

Identification of food safety risks at Virginia farmers' markets and development of a food safety plan to help farmers' market managers

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ABSTRACT

The growing popularity of farmers' markets coupled with a high percentage of produce-related foodborne outbreaks highlights the need for an emphasis on food safety within these markets to protect farmers, patrons and local economies. The number of farmers' markets registered in the United States has almost tripled in the last 15 years. Fresh produce constitutes the majority of food sold at farmers' markets. Between 1998 and 2008, raw produce accounted for almost half of the foodborne illness outbreaks linked to a specific commodity. This research was conducted to identify practices at farmers' markets which may contribute to an increased risk of contamination, assess the microbial quality of produce sold at farmers' markets, as well as to develop a food safety management plan template for market managers to utilize to build their own food safety plan.

Using an observational data collection method, risky food safety practices were identified at Southwest Virginia farmers' markets. While market managers and vendors in three of the five markets observed had formal food safety training, numerous risky food safety behaviors were still observed including temperature abuse, cross contamination opportunities, and poor personal hygiene and sanitation. Additionally, the microbial quality of produce from Southwest Virginia farmers' markets was compared to produce sold at retail using culture based microbiological plating and molecular methods. Total aerobic bacteria and coliforms were enumerated, and the presence of *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella* spp., *Staphylococcus aureus* and generic *E. coli* were determined. A significantly greater quantity of total aerobic

bacteria was isolated from farmers' market leafy greens, onions and tomatoes when compared to a retail grocery store ($P=0.0011$, $P=0.0395$, and $P<0.0001$, respectively). Additionally, one or more target pathogen was isolated from 28 farmers' market samples and 16 retail grocery store samples. The observed risky food safety behaviors along with the bacterial data collected emphasize the need for a pathogen reduction focus on fresh produce not only at farmers' markets, but also with growers and other retail outlets.

To help promote proper food safety practices at farmers' markets, a farmers' market food safety management plan (FSMP) template was developed to address the top five risk factors contributing to foodborne illness as identified by the Centers for Disease Control and Prevention (CDC). The FSMP was evaluated for practicality and feasibility through interviews with market managers in North Carolina and Virginia. Most market managers (66.7%) agreed that the FSMP was practical for their market while only 33.3% agreed that they could implement the plan immediately. Revisions suggested to the FSMP will be made and it will be made available in Virginia and North Carolina in spring 2016.

Dedication

This work is dedicated to the graduate students in Food Science & Technology at Virginia Tech. Thank you for making me a part of your family and for your friendship and continual support and encouragement. I could not have done it without you.

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CHAPTER 1

Literature Review

Locally Grown Food: A Food Safety Review of Farmers' Markets

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ABSTRACT

Farmers' markets are a key food outlet associated with the local food movement. In the United States, the number of registered farmers' markets has almost tripled since 1994. There have been several outbreaks associated with produce purchased from farmers' markets. Many direct farmers and food producers are exempt from the food safety regulations within the Food Safety Modernization Act (FSMA). Because farmers' markets are more loosely regulated than permanent food service operations, there are gaps in training requirements and oversight; there may also be increased opportunities for food to become contaminated and/or pathogen growth in these temporary establishment settings. The purpose of this article is to give a detailed overview of current literature regarding farmers' market food safety practices/behaviors, the microbial quality of farmers' market products, and food safety training options for farmers' market managers and vendors.

INTRODUCTION

Farmers' markets provide a venue in which consumers can develop personal relationships with farmers that grow their food and gain better understanding of how their food is produced (Smithers *et al.*, 2008). The markets are a venue for patrons to interact with local farmers/food producers and connect with other members of the community. These venues are positioned in locations where immediate and direct business can occur between farmers and patrons (Smithers *et al.*, 2008).

In previous literature, definitions of what constitