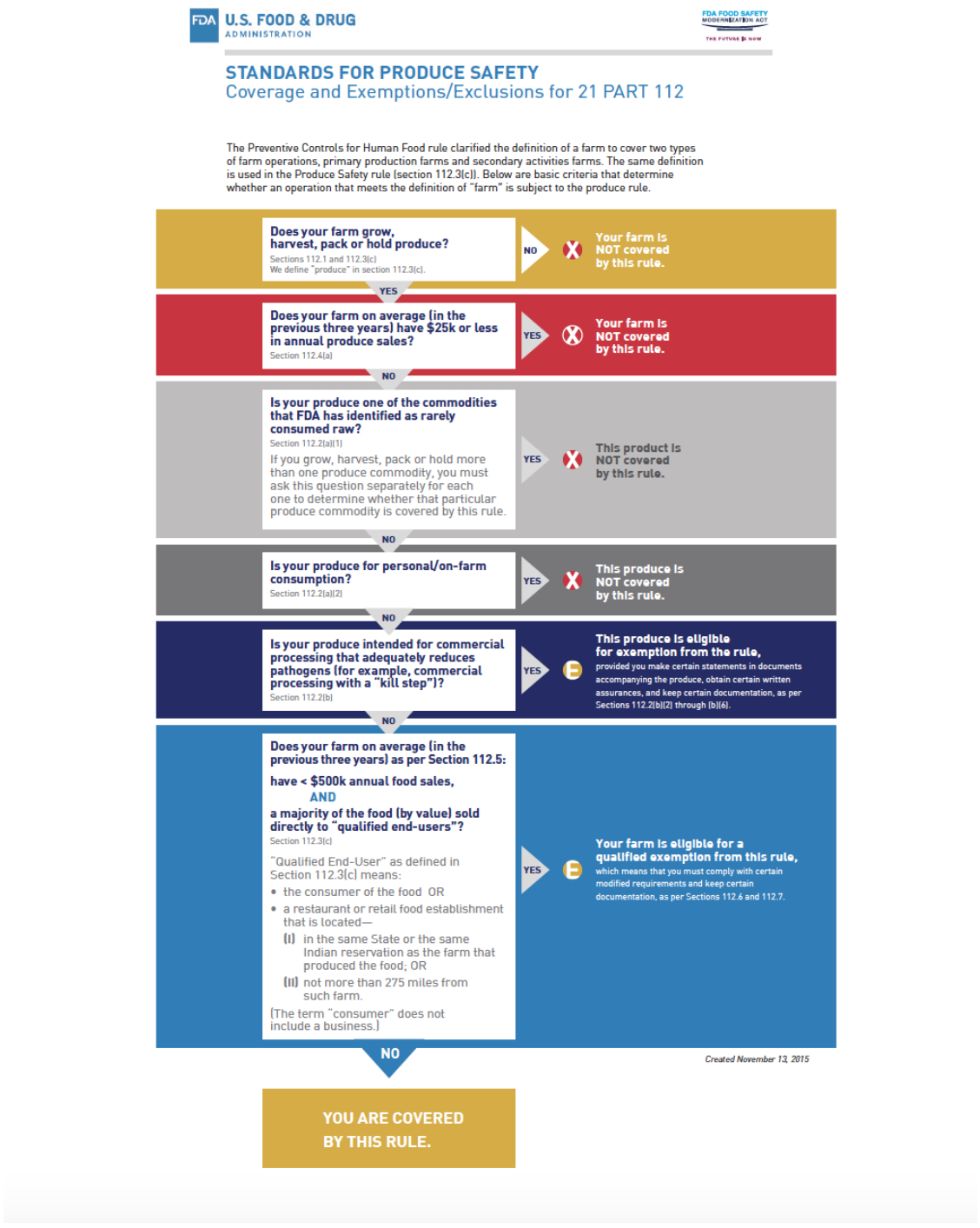

Figure 2.6 Flowchart for covered, not covered, exempt and qualified exempt farms in the Produce Safety Rule (Food and Drug Administration, 2018)

The PSR applies science-based minimum standards to farms which include six key requirements (Food and Drug Administration, 2019). The key requirements are 1.) Agriculture Water, 2.) Biological Soil Amendments, 3.) Domesticated and Wild Animals, 4.) Worker Training Health and Hygiene, 5.) Equipment, Tools and Buildings, and 6.) Sprouts (Food and Drug Administration, 2019).

These key requirements are included in the PSR because they are common vectors for foodborne pathogens. The primary purpose of PAs is to facilitate the movement of produce from sellers to buyers; so, agricultural water and biological soil amendments would not be relevant to discuss in this section because they are only used during the growing and harvesting of produce. However, PAs do have workers, use equipment, tools and buildings, may handle sprouts and can be exposed to domestic and wild animals.

Workers can spread foodborne pathogens by their hands, clothes, shoes, or bodily fluids (Todd et al., 2007). The CDC utilized surveillance data from 16 states from 2014-2016 to find that of the 404 outbreaks that occurred from retail establishments, 58.6% of them were caused by an ill worker (Lipcsei et al., 2019). The subsequent report, the 2017 surveillance data report, was extended to include all 50 states and found that of the 841 foodborne disease outbreaks, 489 (64%) were linked to restaurants where food was prepared (Centers for Disease Control, 2018). Green et al. (2016) found that many of these foodborne diseases from food workers are attributed to handwashing practices that were done either incorrectly or not performed before or after the necessary activities.

In an observational study, examining the handwashing practices for specific work activities where handwashing was recommended, it was found that workers attempted to wash their hands for 32% of the activities and washed their hands appropriately for 27%

of the activities. Attempted and appropriate handwashing rates did vary by work activities and were significantly higher for food preparation ($p<0.05$) than other work activities. However, attempted and appropriate handwashing rates were also found to be significantly lower ($p<0.05$) after workers touched their face, pushed back their hair, rubbed their eyes, or itched their nose. The finding suggested that handwashing practices need to be improved and workers need to be adequately trained on how to wash their hands. (Green et al., 2016).

To minimize the likelihood that a worker may be a source of contamination, the PSR requires that an ill person be excluded from any operation that may result in contamination of covered produce or food contact surfaces until their health condition no longer presents a risk to public health (21 CFR Part 112). The PSR also requires that all workers are trained at least annually and that the training includes when and how workers should appropriately wash their hands (21 CFR Part 112). Furthermore, the PSR mandates personnel are provided with adequate and readily accessible hand-washing facilities (21 CFR Part 112).

The environment in which produce is stored can also increase the risk for foodborne diseases (Bihn et al., 2017). It is required by the PSR that farm buildings are suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities in order to reduce contamination of the produce and food contact surfaces. Additionally, they need to have sufficient space for equipment, take precautions to reduce potential contamination from foreseeable hazards (i.e. separating operations in which contamination is likely to occur), provide adequate drainage, and implement measures to prevent contamination that may occur through floors, walls, ceilings, fixtures, ducts, pipes, drips, or condensation (21 CFR Part 112).

Partially enclosed buildings are of concern because debris or wildlife can transmit foodborne pathogens. Wild animals are able to shed foodborne pathogens through their feces either directly (animals defecate on the produce) or indirectly (animals defecate in soil or water that subsequently comes into contact with the produce). The PSR addresses this issue by requiring farms to take measures reasonably necessary to protect covered produce, food contact surfaces, and food packing materials (21 CFR Part 112). Fully enclosed buildings are easier to control wildlife and debris, but still need to follow the same PSR requirement for partially enclosed buildings. If the building stores any produce in a temperature-controlled room, then the PSR requires that the temperatures be monitored and recorded with instruments that are accurate and precise and are maintained (21 CFR Part 112).

It is important to recognize that theses vectors for foodborne pathogens are present in PAs because it shows that PAs are not risk free and are potential entry points for pathogens to enter the food supply chain. Therefore, PAs should have guidelines to mitigate risk. It should also be noted that all of these risks are associated with the function of holding.

2.4.1.1 Holding

Holding is a key factor in recommending that PAs deserve to be provided with the same resources and guidelines that businesses along the conventional food supply chain are granted. This is because both the PSR and PCHF have standardized guidelines for mitigating the risks associated with holding. The definition of holding is as follows (21 CFR 112):

> Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or

> effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets). But does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks (21 CFR Part 112).

Although this definition may be straightforward for those businesses that grow, harvest, or pack produce, as holding is a logical progression during these processes, it is not as clear for those businesses that do not participate in those functions. PAs, and all AFNs, fall into the category that needs clarity about holding because it could change their specific role in food safety. Currently, the definition of holding does not specify the minimum amount of time a product must be kept in a single location before it is considered as holding. While PAs may not be growing, harvesting, or packaging produce, they could potentially be holding produce which is why the PSR may be the most appropriate food safety regulation for these types of entities.

Contamination during holding can occur at any time. A study by Dawson et al. (2006) demonstrated that it only takes as little as five seconds of exposure to contaminants for pathogens to be transferred at detectable levels (Dawson et al., 2006). Therefore, PAs and the food safety community should focus on the types of activities that occur during the holding period, rather than the amount of time a product is held.

2.5 Preventive Controls for Human Food

The PCHF was included in FSMA because there have been multiple foodborne outbreaks and recalls associated with manufacturing and processing plants. The Peanut Corporation of America (PCA)'s recall was one of the largest recalls to date and was caused by a Salmonella contamination that sickened 714 people and killed 9 (Roman and Moore, 2012; Investigation Information, 2009). It was particularly devastating because company officials knew that their products had been contaminated but continued to ship anyway (Roman and Moore, 2012). This was the first outbreak that resulted in a company official receiving a federal prison sentence for inadequate food safety practices (Roman and More, 2012).

Blue Bell ice cream is another infamous outbreak, caused by listeria, that hospitalized 10 people and killed three (Multistate Outbreak of Listeriosis, 2015; Pouillet et al., 2016). This outbreak is frequently referred to because the company was forced to recall every single product it had shipped because proper cleaning and sanitizing procedures had never been documented (Pouillet et al., 2016). The company recovered but took a drastic financial hit and was forced to lay off 1,450 employees and furlough another 1,400 (Noll, 2015).

The PCHF works to mitigate outbreaks like these from occurring by requiring Current Good Manufacturing Practices (CGMPs) and a food safety plan that includes hazard analysis, preventative controls, oversight and management for preventative controls, a supply chain program, and a recall plan (Centers for Food Safety and Applied Nutrition, 2018).

Although the PCHF does encompass fruits and vegetables, it is important to discuss how it differs from the PSR and how these differences can impact the practicality of applying this regulation to PAs. The first main difference between the PSR and the PCHF is that the PSR only applies to farms while the PCHF only applies to facilities. While the definition for farms has already been defined, the definition for facilities is provided below.

> *Facility* is defined as any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-Bottled drinking water collection and distribution establishments and their structures are not facilities (21 CFR Part 112).

Based on the definitions, the key components that should be highlighted are the manufacturing and processing aspects. Manufactured and processed foods carry certain risks because characteristics of the products are being affected through either the addition of ingredients or a processing step such as heating, acidifying, or irradiation. It is because of these specific risks that are only associated with manufactured or processed foods that these facilities have different standard guidelines for mitigating risks compared to farms that only handle the raw agricultural commodities.

Although holding is mentioned in both the farm and facility definition, the PCHF has more rigorous requirements because the consequence of inadequately manufacturing or processing a product can yield more severe illnesses such as Botulism that is so dangerous one case is considered a public health emergency (Marler, 2019). The

requirements that are necessary for facilities but not farms include hazard analysis and scientific testing for verification of preventive controls.

Hazard analysis is required by facilities because the risk of physical, chemical, and bacterial contamination is of equal risks as compared to farms where bacterial contamination is significantly greater than physical or chemical contamination. To complete a hazard analysis, the facility must look at all aspects of their operation and organize them in chronological order. The facility must then examine each step and determine the possible actions that could lead to contamination and attach a detailed preventive control to mitigate those risks. In addition, they must have a verification component to ensure the preventive controls are properly in place.

The verification component itself could be a reason that the PCHF would be an undue burden on PAs if they are not manufacturing or processing products. This is because it can require scientific testing which would require the PAs to take and send samples to a laboratory which is costly in both a monetary and time aspect.

It is important that the activities being performed in PAs are properly understood to be able to appropriately determine which regulation is most applicable to their operation. This is because if PAs are trying to comply with a regulation that focuses on activities that are not performed at the PAs, then the PAs will be inefficiently allocating resources to food safety risks. Therefore, if PAs are only handling raw agricultural commodities and are not manufacturing or processing products, then the PSR would be most appropriate regulation. However, if they are manufacturing and processing and are changing characteristics of products then the PCHF would be the most appropriate regulation.

CHAPTER 3. **MATERIALS AND METHODS**

3.1 Understanding the Produce Safety Rule

To be able to identify food safety risks in the PAs, a comprehensive understanding of the PSR was necessary. The completion of the Produce Safety Alliance (PSA) grower training provided a basic understanding of the standards that were expected of produce farms, but the PSA train the trainer course provided a deeper insight of why and how the PSR was designed. Becoming a lead trainer for the PSA grower training course was more intensive than the PSA train the trainer course because, in order to pass, it required that the trainer be able to demonstrate that they can apply the PSR to various situations. The On-Farm Readiness Review took all the PSA trainings from the classroom to the field and required full knowledge of the PSR to assist farmers in passing their federal audits. Because of the in-depth knowledge these courses provided on the PSR a survey could be designed to determine what practices PAs performed that yielded significant risks to food safety.

3.2 Development of the Survey

The purpose of this survey was to collect data that could be used to determine what food safety program would be most appropriate for the PAs based on their functions, food safety practices, and food safety training needs. The survey began with demographic questions to provide basic data about the PAs. These questions included: where the PA was located, how many employees did they have, how many vendors/growers participated each year, and what type of produce was sold at the auction. Originally, the survey included questions about the average number of sales over the course of three years. This question

derived from the classification of whether a farm was covered by the PSR based on their sales. However, this question was taken out due the probability of a low response rate because many businesses do not like to disclose monetary information.

The next set of questions wanted to focus on food safety practices that were already occurring in the PA. This was to find out if the PAs already had a baseline knowledge about food safety, or if they did not understand that they were susceptible to becoming a source of contamination. These questions were based on the PSR standards for farms and included questions pertaining to cleaning and sanitation policies, whether they had a food safety manager, training for that manager and trainings for workers.

The survey also included questions pertaining to trainings the PAs may require of the growers/vendors for them to participate in the PA. All these questions included possible answers that were accepted by the PSR as well as answers that alluded to practices included in other food safety programs such as GAP/GHP. The following set of questions sought to answer whether produce auctions were vulnerable to food safety risks based on the types of functions they performed. These questions were designed to find out how many, if any, PAs grew, harvested, packed, manufactured, processed or held produce. Growing, harvesting, packing, and holding are all functions covered under the PSR; manufacturing and processing are covered under Preventive Controls for Human Food, another rule by FSMA.

Because there was uncertainty of how long a product must be kept to meet the definition of holding, a follow up question asking about the length of time produce was kept at the auction site was asked. The PAs would also be asked if they used a temperature-controlled room(s) as these specific storage areas are required by the PSR to be regularly

monitored. It was known previous to the survey that some PA allowed farmers to pack their produce at the auctions; therefore, a question was developed to determine how many PAs allowed this practice to occur. The final set of questions were based on topics covered by the PSA grower training course but were not required by the PSR. They included questions regarding their trackability and recall systems, if they had one, and whether the PA had been part of a recall. The final question was to determine if the PAs felt that they had enough resources to implement food safety.

All questions were evaluated by Mr. Schrock, board member of Lincoln County Produce Auction, lead trainer for PSA grower training, and member of the Plain community, to ensure the survey would be appropriate and comprehensive to all possible participants. The survey consisted of 25 questions and utilized skip logic to avoid presenting questions that were not applicable to the participating PA. To decrease the risk of survey fatigue and so that the survey could be completed in less than 10 minutes, 24 of the 25 questions were multiple choice. Since the majority of PAs were owned by Plain community members, the survey needed to be sensitive to their culture. The distributed version of the survey can be found in Figure 3.1.

3.3 Sample Population and Distribution

The sample population for this study were PAs in the Eastern half of the United States. Contact information for 68 PAs was obtained through the 2015 "Directory of Produce Auction and Co-ops" as well as online research. However, only 61 PAs were contacted due to disconnection of phone lines, or closure of the PA. Because most PAs were owned by Plain community members, the majority of PAs were located in the Eastern

states where the Plain population was highest. To maintain uniformity throughout the surveys, the respondent had to be at least 18 years of age and had the ability to make day-to-day food safety changes at the PA.

Calling the participants and delivering the survey over the phone was deemed the best method to obtaining a high response rate. Due to the locations of the PAs, it was not practical to physically deliver the survey in person and there was a fear that mailing the surveys would yield in low participation. E-mailing surveys was not chosen due to religious practices of the Plain community member that prohibits the use of computers. The survey was conducted between October 2019 - February 2020. All 68 PAs were called. Calls were made Monday - Friday at various times of the day to maximize the probability of participation.

3.4 Institutional Review Board of the University of Kentucky

The survey protocol had to be submitted to the Institutional Review Board of the University of Kentucky (IRB) for exemption. To be classified for exemption, the survey had to collect and report data in an ethical manner and protect the identities of the participants. To avoid cold calling each PA was called at least twice. The first call was to introduce the survey, explain its significance, and to receive their informed consent to be included in the survey. The second call was to distribute the survey. Before administering the survey, a cover letter, also approved by IRB, was read to the participant that explained that there were no known risks to taking the survey and that there were not any consequences for not participating. To protect the privacy of the participants, all results are reported in aggregate, meaning that responses could not be traced back to a particular PA.

3.5 Statistical Analysis

All information was recorded using Qualtrics and reported in aggregate. Qualtrics was also used to analyze all data entries. Descriptive analyses were conducted for all survey questions.

Produce Auction Survey

Q1 In which state is the produce auction located?
- o Illinois
- o Indiana
- o Kentucky
- o Maryland
- o Missouri
- o New York
- o Ohio
- o Pennsylvania
- o Tennessee
- o Wisconsin

Q2 How many years has the produce auction been in operation (years)?
- o Less than a year
- o 0-5 years
- o 6-10 years
- o 10+ years

Q3 Do you have a designated food safety person?
- o Yes
- o No
- o The board members for the auction decide equally
- o Other, please explain _____

Display This Question:
If Q3 = Yes

Q4 Has the designated food safety person or board member(s) participated in any food safety trainings?
- o Yes
- o No

Display This Question:
If Q4 = Yes

Q5 What food safety trainings have they participated in? Select all that apply.

- Produce Safety Alliance Grower Training
- Good Agricultural Practices Training
- Produce Best Practices (KY Only)
- Preventative Controls for Human Food
- Other, please name_____

Q6 What type of produce is sold at the produce auction? Select all that apply.

- Fruit
- Leafy Greens
- Root Vegetables
- Summer Squash
- Winter Squash
- Sprouts
- Tomatoes
- Other Vegetables
- Other_____

Q7 Do you have written policies for cleaning/sanitizing at the produce auction?

- Yes
- No

Display This Question:
If Q7 = Yes

Q8 What are your policies for cleaning/sanitizing at the produce auction? Select all that apply?

- Restrooms
- Auction floor(s)
- Equipment
- Kitchen/ food preparation areas
- Storage areas
- Other _____

Q9 How many people are employed at the produce auction (full/part-time)?

- 0-5
- 6-10
- 11-15
- 16-20
- 20+

Q10 Do you require your employees to be trained in Food Safety?

- Yes
- No

Display This Question:
If Q10 = Yes

Q11 What types of trainings do the employees participate in? Select all that apply.

- Trainings that the Produce Auction Creates
- Good Agriculture Practices Training
- Produce Best Practice Training (KY only)
- Produce Safety Alliance Grower Training
- Preventative Control for Human Food
- Other _____

Display This Question:
If Q11 = Trainings that the Produce Auction Creates
Or Q11 = Good Agriculture Practices Training
Or Q11 = Produce Best Practice Training (KY only)
Or Q11 = Produce Safety Alliance Grower Training
Or Q11 = Preventative Control for Human Food
Or Q11 = Other

Q12 How often are the employees trained? Select all that apply.

- After they are hired
- Annually
- Other _____

Q13 In the last 5 years, what has the produce auction done in regard to food safety? Select all that apply.
Nothing, food safety has already been established at this produce auction

- Participated in a 3rd Party Audit
- Participated in Facility (internal) Audit
- Developed a Food Safety Plan
- Other _____

Q14 On average, how many vendors/growers participate in the produce auction per year?

- 1-50
- 51-100
- 101-150
- 151-200
- 201-300
- 301-400
- 401-500
- 501+

Q15 Do you require vendors/growers to have any certificates in regard to food safety such as Good Agriculture Practices, Produce Safety Alliance Grower Training, Preventative Controls for Human Food, etc.?

- Yes
- No

Display This Question:
If Q15 = Yes

Q16 What type of certificate(s) do you require vendors/growers to have to be able to sell at the produce auction? Select all that apply.

- o Good Agriculture Practices Training
- o Good Agriculture Practices Audit
- o Facility (internal) Audit
- o Produce Best Practices (KY only)
- o Produce Safety Alliance Grower Training
- o Preventative Controls for Human Food
- o Other _____

Q17 What type of functions does the produce auction perform? Select all that apply.

- o The auction holds products
- o The auction grows products
- o The auction harvests products
- o The auction packages products
- o The auction manufactures products
- o The auction processes products
- o None of the above

Display This Question:
If Q17 = The auction processes products

Q18 What type of processes does the produce auction perform?

- o Treating to manipulate the ripening of raw agricultural commodities
- o Hulling or shelling products
- o Other _____

Q19 On average, how long is produce kept at the auction site (from the time it is brought in, to the time it is picked up)?

- o Less than 1 hour
- o 1-3 hours
- o 3-6 hours
- o 6-9 hours
- o 9-12 hours
- o 12+ hours

Q20 Does the produce auction ever store products in a temperature-controlled storage area (e.g. refrigerator, cold room, refrigerated truck)?

- o Yes
- o No

Q21 Does the produce auction's, vendors/growers ever package the products at the auction site?

- Yes
- No

Q22 Does the produce auction have a traceability system?

- Yes
- No

Q23 Does the produce auction have a recall plan?

- Yes
- No

Q24 Has the produce auction ever had a recall?

- Yes
- No
- Not sure

Q25 What resources do you wish were accessible, or more accessible, in regard to incorporating more food safety?

Figure 3.1 Produce Auction Survey

CHAPTER 4. **RESULTS**

4.1 Characteristics of Produce Auctions

A total of 38 PAs participated in the survey. General characteristics of the PAs are displayed in Tables 4.1-4.4 and include the location of the PAs, number of years they have been in operation, their size (based on number of employees and vendors/growers), type of produce that is sold, the function(s) they perform, and the length of time the produce is at the PAs. Pennsylvania had the largest number of PAs that participated, accounting for approximately 24 % of the responses. Ohio, New York, and Indiana followed close behind with 16%, 16%, and 16% respectively (Table 4.1). The majority of PAs, 71 %, have been in operation for more than ten years, while 26% have been in operation from six to ten years (Table 4.2). Only one PA has been operating for one to five years, and there were no new PAs within the last year (Table 4.2). There was a wide range on the number of growers/vendors participating at the PAs. While 40% of PAs had more than 500 growers and vendors, 42% had 1-100 growers/vendors (Table 4.3). The remaining 18% of PAs had an average of 101-400 growers/vendors participating (Table 4.3). To help with the PAs, both fulltime and part-time employees were hired. The majority (82%) of the PAs hired one to ten employees throughout the year, while the remaining 18% employed 11 or more people to work in the PAs (Table 4.4).

Table 4.1 State the Produce Auction is Located

	Count	Percent
State	n = 38	
Illinois	3	7%
Indiana	6	16%
Kentucky	3	7%
Maryland	1	3%
Missouri	1	3%
New York	6	16%
Ohio	6	16%
Pennsylvania	9	24%
Tennessee	1	3%
Wisconsin	2	5%

Table 4.2 Number of Years the Produce Auction has been in Operation

	Count	Percent
No. Years	n = 38	
Less than a year	0	0%
1-5	1	3%
6-10	10	26%
10+	27	71%

Table 4.3 Average Number of Growers/Vendors that Participate in the Produce Auction

	Count	Percent
No. Growers/Vendors	n = 38	
1-50	7	18%
51-100	9	24%
101-150	1	3%
151-200	3	7%
201-300	1	3%
301-400	2	5%
401-500	0	0%
501+	15	40%

Table 4.4Average Number of Employees that Work at the Produce Auction (Full/Part-Time)

	Count	**Percent**
No. employees	n = 38	
1-5	12	32%
6-10	19	50%
11-15	3	8%
16-20	1	2%
20+	3	8%

4.2 Types of Produce and Functions of the Produce Auction

Tables 4.5-4.9 refer to the types of produce sold at the auctions, and the functions that the PAs allow by the farmers, the functions the PAs perform, the duration that the produce is kept on sight and the condition it is stored in. While none of the PAs handle sprouts, all of the PAs handle tomatoes, summer squash, winter squash, and produce that classified as "other" such as green onions, bell peppers, etc., 97% handle root vegetables, 92% handle fruit, and 87% handle leafy greens. 8% of the PAs allowed the growers/vendors to package produce at the auction site (Table 4.6) Table 4.7 displays the function(s) that the PAs identify performing. All of the PAs reported that they did not grow, pack, harvest, manufacture, or process any produce at the auction site. However, over a quarter (29%) of the PAs stated that they held produce. Because none of the PAs identified as processing produce, there were no responses for the subsequent question of the type of processing they performed. The survey found that 16%, 75% and 8% of PAs kept produce on site from zero to three hours, three to six hours, and six to nine hours respectively (Table 4.8). Additionally, 13% of PAs utilized temperature-controlled rooms for storage (Table 4.9).

Table 4.5 Type of Produce Sold at the Produce Auction

	Count	Percent
Type of Produce	n = 38, participants were allowed to list more than one answer	
Leafy Greens	33	87%
Tomatoes	38	100%
Summer Squash	38	100%
Winter Squash	38	100%
Fruit	35	92%
Root Vegetables	37	97%
Sprouts	0	0%
Other	38	100%

Table 4.6 Does the Produce Auction Allow Growers/Vendors to Package Produce at the Auction Facility?

	Count	Percent
Response	n = 38	
Yes	3	8%
No	15	92%

Table 4.7 Functions Performed by the Produce Auction

	Count	Percent
Type of Function	n = 38, participants were allowed to list more than one answer	
Packaging of Produce	0	0%
Growing of Produce	0	0%
Harvesting of Produce	0	0%
Manufacturing of Produce	0	0%
Processing of Produce	0	0%
Holding Produce	11	29%
None of the above	27	71%

Table 4.8 Average Length of Time Produce is Kept at Produce Auction (from time it is brought in, to the time it is picked up)

	Count	Percent
Length Produce is at the PA (hours)	n = 38	
1-3	6	16%
3-6	29	76%
6-9	3	8%
9+	0	0%

Table 4.9 Does the Produce Auction Store Produce in Temperature Controlled Room(s)?

	Count	Percent
Response	n = 38	
Yes	5	13%
No	33	87%

4.3 Food Safety Practices at the Produce Auctions

A summary of food safety practices and training that occur at the PAs are represented in Table 4.10-4.15. The study found that 60% of the participating PAs have written cleaning/sanitizing policies (Table 4.10). The PAs who did have these written policies were then asked the areas the policies covered. Of this subgroup, 96% had a written policy for the auction floor, 91 % had a written policy for the restroom(s), and 65%, 39%, and 17% had written policies for equipment, storage areas and kitchen/food preparation areas, respectively (Table 4.11). There were no policies written for any other area outside of what was listed. Within the last five years, there were PAs that completed a facility (internal) audit (13%), 3rd party GAP audit (13%), food safety plan (26%), and/or implemented other food safety measures such as signage (13%) while 37% of the PA reported that they did not need to improve their food safety practices or trainings in the last five years (Table

4.12). Although all of the PAs have a traceability system (Table 4.13), 18% of the PA do not have a recall plan in place (Table 4.14). None of the PAs have ever taken part in a recall (Table 4.15).

Table 4.10 Does the Produce Auction have Written Cleaning/Sanitizing Policies?

	Count	**Percent**
Response	n = 38	
Yes	23	60%
No	15	40%

Table 4.11 Designated Areas Covered by the Written Cleaning/Sanitizing Policies at the Produce Auctions

	Count	**Percent**
Designated Areas	n = 23, participants were able to list more than one answer	
Auction Floor	22	96%
Restrooms	21	91%
Equipment	15	65%
Storage Areas	9	39%
Kitchen/Food Prep. Areas	4	17%
Other	0	0%

Table 4.12 Food Safety Practices the Produce Auction has Implemented in the Last Five Years

	Count	Percent
Food Safety Practices	n = 38, participants were able to list more than one answer	
3rd Party GAP Audit	5	13%
Facility (internal) Audit	5	13%
Developed a Food Safety Plan	10	26%
Other	5	13%
Food Safety Has Already Been Established Prior to Five Years Ago	14	37%

Table 4.13 Does the Produce Auction Have a Traceability System?

	Count	Percent
Response	n = 38	
Yes	38	100%
No	0	0%

Table 4.14 Does the Produce Auction have a Recall Plan?

	Count	Percent
Response	n = 38	
Yes	31	82%
No	7	18%

Table 4.15 Has the Produce Auction Ever had a Recall?

	Count	Percent
Response	n = 38	
Yes	38	100%
No	0	0%

4.4 Food Safety Trainings at the Produce Auction

Food safety trainings for the designated food person, employees, and growers/vendors are represented in Tables 4.16-4.23. Many (66%) of the produce auction had a designated food safety person who is able to make day-to-day decisions about food safety, while 5% of the PAs had a board of members to make decisions collectively (Table 4.16). The remaining 29% of PAs did not have a designated person or party making food safety decisions (Table 4.16). Of the 71% of PAs that had a designated food safety person or board to make food safety decisions, all of them had completed a food safety training (Table 4.17). There were four different trainings that the PAs could select, they had the option to select multiple trainings, in addition to an "other" category for any trainings not listed. 85% of the designated food safety person or board had completed a GAP Training, 74% completed a PSA grower training, 4% completed a PCHF training, 4% completed a PBPT (Table 4.18). 74% of the PAs required that their employees attend a training as well (Table 4.19). Approximately 32% of employees completed a GAP training, 7% completed a PSA grower training, and 96% completed a training that the PAs created (Table 4.20). None of the employees have taken a PCHF training or any other training than the ones listed (Table 4.20). The PAs were then asked if when these trainings were offered to the employees and responses could include hired, annually, and/or seasonally. It was found that 68% trained their employees after they were hired, 54% trained their employees annually, and 18% trained their employees seasonally (Table 4.21). Furthermore, 18% of PAs required that their growers/vendors completed a food safety training/audit (Table 4.22). For the PAs that had said they required that their growers/vendors completed a food safety training/audit, 71% required them to complete a GAP training, 14% required a

passed GAP Audit, and 29% required the completion of a training that the auction created (4.23). None of the PAs commented that they wished more food safety resources were made available to them.

Table 4.16 Does the Produce Auction have a Designated Food Safety Person?

	Count	**Percent**
Response	n = 38	
Yes	25	66%
No	11	29%
A board Decides Equally	2	5%

Table 4.17 Has the Designated Food Safety Person or Board Member(s) Completed a Food Safety Training?

	Count	**Percent**
Response	n =27	
Yes	27	100%
No	0	0%

Table 4.18 Food Safety Trainings the Designated Food Safety Person or Board Member(s) Have Taken

	Count	**Percent**
Type of Food Safety Training	n = 27, participants were able to list more than one answer	
GAP Training	23	85%
PSA Grower Training	20	74%
PCHF	1	4%
PBPT	1	4%

Other	0	0%

Table 4.19 Does the Produce Auction Require its Employees to Complete a Food Safety Training

	Count	**Percent**
Response	n=38	
Yes	28	74%
No	10	26%

Table 4.20 Food Safety Trainings the Produce Auction Employees Have Completed

	Count	**Percent**
What trainings have the produce auction employees completed?	n = 28, participants were able to list more than one answer	
GAP Training	9	32%
PSA Grower Training	2	7%
PCHF	0	0%
Trainings the Auction Creates	27	96%
PBPT	0	0%
Other	0	0%

Table 4.21 Frequency Employees are Trained

	Count	**Percent**
Response	n = 28, participants were able to list more than one answer	
After Hiring	19	68%
Annually	15	54%
Seasonally	5	18%

Table 4.22 Does the Produce Auction Require Growers/Vendors to Complete a Food Safety Training

	Count	**Percent**
Response	n = 38	
Yes	7	18%
No	31	82%

Table 4.23 Food Safety Trainings/Audits Growers/Vendors Have Completed

Type of Food Safety Training	n = 7, participants were able to list more than one answer	
GAP Training	5	71%
GAP Audit	1	14%
PSA Grower Training	0	0%
PCHF	0	0%
Trainings the Auction Creates	2	29%
PBPT	0	0%
Other	0	0%

CHAPTER 5. **DISCUSSION**

5.1 Introduction

In today's world, a good reputation is difficult to build but easy to break. It is for this reason that many produce auctions (PAs) have recognized the importance of food safety, as a foodborne outbreak could damage their reputation significantly, and are looking for guidelines to help protect their business. The Food Safety Modernization Act (FSMA)'s Produce Safety Rule (PSR) uses science-based minimum standards for farms who grow, harvest, hold, and/or pack produce to mitigate food safety risks and minimize the likeliness that these farms will be implicated in a foodborne outbreak. Unfortunately, because PAs are not defined as a farm or a facility, PAs are left uncertain if one regulation would be more appropriate for their specific operation than the other. To address this issue, this study was designed to collect information about the PAs functions, food safety practices, and food safety trainings. The data was then discussed in the context of the PSR and PCHF to understand which regulation would be the most appropriate for the PAs.

There were 38 PAs (a 62% response rate) that participated in this survey from ten states (Figure 5.1). The states with the highest number of participating PAs were located in the northeastern region of the country where the Plain populations, who utilize PAs as a common marketplace, are most dense (Stoltzfus, 2019). The significance of PAs in these communities is seen through the length of time they have been in operation, with 71% of the PAs having been in operation for more than ten years (Figure 5.2). Furthermore, the remaining 29% of PAs that have been established in the last ten years indicate the growing need for this type of outlet. In this discussion, I will 1) summarize the findings pertaining

to the PAs size, types of produce, functions, food safety practices, and food safety trainings, and 2) discuss how those findings relate to the applicability of the PSR to PAs.

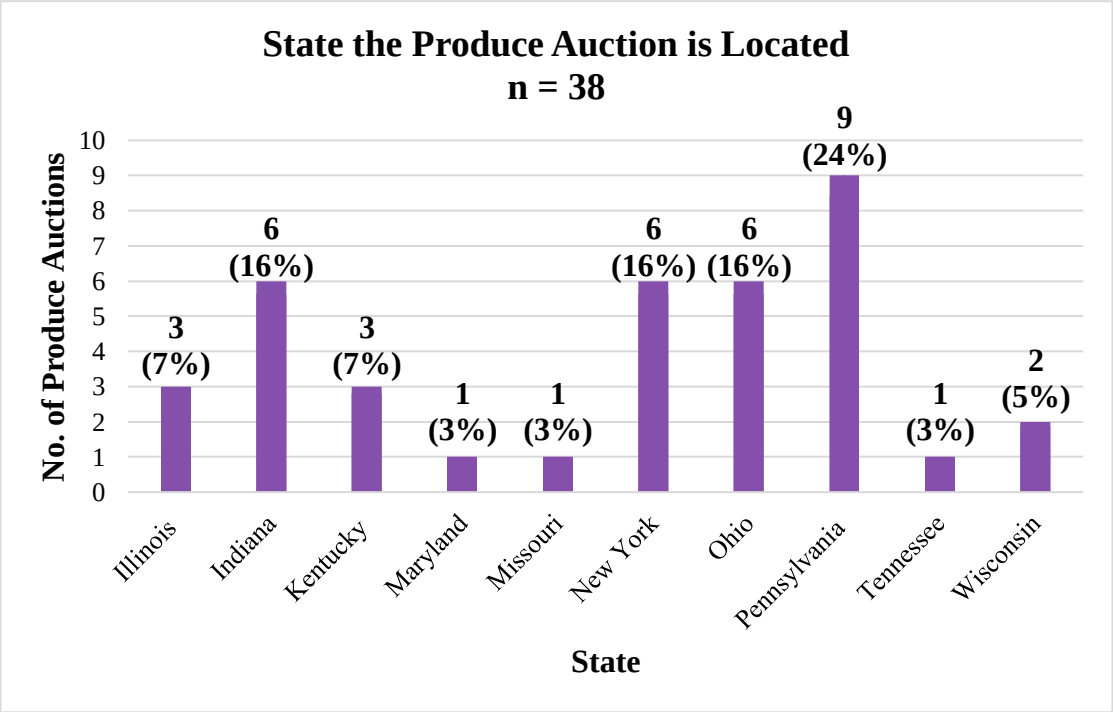

Figure 5.1 State the Produce Auction is Located

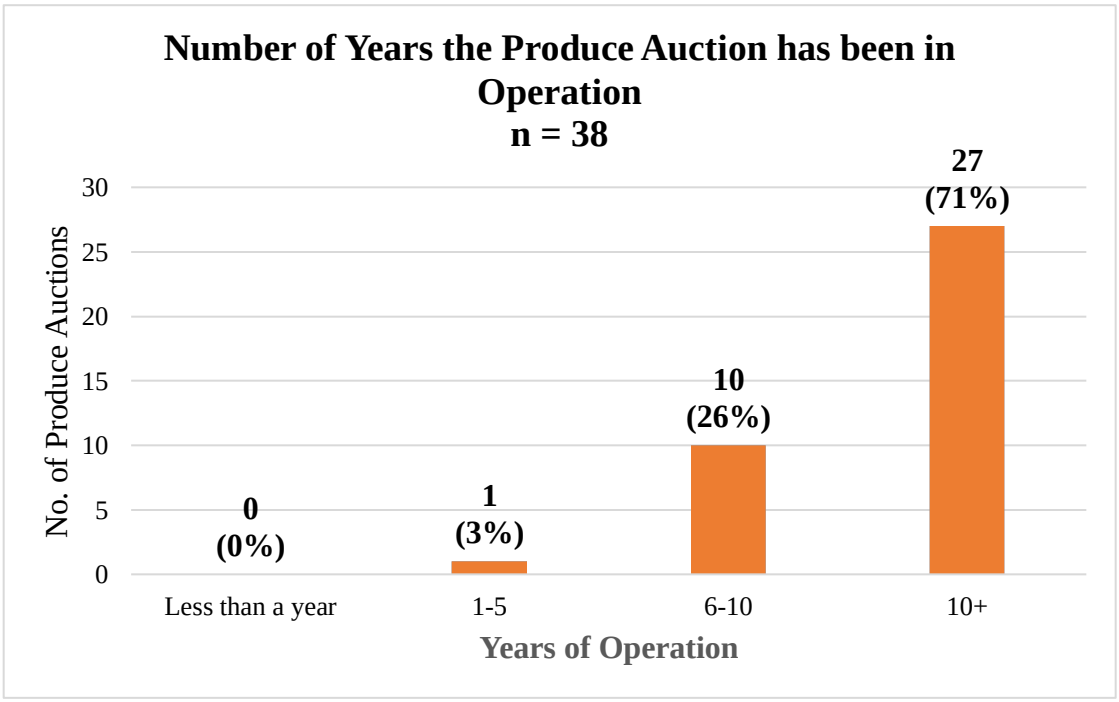

Figure 5.2 Number of Years the Produce Auction has been in Operation

5.2 Size of the Produce Auctions

The size of the PAs is important because it can be an indicator for the amount of relative risk that is present. This is because larger PAs have more produce and people, which are vectors for foodborne pathogens. Furthermore, if a large PA is a source for contamination then the consequences are likely to be more severe compared to a small PA because more produce is likely to have reached consumers. Although it would have been preferred to gauge the size of the PA using their annual produce sales, the sensitivity of financials redirected the size of PAs to be measured by the number of growers/vendors and employees that participated in the auction.

This study found that 40% of the participating PAs had more than 500 growers/vendors, while 42% of the PAs had less than 100 growers/vendors (Figure 5.3). The results also showed that 82% of the PAs had ten or less employees and that 8% of the PAs had more than 20 employees. The FDA has addressed the concern, pertaining to size, by requiring that all farms that make over $25K in annual produce sales comply with the PSR. For the purpose of this discussion, we are assuming that all PAs made more than $25K in annual produce sales and; therefore, based on size, would benefit from the PSR.

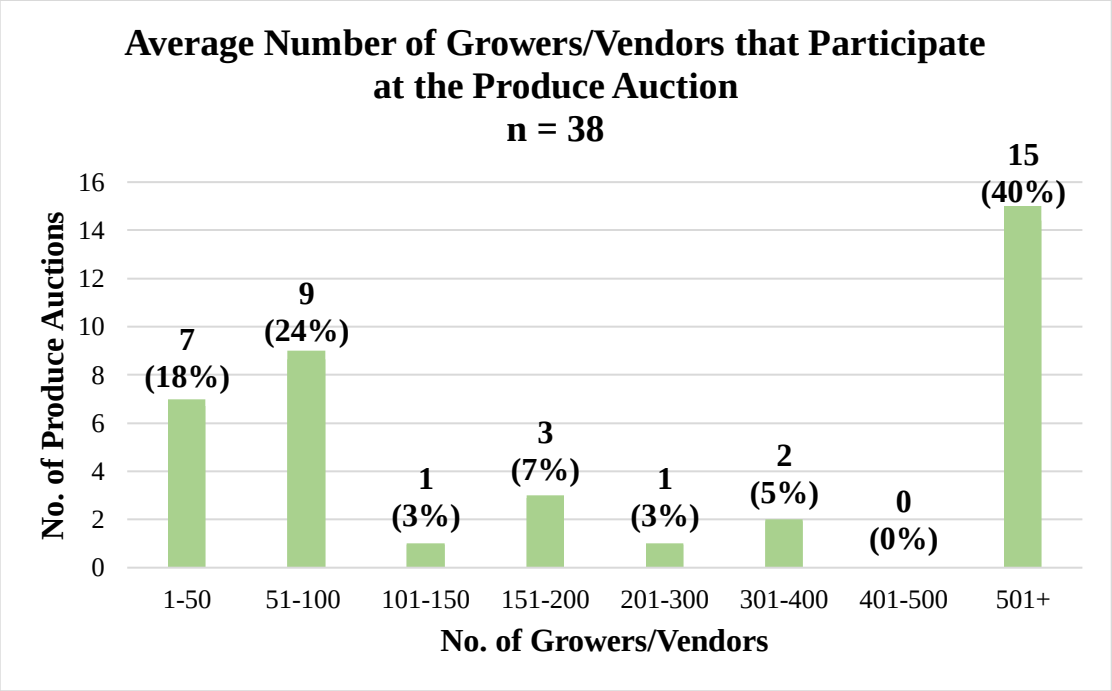

Figure 5.3 Average Number of Growers/Vendors that Participate in the Produce Auction

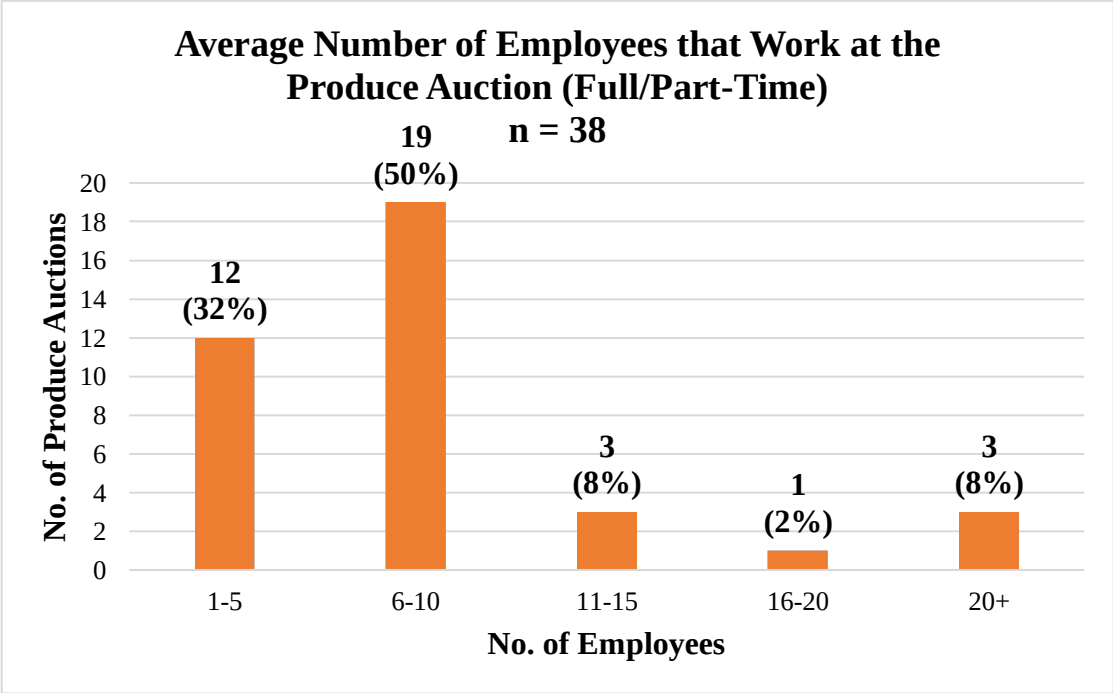

Figure 5.4 Average Number of Employees that Work at the Produce Auction (Full/Part-Time)

5.3 Type of Produce at the Produce Auctions

In addition to size, the PSR standards would be the most applicable for PAs because it provides food safety guidelines that are specific for fruits and vegetables. Although produce, in general, is a high-risk commodity, certain types of produce carry higher levels of risk for foodborne pathogens depending on how they are grown, the type of surface they have (i.e. smooth versus porous versus bumpy), and whether or not the fruit or vegetable has antimicrobial properties.

The chart provided by the Produce Safety Alliance (PSA) shown below (Figure 5.5) summarizes the number of foodborne outbreaks attributed to the different types of produce (Bihn et al., 2017). From the chart, it can be seen that sprouts are one of the most common sources in produce related outbreaks. This is because the microbial contamination of sprouts readily occurs due to the optimal conditions that are present during the germination and sprouting process and makes them a common source for produce related foodborne outbreaks (Yang et al., 2013). It is also for this reason that the PAs were asked if they handled sprouts. PAs were also asked if they handled leafy greens because they are also implicated in many produce related outbreaks due to the crevices on the surface that make removing pathogens difficult. Tomatoes, summer squash, winter squash, fruit, root

vegetables and an "other" category were also included as choices for this question to collect insight into the range of produce that PAs handle.

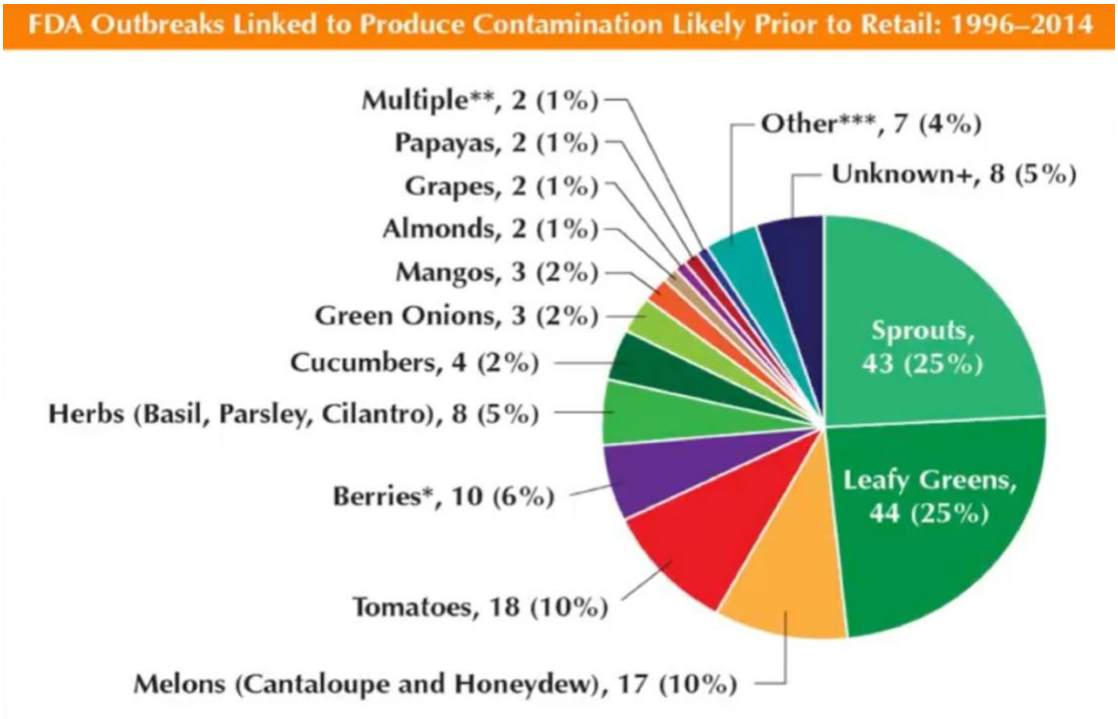

Figure 5.5 FDA Outbreaks Linked to Produce Contamination Likely Prior to Retail: 1996-2014 (Bihn et al., 2017)

This study found that all of the PAs that participated reported that they handled winter and summer squash, tomatoes, and produce categorized as "other" that could include produce such as peas, broccoli, or beans, while 97% handled root vegetables, 92% handled fruit, 87% handled leafy greens, and 0% handled sprouts (Figure 5.6). The only commodity that has additional guidelines in the PSR are sprouts because of the unique nature they are grown and harvested. The remaining commodities are all addressed the same because the uniformity of food safety practices better mitigates food safety risks. This is because produce farms often handle a variety of produce and by having the workers use the same food safety practices for all of the produce, the more likely the workers will

implement these practices efficiently. It is also because the PAs handles raw agricultural commodities that the PSR would best apply to the PAs

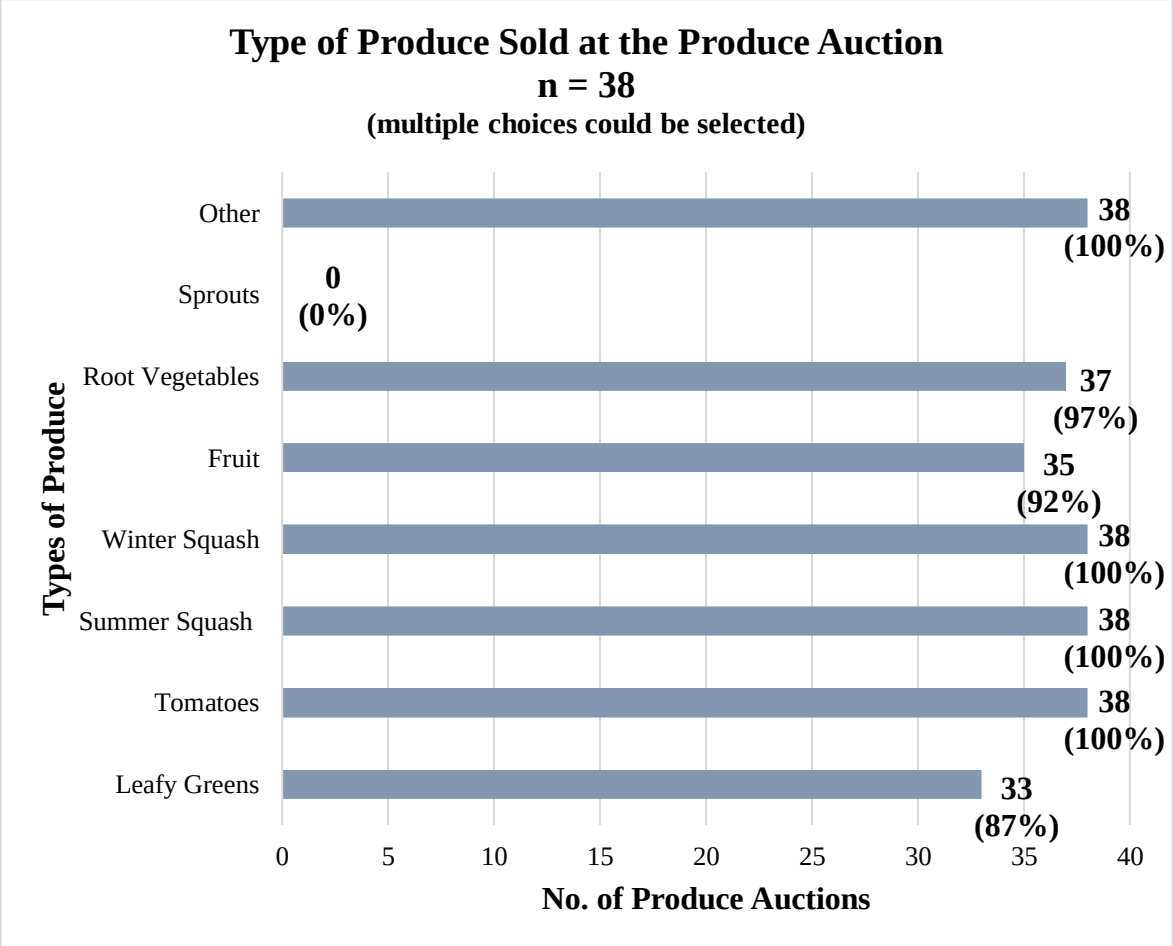

Figure 5.6 Types of Produce Sold at the Produce Auction

5.4 Functions at the Produce Auctions

Identifying what type of function(s) that are performed at the PA is critical to understanding why and how the PSR is appropriate for the PAs. The six functions that PAs could identify in performing were growing, harvesting, packing, holding, processing, or manufacturing produce. Growing, harvesting, packing, and holding are functions that the PSR addresses, while the PCHF addresses processing, manufacturing, packaging, and holding of food.

Holding was identified by 29% of the PAs and was the only function that was identified (Figure 5.7). The inconsistency of PAs identifying holding as a function may be due to the current language of the definition which does not include a minimum amount of time a product must be kept before it is considered "held." However, based on the results of the survey, all of the PAs kept produce at the auction site for at least an hour, which is sufficient amount of time for contamination to occur, and 76% of the PAs kept produce for an average of four to six hours (Figure 5.8).

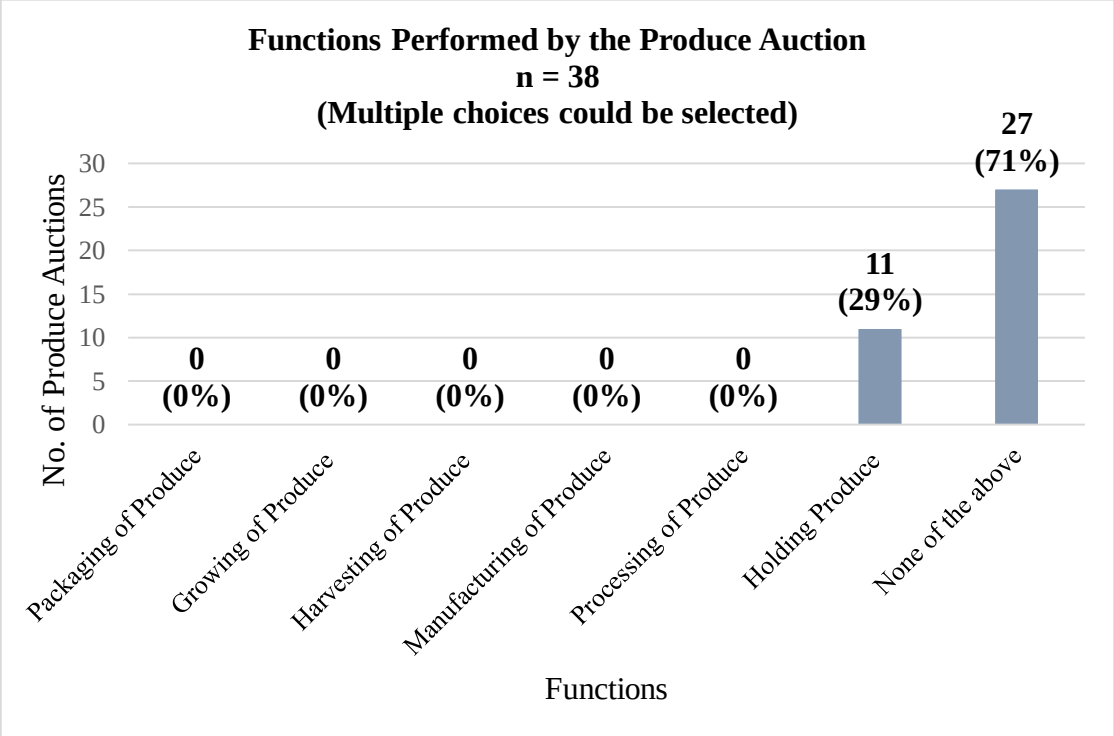

Figure 5.7 Functions Performed by the Produce Auction

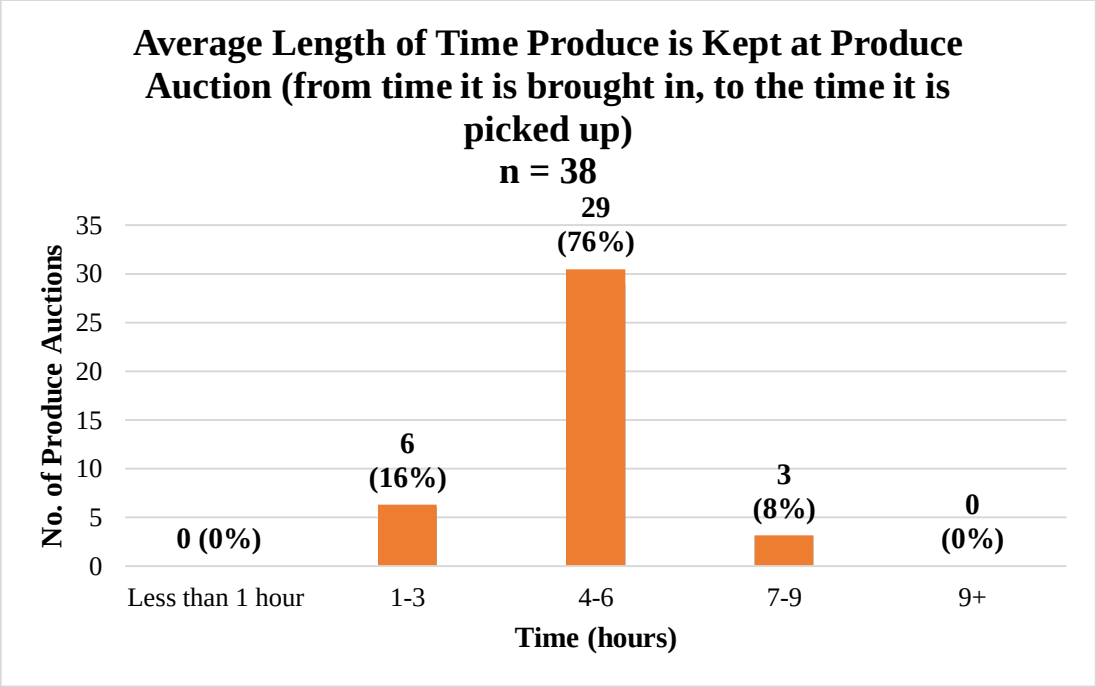

Figure 5.8 Average Length of Time Produce is Kept at the Produce Auction

It is important that PAs understand why holding is applicable to their establishment because it can help them recognize the risks that are associated with the function. The risks that are associated with holding extend to people, equipment, the environment, domestic animals and wildlife which have the ability to contaminate produce with foodborne pathogens and are all present at the PA. It is for this reason, that the PAs want the most comprehensive food safety program to mitigate these types of risks, and the PSR would be the best choice.

As previously stated, holding is covered by both the PSR and PCHF. However, the PSR is most appropriate for PAs for two main reasons. First, the PSR focuses on raw agricultural commodities while the PCHF focuses on commodities that will be manufactured or processed. Because PAs do not manufacture or process foods, they will not encounter risks associated with these functions, such as the growth and transmission of pathogens from cooking or acidifying foods incorrectly, and do not have hazards that could

potentially adulterate the products. Secondly, PSR has standards that are more practical for PAs. The PCHF does not have practical standards for PAs because it requires verification of the preventive controls that would include sending product and environmental samples to be sent for scientific testing processes.

Sending samples for testing is impractical for the PAs because of the amount of time it would take to send samples and receive results. Bacterial tests, such as ones for *E. coli*, Salmonella, or Listeria, can take three to five days (Bobal et al., 2019). However, from Figure 5.8, none of the PAs kept produce for more than nine hours, which would mean that the results of the samples would not be completed before the produce was transferred from the seller to buyer. If PAs had to verify their preventive controls through scientific testing processes, they would have to store the produce in an area, such as a warehouse that facilities use, where the environment can be easily controlled and monitored. Expecting PAs to include these types of areas to store produce until the test results are complete is not practical, especially for PAs that do not use electricity which is needed to control the temperature of these environments. Because PAs are not designed to store products for extended lengths of time, it is not possible for them to verify their preventive controls using scientific testing processes, a requirement of PCHF. Therefore, it is not reasonable for PAs to be covered under the PCHF.

Although produce is held at the auction for less than a day, some PAs use temperature-controlled room(s), such as refrigerators, to store specific produce, like lettuce, to maintain its quality. Produce that is kept in temperature-controlled room(s) is of particular concern because there are pathogens, such as *Listeria monocytogenes* that is linked to complicated pregnancies, birth defects, and miscarriages, that thrive in cooler

environments. Transmission of these pathogens is often through the condensation that drips from the cooling unit onto the produce.

It was reported that 13% of PAs utilized temperature-controlled room(s) to store produce (Figure 5.9). The PSR has guidelines for temperature-controlled rooms to mitigate the food safety risks, and PAs that use these types of storage rooms would benefit greatly from following these requirements that include monitoring of temperature and condensation on a regular basis and recording the data. Recording the data for monitoring activities is also important because if the PA were to be implicated in a foodborne outbreak then the data would help the PA to narrow down when the produce may have been contaminated and allow them to recall only the produce that was contaminated from that point.

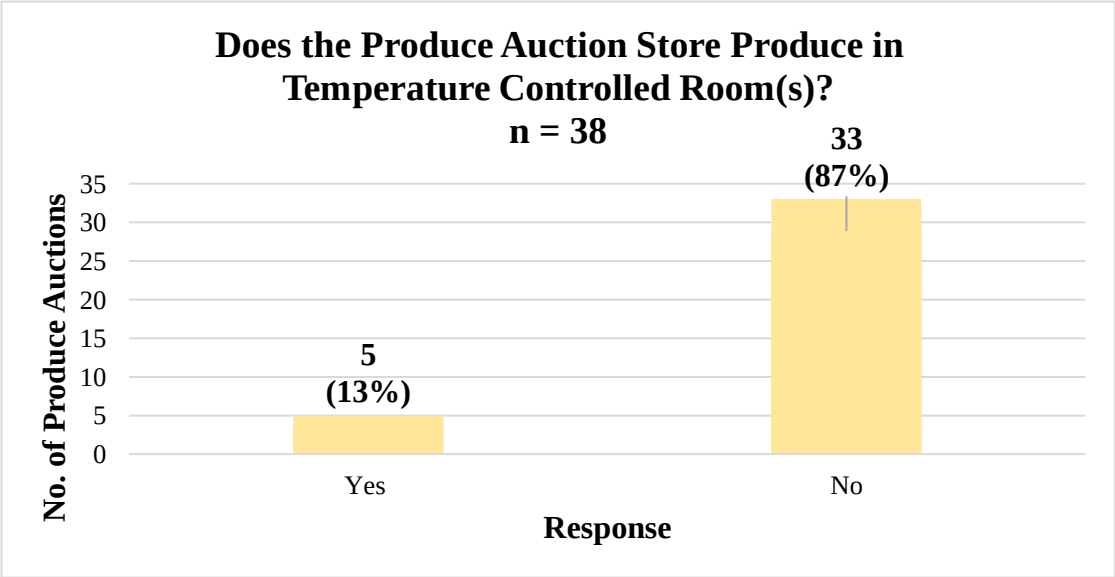

Figure 5.9 Does the Produce Auction Store Produce in Temperature Controlled Room(s)?

Although none of the PAs packaged produce, 8% of the PAs allowed the growers/vendors to package produce at the auction site, or on its premise (Figure 5.10). Packaging is addressed by both the PSR and PCHF because there are many risks associated

with the process including the opportunity for Clostridium Botulinum toxin to form. To address these risks, packaging should be done in a building that has clean food contact and non-food contact surfaces (21 CFR Part 112). Although it may not be directly the PAs fault if the source of an outbreak was from packaging done by the grower/vendor at the auction site, this situation still has the potential to harm consumers and tarnish the PAs reputation. For this reason, complying with the PSR, could reduce this possibility.

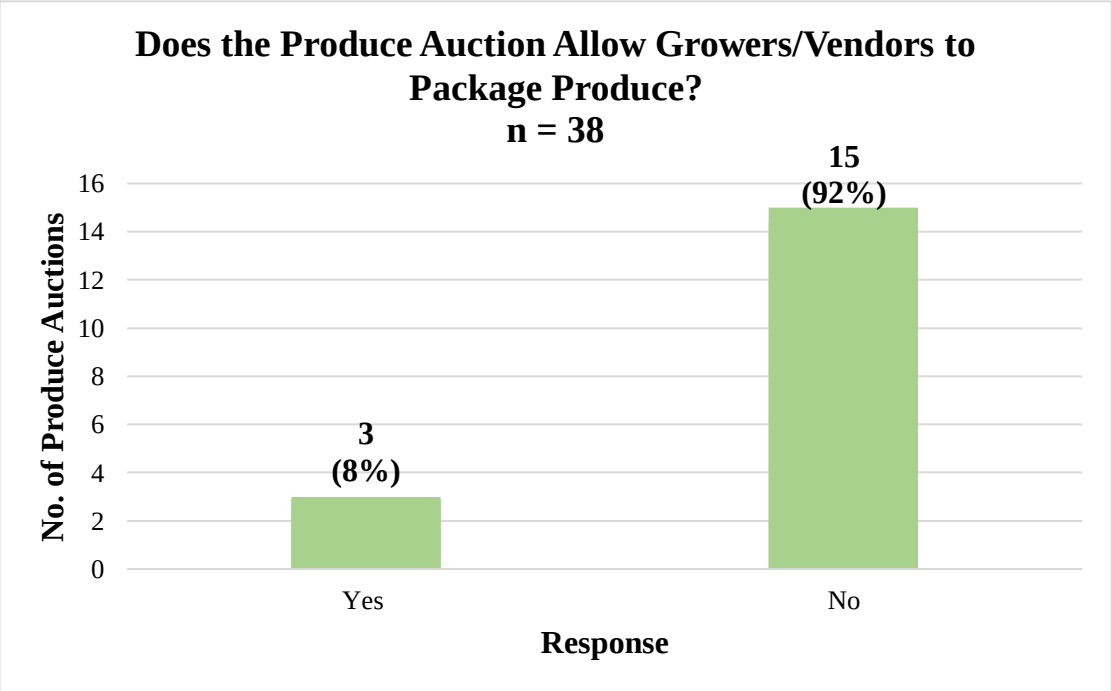

Figure 5.10 Does the Produce Auction Allow Growers/Vendors to Package Produce?

5.5 Food Safety Practices at the Produce Auction

Insights into the PAs' current knowledge and attitude towards various food safety practices are important for understanding what food safety risks are being addressed by the PAs, how they are addressing them, and how the PSR could help them to further mitigate those risks. Written food safety policies are one such practice that are used to set expectations for employees and outline the steps that need to be taken for certain

procedures to be done regularly and consistently. Policies for cleaning and sanitizing areas with food and nonfood-contact surfaces were of particular interest because they are a potential source for contamination. The areas that this survey covered were the auction floor, restroom(s), equipment, storage areas, and kitchen/food preparation areas. There was also an "other" category if PAs had written cleaning and sanitizing policies for areas outside of these categories.

More than half (61%) of PAs surveyed had at least one type of written policy (Figure 5.11). The PAs that had written cleaning and sanitizing policies typically had them for the auction floor and the restrooms, 96% and 91% of the PAs respectively (Figure 5.12). This was expected as the auction floor and restrooms are areas where the most amount of foot traffic occurs, since employees and visitors are allowed in these areas. Equipment was addressed by 65% of the PAs that had written cleaning and sanitizing policies. This indicates that PAs may not understand that equipment can be considered as a food contact surface and has the ability to transmit pathogens in a similar manner that people can if they were to touch a contaminated surface and then the produce (Figure 5.12). The low number of PAs that reported having written cleaning and sanitizing policies for storage areas (39%) also emphasize the notion that PAs are not receiving proper education on all of the ways that pathogens can travel (Figure 5.12). Written cleaning and sanitizing policies by the PAs for the kitchen and food preparation areas were not as much of a concern after learning that the majority of these areas are operated separately from the auction and are regularly inspected by the state health department. However, if the kitchen and food preparation area was operated under the PA, then PAs should understand that written cleaning and sanitizing

policies for these areas are a food safety practice that could protect their business by further mitigating food safety risks.

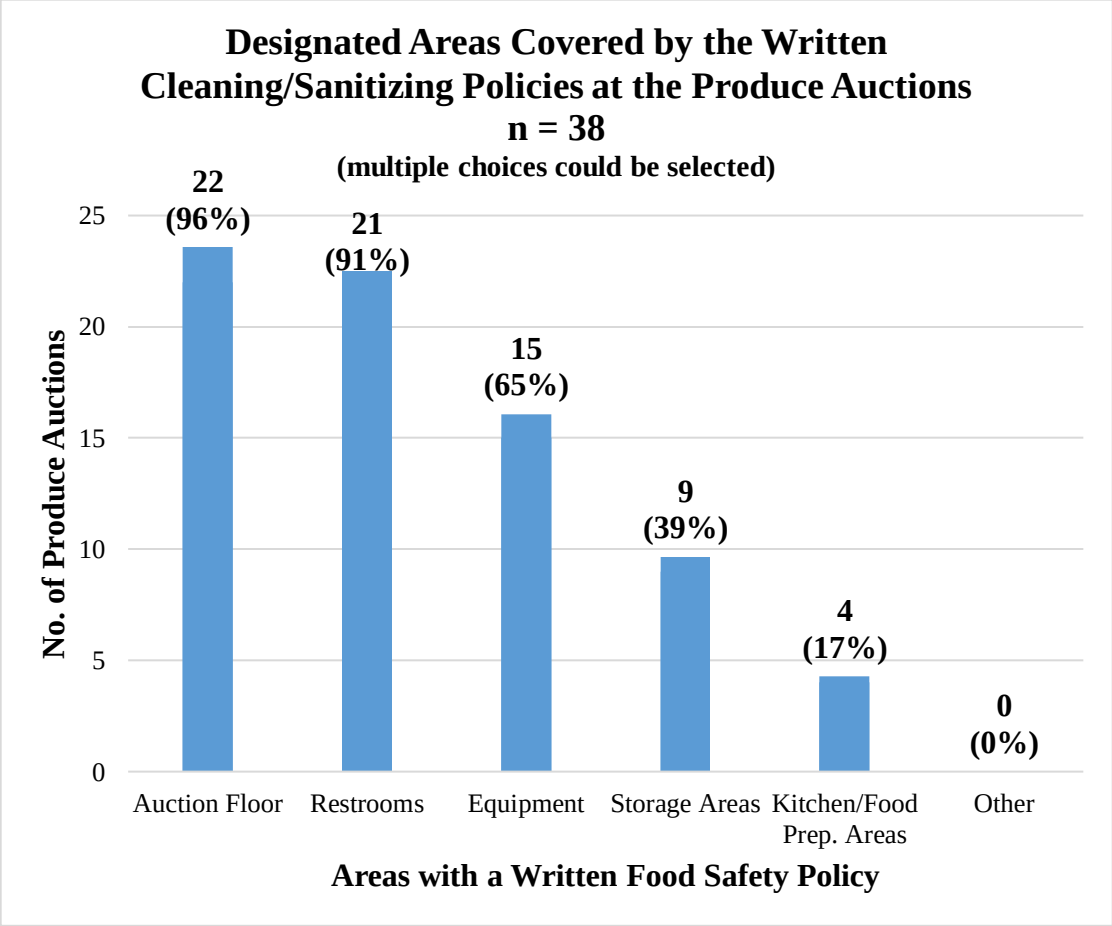

Figure 5.11 Does the Produce Auction have Written Cleaning/Sanitizing Policies?

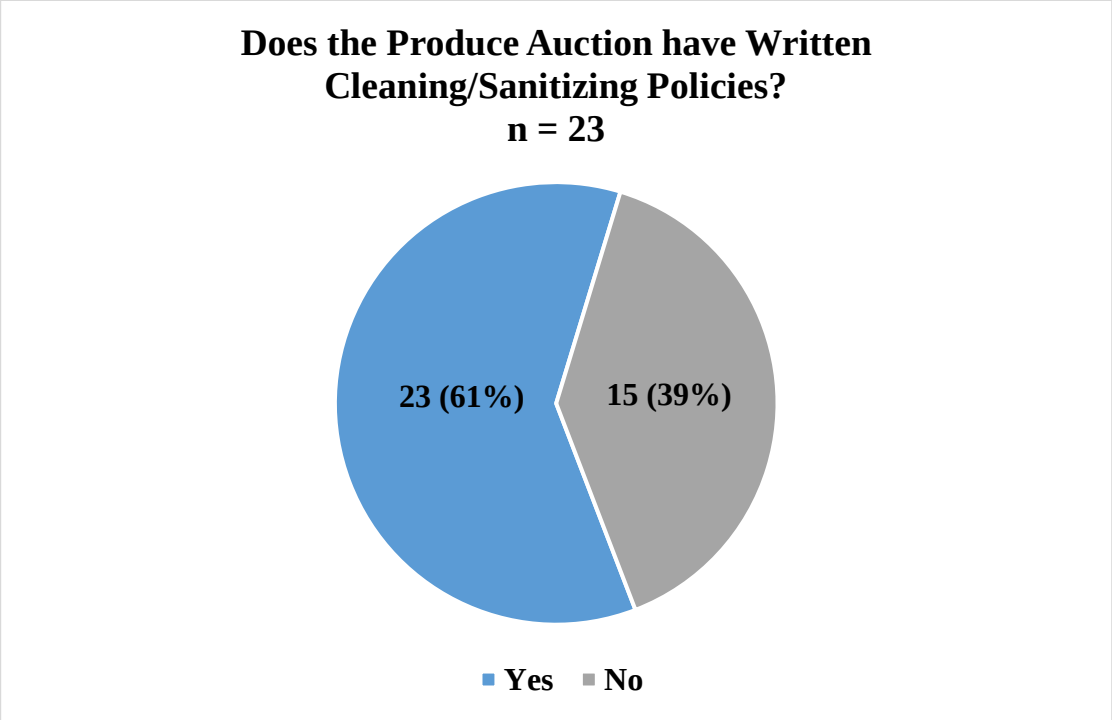

Figure 5.12 Designated Areas Covered by the Written Cleaning/Sanitizing Policies at the Produce Auctions

In addition to written food safety policies, data about PAs participation in 3rd Party GAP Audits, facility (internal) audits, food safety plans, or other food safety practices within the last five years was also collected using this survey. Only food safety practices that were implemented in the last five years were of interest because there have been many updates and advancements in food safety, such as the PSR, during this timeframe. Audits are important because they are a systematic approach to ensuring that food safety is properly addressed. The two types of audits that were included in the survey were 3rd Party GAP Audits and facility (internal) audits. 3rd Party GAP audits are done voluntarily but are frequently completed by farmers who have buyers that require this certificate for business. The 3rd Party GAP audits are performed by an auditor who is independent of the farm. The auditor uses a standardized checklist to determine if the farm is in compliant with the requirements. If the farm is not in compliance with the requirements, then the buyer may

decide to buy their products from another farm. Facility (internal) audits use the same systematic approach but are less formal than the 3rd Party GAP audits. Rather than having an independent auditor evaluate the business, the business is evaluated by someone who works for the company; in this case it would most likely be the designated food safety person. The assigned individual then determines if the business "passes" the audit based on standards that were created prior to the audit.

According to the survey 13% of PAs completed a 3rd Party GAP Audit and 13% completed a facility (internal) audit (Figure 5.13). Although audits are not a part of the PSR, they are recommended because they are a useful practice that can help the PAs evaluate and verify food safety practices that are in place. Furthermore, audits can use the evaluations to determine if resources for food safety practices are being distributed efficiently, or if there can be restructuring to save the PAs more time and money.

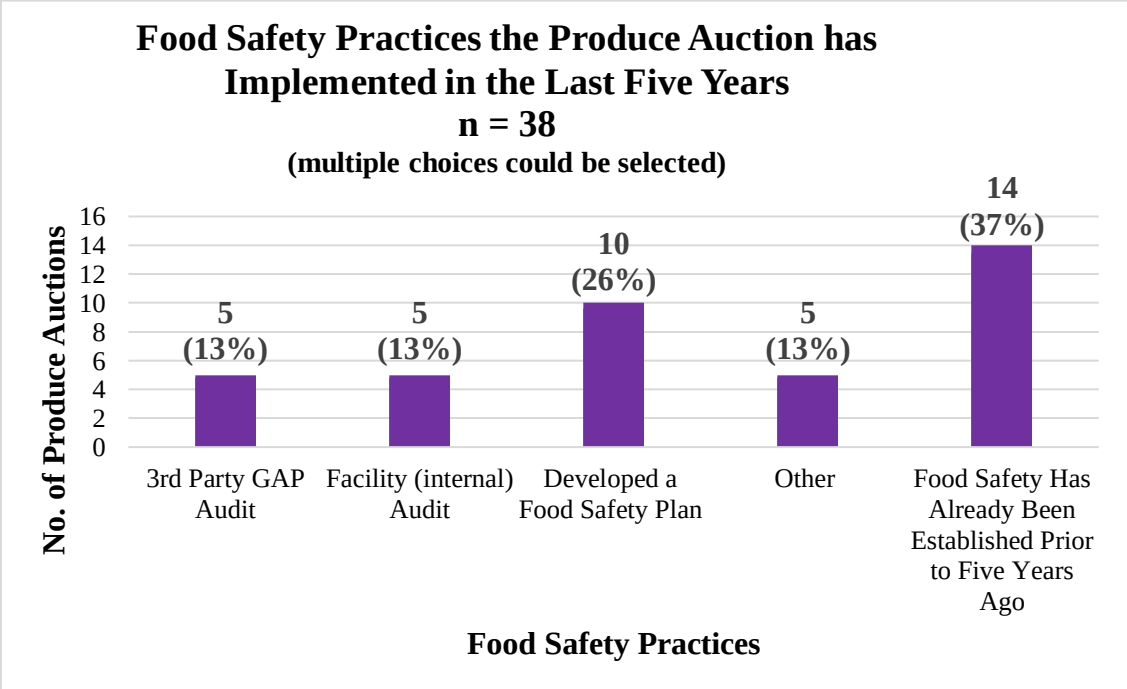

Figure 5.13 Food Safety Practices the Produce Auction has Implemented in the Last Five Years

In addition to audits, food safety plans are useful to businesses because they allow a holistic view of the operation and help organize food safety into a logical flow that can aid in the implementation, evaluation, and/or verification of food safety practices. Examples of information that can be found in a food safety plan include, but is not limited to, the layout of the PA, the emergency contacts, written cleaning and sanitizing policies, traceability systems and recall plans. From the results, 26% of the participating PAs reported that they had developed a food safety plan in the last five years (Figure 5.13).

There was also a category of food safety practices labeled as "other" that 13% of the PAs reported implementing and could include practices such as signage, visitor waivers, or standard operating procedures (Figure 5.13). It is important that we understand how many PAs are implementing various food safety practices because it provides us a measurement that indicates the level of awareness that PAs have towards food safety.

One of the easiest ways that the reputation of PAs can be damaged is by being implicated in a foodborne outbreak and having to recall products. Fortunately, none of the participating PAs have been in a recall to date (Figure 5.14). However, this does not suggest that PAs do not carry risks and are immune from being a source of contamination. PAs have inherent risk and as such cannot be certain that all sources of contamination are mitigated. Therefore, PAs should have a traceability system and recall plan in place. A traceability system is the ability to trace a product one step back and one step forward in the food supply chain. A recall plan is the process of using the traceability system that enables the PAs to recall products efficiently. These two components are critical to

minimizing the consequences that follow a foodborne outbreak because they minimize the potential number of people who may get sick from the contaminated products.

Traceability and recall are particularly important for PAs because they sell at the wholesale level and therefore, are not selling the majority of their produce to a qualified end-user. If PAs were selling primarily to qualified end-users, then traceability and recalls would not be as complicated because if an outbreak were to occur researchers could easily trace the food of interest back to the PA. However, the wholesale component makes traceability and recalls more complex because produce will not go directly to a consumer, but rather move further along the food supply chain.

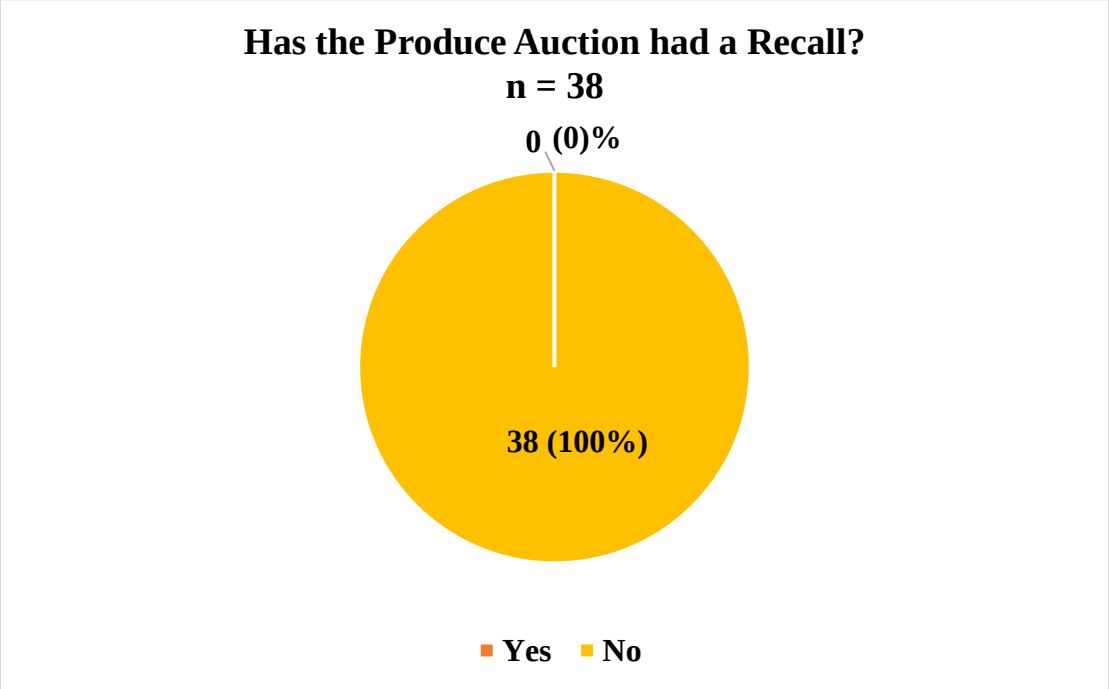

Figure 5.14 Has the Produce Auction Ever had a Recall?

All of the PAs reported that they had a traceability system, but only 82% of the PAs reported having a recall plan (Figure 5.15, Figure 5.16). Although the PSR does not require a traceability system or recall plan, it does recommend that businesses have them in the

event that an outbreak were to occur. This is because traceability allows for sources of contamination to be identified quickly and recalls minimize the amount of potentially contaminated products from being consumed.

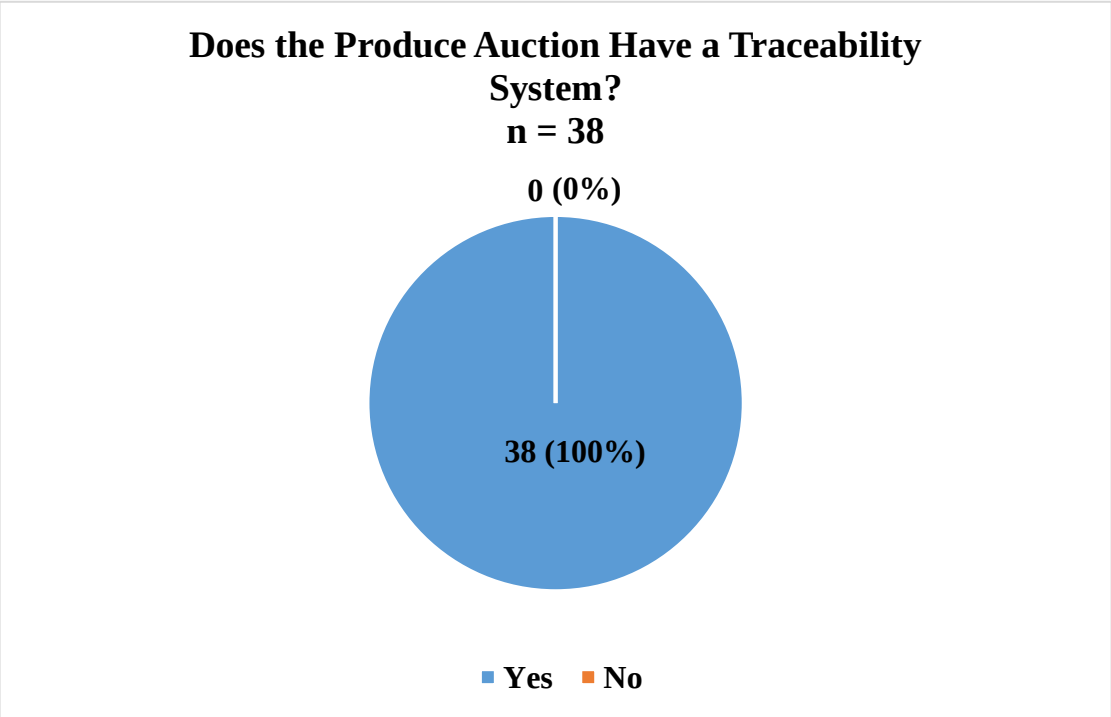

Figure 5.15 Does the Produce Auction have a Traceability System?

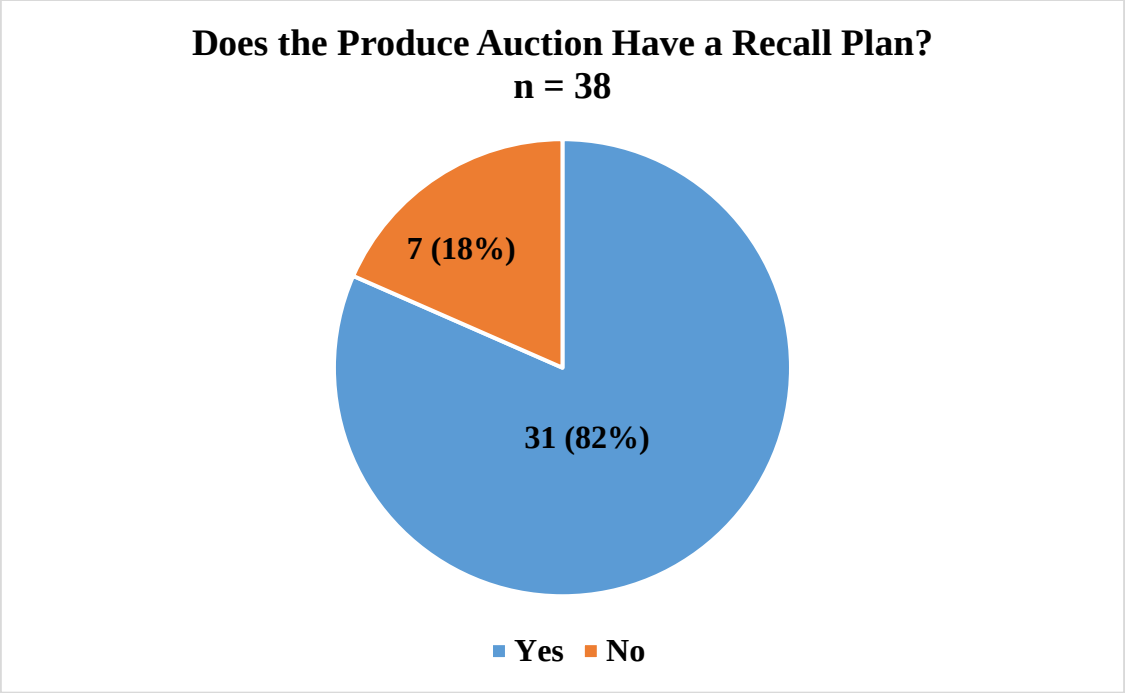

Figure 5.16 Does the Produce Auction have a Recall Plan?

5.6 Food Safety Training at the Produce Auction

Attending and actively participating in food safety trainings is essential for all food handlers because the trainings are designed to provide information on why, what, and how risks should be addressed in the food industry. There are a variety of food safety trainings that a person could complete to be aware of food safety risks and understand how to minimize such risks. These trainings include GAP training, PSA grower training, PCHF training, PBPT, and a training that the auction creates. GAP training has been provided to farmers for the last 20 years and provides an understanding of how to minimize microbial risks for fruits and vegetables that are produced, packed, handled, and stored. The GAP training prepares farmers to be in compliance with the requirements of a 3rd Party GAP audit. The PSA grower training is essential for those businesses who need to be in

compliance with the PSR. The PSA grower training differs from the GAP training because it is a federal regulation rather than a voluntary program. PCHF training is also a federal requirement but is only necessary if the business processes or manufactures food products. Businesses may take this training even if it does not apply to them because it provides further information on minimizing food safety risks. PBPT is required by vendors at farmer's markets and roadside stands, approved by the Kentucky Department of Agriculture, that wish to hand out food samples (Kentucky Department of Agriculture, 2019).

PAs have three potential groups of people who could be responsible for food safety: the designated food safety person, the employees, and the growers/vendors. A designated food safety person is someone who is responsible for the implementation and compliance of all food safety practices. Employees can work either part- or full-time but all of them need food safety training because they are potential vehicles for pathogen transmission. Growers/vendors are visitors in the PAs and also need to receive food safety training because they too can potentially transmit pathogens. Although all three categories of people have the potential to be a source of contamination, they do not need to have the same type of food safety training because their role in the PAs carry different levels of risk. The PSR addresses this concept by requiring that a designated food safety person, who will need to take a PSA grower training, is appointed, that the employees receive a food safety training that is only pertinent to their job duties upon hiring and once annually, and that visitors are made aware of the food safety policies that the business may have in place (21 CFR Part 112).

Assigning a designated food safety person is important because it allows for food safety risks to be dealt with efficiently. However, because the designated food safety person has the authority to make all of the decisions regarding the implementation and revisions of food safety practices it is necessary for them to be educated on all potential risks within the business. It is for these reasons that PAs were asked if they had a designated food safety person and if so, did the PA require them to complete a food safety training. The PAs were then asked what type of training the designated food safety person was required to take.

According to the results of the survey, 66% of the PAs reported that they had a designated food safety person and that they required the designated food safety person to attend a food safety training (Figure 5.17, Figure 5.18). The results also showed that another 5% of the PAs did not have a designated food safety person, but rather had a board comprised of PA members that decided on food safety practices together (Figure 5.17). These PAs also required that these people take a food safety training, which also indicate that PAs understand the necessity of training for the implementation of proper food safety practices (Figure 5.18). The GAP training was required by the most PAs (85%) while the PSA grower training followed closely behind with 74% of PA requiring this training (Figure 5.19). These two trainings were likely the most popular because they specifically cover produce. The GAP training may have been required by more PAs than the PSA grower training because many of the designated food safety people and board members are also farmers and may have needed GAP training for their personal farms. The PSA grower training is also needed for farmers but only covers farms that make more than $25K in annual produce sales, unlike GAP training that can be required by buyers for farms of any size. The PCHF training and PBPT were only completed by one PA each (Figure 5.19).

Low requirement rates for these trainings were expected because the PCHF does not apply specifically to produce and the PBPT is only offered in Kentucky.

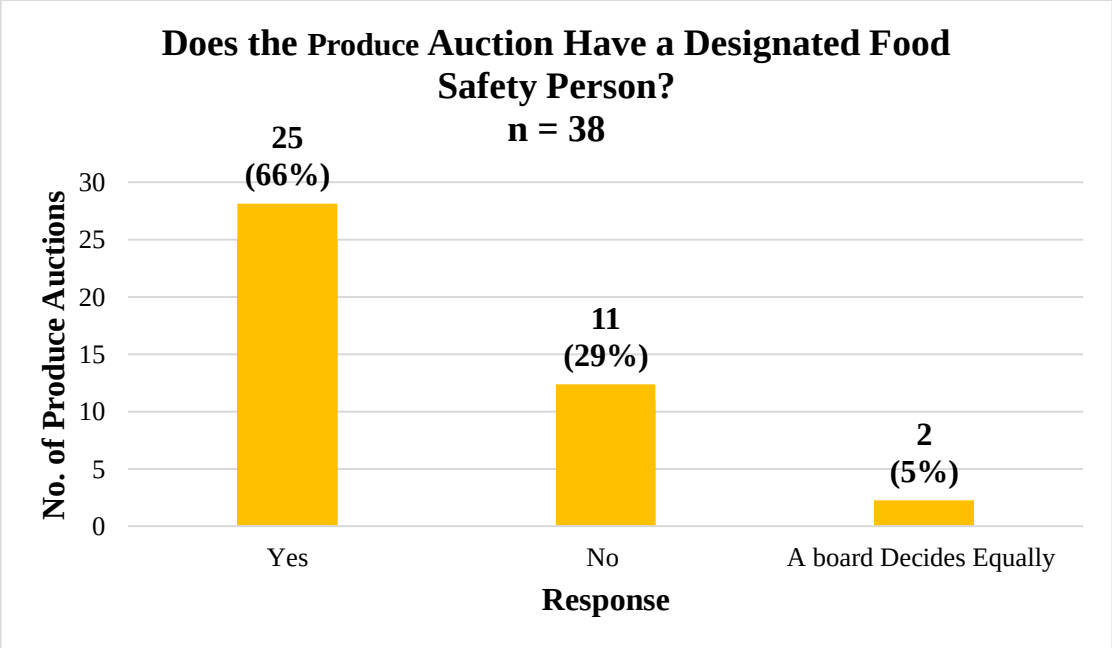

Figure 5.17 Does the Produce Auction Have a Designated Food Safety Person?

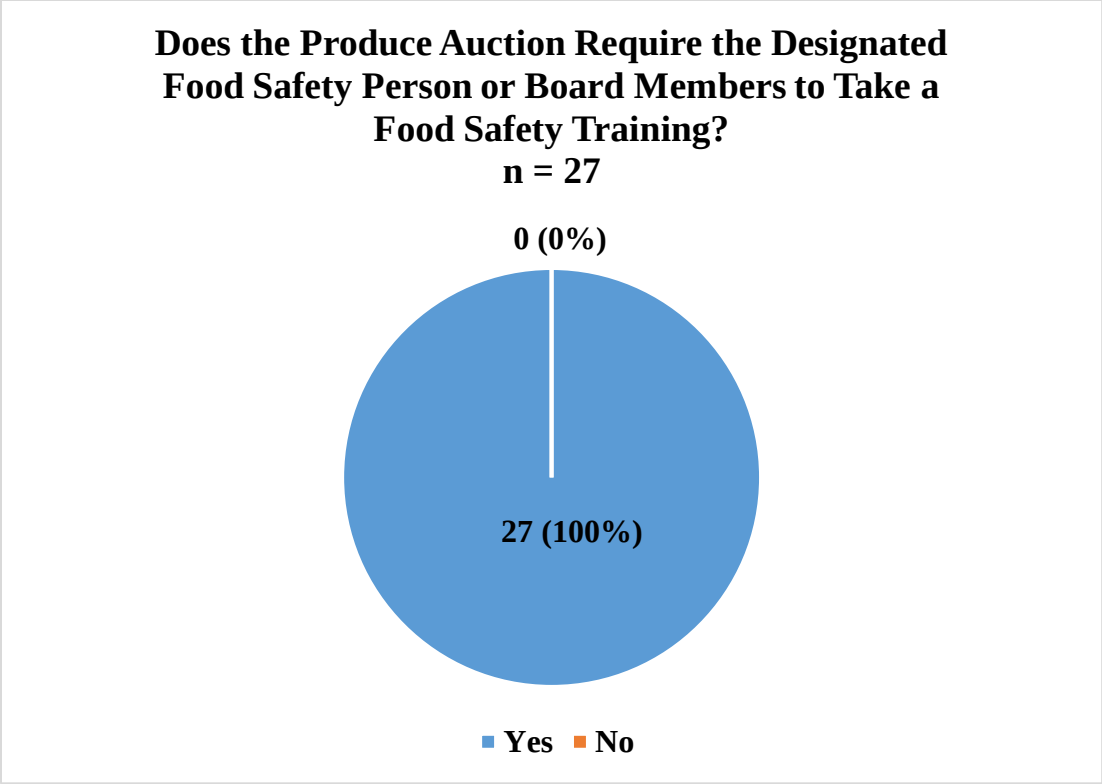

Figure 5.18 Does the Produce Auction Require the Designated Food Safety Person or Board Members to Complete a Food Safety Training?

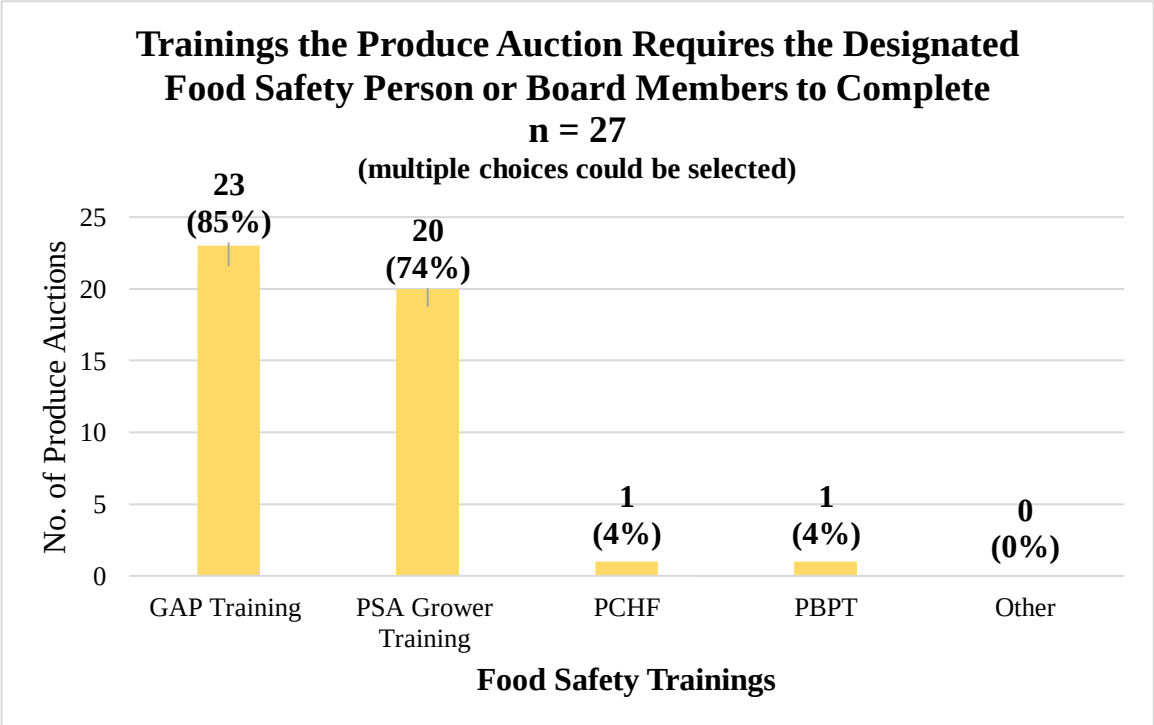

Figure 5.19 Trainings the Produce Auction Requires the Designated Food Safety Person or Board Members to Complete

It is necessary for employees to be educated on food safety because they are vectors for foodborne pathogens and can contaminate the produce via their hands, clothes, shoes, or bodily fluids. However, because their responsibilities are not as extensive as the designated food safety person's they do not necessarily have to complete a food safety training of the same caliber.

The study found that 74% of the PAs reported that they required their employees to take at least one food safety training (Figure 5.20). Most PAs (96%) created a food safety training specifically for their employees (Figure 5.21). It is likely that auctions created their own trainings for their employees because it was more cost effective as the PA did not have to pay for their employee(s) to go to a formal training, and the training could be made shorter than a formal training. GAP training was required by 32% of the PAs and may have been used because it covers the basics of food safety for produce, and because the employees may have already taken this training if they had a personal farm (Figure 5.21). Lastly, there were PAs (7%) who required the PSA grower training for their employees (Figure 5.21). This again, may be because the employees have personal farms and have already taken this training. According to the PSR, any of these trainings are appropriate for the PAs' employees (21 CFR 112).

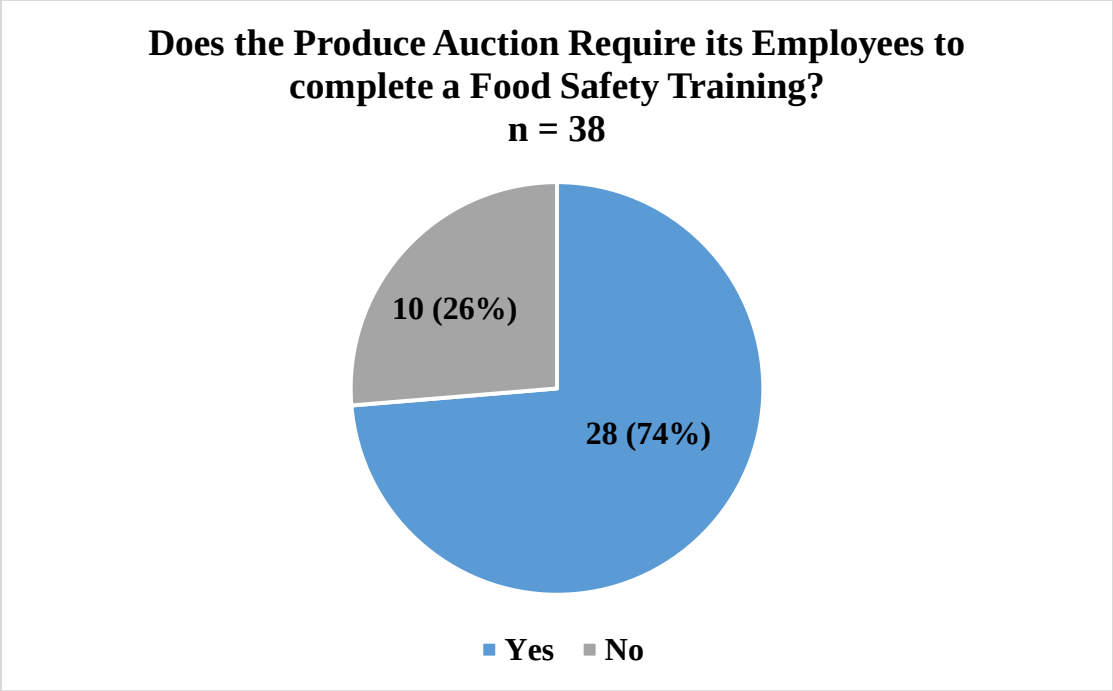

Figure 5.20 Does the Produce Auction Require Its Employees to Complete a Food Safety Training?

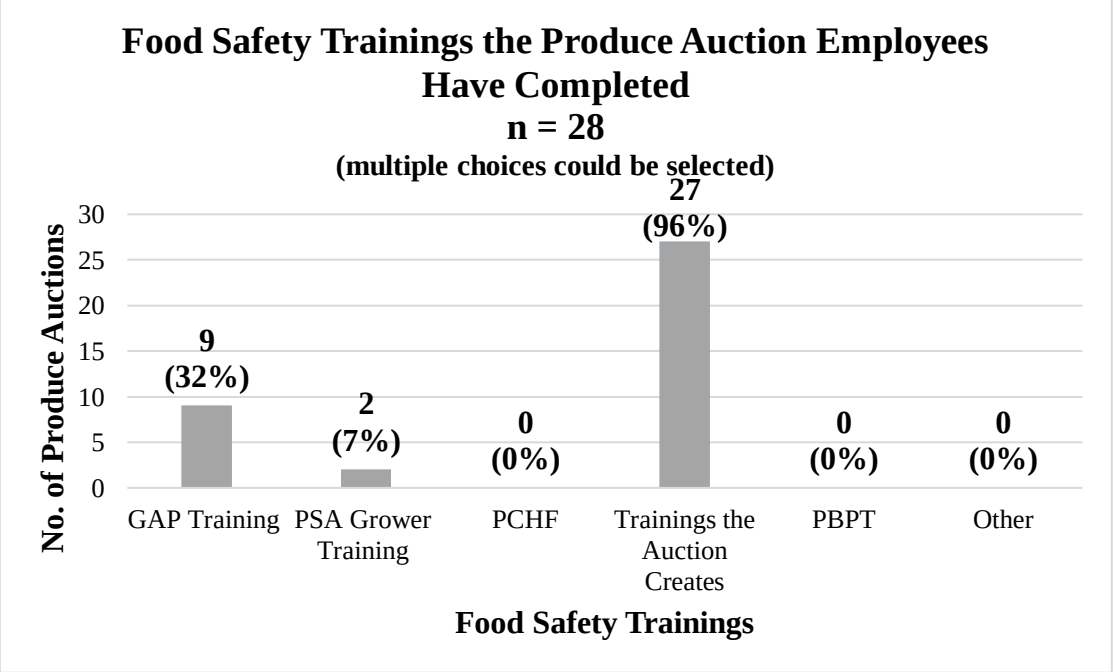

Figure 5.21 Food Safety Trainings the Produce Auction Employees Have Completed

As stated previously, the PSR requires that the employees complete a food safety training upon hiring and a subsequent training at least once a year after their hiring date (21 CFR Part 112). For the PAs that required their employees to complete at least one food safety training, 68% of the PAs trained their employees after they were hired, 54% of PAs trained their employees at least annually, and 18% of PAs trained their employees seasonally (Figure 5.22). It is important that PAs train their employees upon hiring and at least once a year after their hiring date to ensure that food safety remains a priority throughout the employee's duties and to provide the employee with the most recent food safety practices.

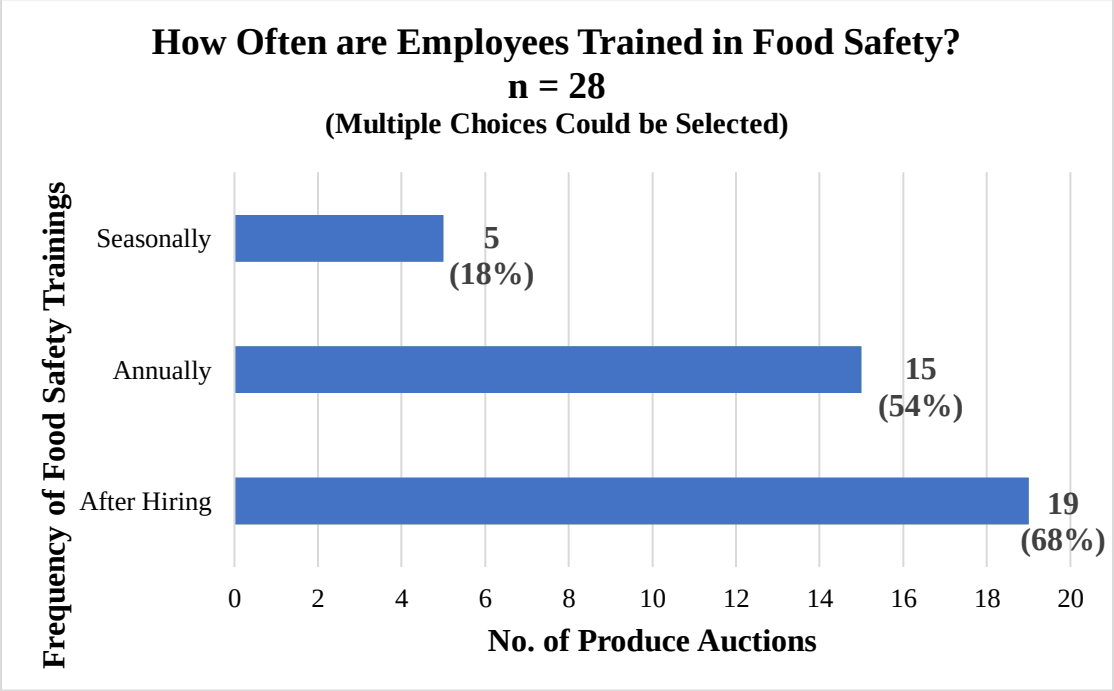

Figure 5.22 Frequency of Employee Food Safety Trainings

The typical interaction between visitors and produce is limited within the business. It is for this reason that GAP, the PSR or PCHF do not require that the visitors complete a formal food safety training, but rather require that they be made aware of food safety

policies that the business has in place, such as washing hands before entering areas with produce. However, the role of the growers/vendors within the PAs is much more complex than the type of visitors that these food safety programs address because the growers/vendors are bringing produce from their farm into the PAs. This is a practice that is unique to PAs and is risky because if the farm is bringing in produce that could have been contaminated at their farm, then there is an increased chance that cross contamination to the other lots of produce at the PA could occur. It is for this reason that the PAs were asked if they required their growers/vendors to complete a food safety training and if so, which food safety training did they require.

It was reported that 18% of the PAs that participated in the survey required their growers/vendors to complete a food safety training (Figure 5.23). Of PAs that required their grower/vendor to complete a food safety training, 71% of the PAs required their growers/vendors to complete a GAP training, 14% of the PAs required their growers/vendors to pass a Third-Party GAP audit, and 29% of the PAs required their growers/vendors to complete a training the auction created (Figure 5.24). It is likely that the GAP training was the preferred training compared to a training the auction creates because it covers basic food safety practices and the auction is not responsible for developing and distributing an additional training. It was surprising that the PAs required a Third-Party GAP audit because they are costly for the farms and have to be done annually. However, the completion of the audit does ensure the PAs that the farms are taking the necessary measures to mitigate food safety risks.

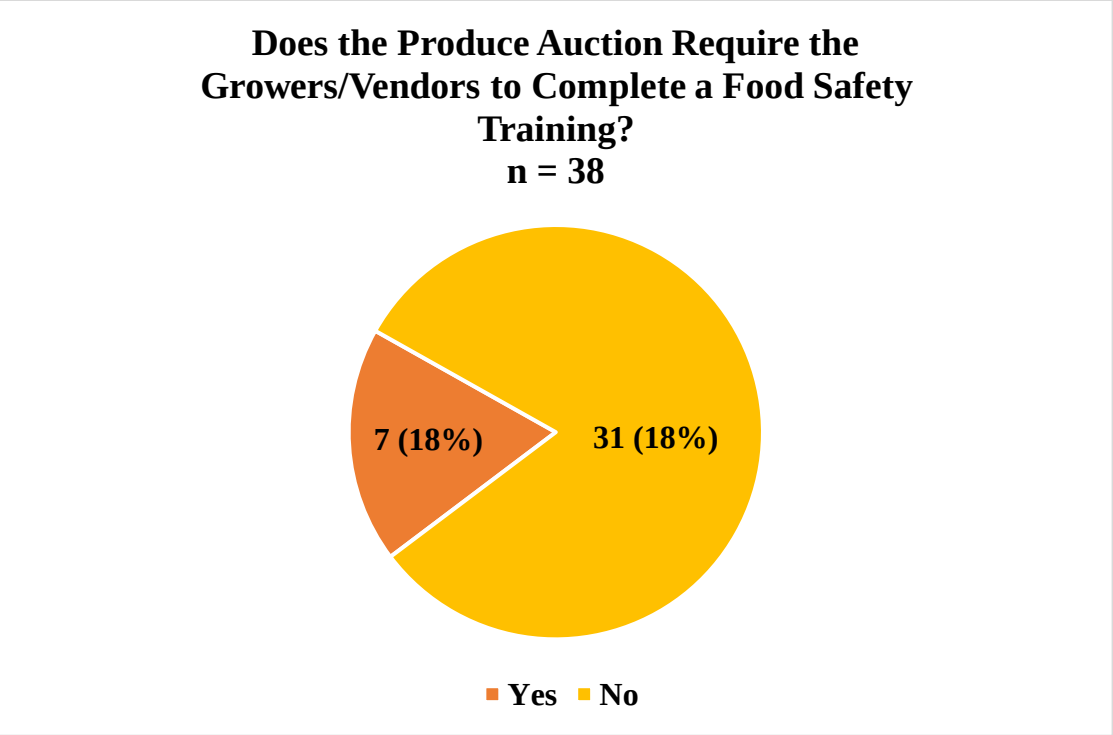

Figure 5.23 Does the Produce Auction Require Growers/Vendors to Complete a Food Safety Training?

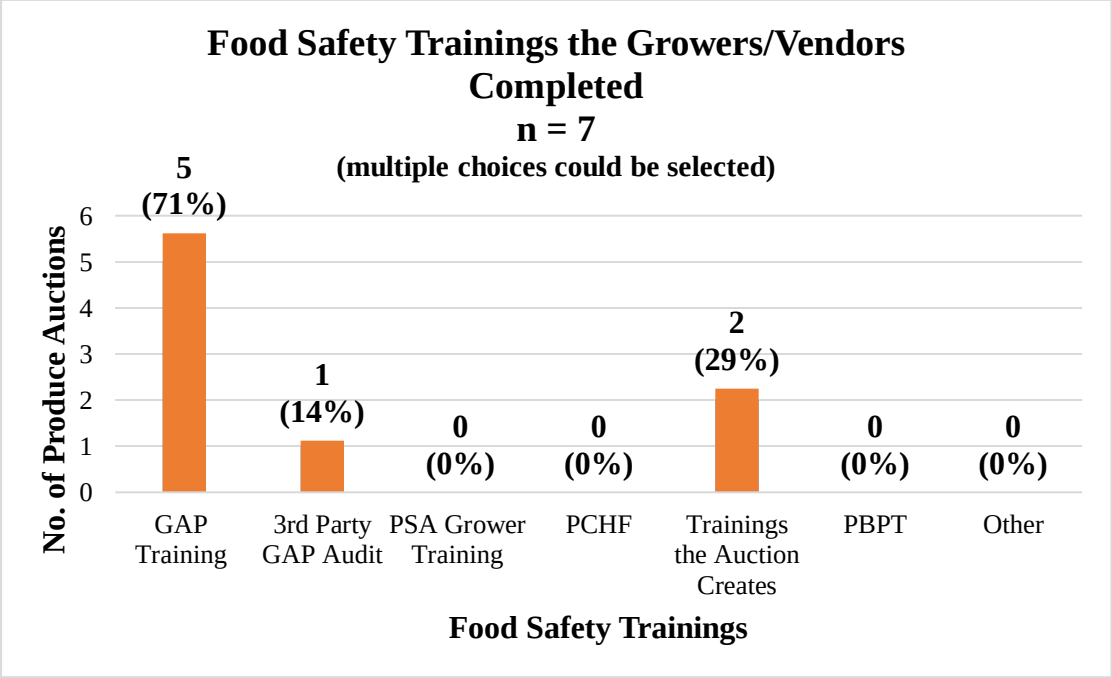

Figure 5.24 Food Safety Trainings the Growers/Vendors Completed

The completion of a food safety training can be compared to a certificate of analysis that other food businesses require when new products are brought into their building. A certificate of analysis is a document that confirms, with evidence of testing, that the product being delivered meets certain specifications. However, because testing is not practical in this setting, a food safety certificate could be substituted for the certificate of analysis and is a measure that PAs could implement to minimize the possibility of pathogens being introduced into their environment.

5.7 Recommendations

From on the results of the survey, the PSR would be the most appropriate and applicable food safety program for PAs. This is because PAs hold produce and the risks, such as buildings, workers, visitors, equipment, and domestic animals and wildlife, associated with holding are addressed by the PSR. To comply with the PSR, the PAs must appoint a designated food safety person and have that person take a PSA grower training course. This training is essential because it includes the requirements of the PSR in addition to providing examples of food safety practices that would satisfy the requirements.

Because PAs are not required, at this time, to comply with the PSR they will not be subject to an inspection by state or federal authorities. However, if the PAs would like to ensure that they are taking all of the necessary precautions to mitigate food safety risks then they would benefit from a facility (internal) audit. PAs could also check with their local extension agent to find out if their state has the resources to set up an On-farm Readiness Review, a walkthrough with a person who has been trained to help farms prepare for an inspection, for their auction.

In addition to complying with the PSR, it is also recommended that PAs develop a food safety plan. The food safety plan will allow the PAs to map out places where the produce is most likely to be contaminated and help them address those risks accordingly. For instance, PAs may notice that there are a lot of horses or other working animals in their parking lot. To minimize the potential of cross contamination from horses to the produce, the PA may require that all visitors wash their hands and rinse their shoes before entering the PA. The food safety plans can also keep the PA organize all of its policies and records for trainings, cleaning and sanitizing, and/or pest management.

Lastly, it is recommended that the PAs are all in contact with their local extension agents. Because many of the PAs do not have access to the internet, where the majority of food safety information is published, communication with the extension agent is crucial. These extension agents are responsible for helping anyone handling food and will be able to organize various food safety trainings or workshops for the PAs that can are delivered in a manner that is sensitive to their needs and will help educate the owners and employees of the PAs in mitigating food safety risks.

It should be noted that this recommendation is for PAs that only hold produce. If a PA were to grow, harvest, or packing produce, meaning that they were removing produce from the place they were grown or placing them into container, then their business would fall under the definition of a farm and they would have to comply with the PSR. If a PA were to manufacture or process produce, meaning that they are adding a substance or process to affect the characteristic of produce, then the PA would have to register as a facility and comply with PCHF.

5.8 Limitations

There were several limitations for this study. The first limitation was the method of data collection. Based on the locations of the PAs it was not practical, due to financial and time constraints, to visit these PAs and deliver the survey in person. Additionally, the PAs are mainly operated by members of the Plain community who do not utilize email. Mailing was an option, but surveys delivered through mail limited interaction with the participants and a lower response rate was predicted. Although many of the PAs could be reached by phone, the PAs typically had only one phone. This hindered the ability to achieve a higher response rate because many of the PA could not afford to tie up their phone line with calls that were not directly business related. The second limitation was the inability to ask survey questions about financials, due to a predicted low response rate. This was also a limitation because it could have yielded important information regarding how much produce was sold at the auction and better supported the reasoning for PAs to comply with the PSR. The third limitation was that the answers for the survey were self-reported. Self-reported answers could be inaccurate or incomplete which could skew the results. For this study, inaccurate or incomplete answers may have led to the belief that more PAs had a better understanding and were participating in more food practices than in actuality.

5.9 Future Studies

It is recommended that PAs should be covered under the PSR, but the development of a training specific for PAs or other AFNs could be explored. For instance, there are PAs that allow potential buyers to pick up produce and examine it before buying it.

Although the PSR requires that all visitors are aware of their policies, such as handwashing, it should be addressed more extensively because it is an activity that carries a severe consequence if contamination were to occur. A practice that is not in the PSR, but could be implemented by the PAs, is to require hand sanitizer or single-use gloves near the produce for the buyers to use. PAs also have growers/vendors bringing in produce that could be contaminated and be a source for an outbreak. Many other businesses, like manufacturing plants, require companies that bring in products to provide a certificate of analysis to ensure that the incoming products meet certain standards. Requiring that the growers/vendors complete a food safety training could be used to reduce the risk of growers/vendors bringing in contaminated products.

In addition to trainings that include specific guidelines for the activities performed in PAs, there should be research into developing a training that is sensitive to the Plain community culture. This would include at least two objectives. The first would be developing a manual that is written with verbiage that is easily understood by a broad audience and has quality pictures. The second would be creating a questionnaire or other type of evaluation to assess the participants knowledge of the material presented and determine if it is sufficient for them to receive the certificate.

Furthermore, PAs represent only a fraction of AFNs. AFNs such as food hubs, fair trade, or community supported agriculture programs are also handling produce with no specific guidelines in place. Increased data collection for these other AFNs could further encourage policy and law makers to look more closely at their unique operations and support food safety efforts by creating guidelines specifically for AFNs.

CHAPTER 6. **CONCLUSION**

Food safety is important because it can impact public health, economic burdens and food security, and it is for these reasons that food safety standards have been re-evaluated and addressed at the federal level through FSMA. Although this new regulation is progressive on various levels, there remain gaps in food safety along the food supply chain. PAs are an example of the gaps in the food supply chain and are businesses that allow small-scale farms to participate at the wholesale level. PAs handle fresh fruits and vegetables, commodities that have been implicated in many foodborne outbreaks, and are being overlooked in the current regulations. Because of this oversight, PAs and other alternative food networks alike, have not been provided with food safety standards that can help mitigate food safety risks and protect their businesses from being a source in an outbreak. To address this issue, this study was designed to collect information on various food safety aspects within PAs and be able to provide them with a recommendation to which food safety program would be most appropriate for their business.

Determining the type of function that best described the PAs was key in understanding which food safety program was most applicable for their business because each function is associated with a different set of practices that have various levels of risk. Based on the results, it was concluded that PAs are holding produce. Although holding is covered by both the PSR and PCHF, the PSR would be the most appropriate food safety program for PAs because it focuses on raw agricultural commodities rather than commodities that are manufactured and processed and are covered by the PCHF. Furthermore, because the PCHF is for manufacturing and processing products it has more rigorous standards, such

as scientific testing for verifying preventive controls, that would not be practical for PAs to abide by.

The specific risks associated with holding come from food and non-food contact surfaces in the building, environmental factors, such as dirt and debris, domestic animals and wildlife, employees and visitors and are all present in PAs. Written cleaning and sanitizing policies, the utilization of audits, food safety plans, a traceability system and recall plan, appointment of a designated food safety person, and implementation of trainings for the designated food safety person, employees, and growers/vendors were all used as measurements to understand if and how PAs were addressing food safety risks.

From the results of the survey, we saw that only 61% of PAs had a written cleaning and sanitizing policy for at least one area of the PAs, but that none of the PAs had a policy for all of the areas of concern. It is important that cleaning and sanitizing is done properly and regularly to minimize the potential of pathogens being transmitted from food and non-food contact surface onto the produce.

The results also showed that only 13% of the PAs were assessing their food safety practices using either a Third-Party GAP audit or a facility (internal) audit. Although these audits are not a requirement for the PSR they do allow PAs to ensure that the food safety practices are being implemented efficiently. In addition to audits, a food safety plan is also a tool that can be utilized to organize food safety throughout the PA. Of the participating PAs, 29% of them reported that they had developed a food safety plan. Other food safety practices such as signage, waivers, or standard operating procedures could have also been implemented to mitigate food safety risks but only 5% of PAs reported having these practices.

The implementation of a traceability system and recall plan can greatly benefit the PAs if there is a quality control problem, or if a foodborne outbreak were to occur. All of the PAs had a traceability system, but the 18% of the PAs did not have recall plan which is a problem because a traceability system cannot be utilized efficiently without a recall plan.

In order for PAs to be able to implement food safety practices, they need to have a designated food safety person that has an understanding of basic food safety principles and the authority to assign and monitor food safety responsibilities to the various parties of people that participate in the PA. The results showed that 66% of the PAs had a designated food safety person that completed at least one food safety training.

Employees make up one of the groups of people that participate in the PAs and are responsible for food safety because they have the ability to transmit pathogens onto the produce. It is for this reasons that employees should be trained upon hiring and once annually on the food safety practices that are associated with their duties. While 74% of the PAs did train their employees on food safety principles, not all of these PAs trained their employees after they were hired or at least once annually.

The second category of people that the designated food safety person needs to address are the growers/vendors who are able to transmit pathogens the same way as employees and also through the produce that they are bringing to the auction. It is because of the growers/vendors ability to introduce contamination into the auction through their produce that the PAs should require the growers/vendors to complete a food safety training to minimize this risk. Currently, according to the survey, 18% of the PAs require that their growers/vendors complete a food safety training.

Overall, the inconsistencies in the responses by PAs for each measurement indicates that PAs are not being provided with the proper food safety education. This is a concern because the inconsistencies in addressing food safety risks can increase the risk for a PA to be a source for contamination that could cause an outbreak. Not only would this outbreak be devastating for the PA that would be implicated in the outbreak, but the entire image PAs could be tarnished, which would have its own rippling effects as PAs are intertwined with their local economy.

Because the PSR addresses the risks that are present in PAs, in a manner that is applicable and appropriate for their unique operation, it is recommended that PAs comply with the PSR. Compliance with the PSR could bolster the PAs' reputation by instilling confidence in buyers because it can serve as a signal or be a form of verification to the buyers that the PAs are taking the necessary measures to mitigate food safety risks. Whether PAs want to mitigate risks to protect consumers health, decrease the economic burden, protect an image, or all of the above, PAs that comply with the PSR will be doing their part in closing the food safety gaps in the food supply chain.

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Publications

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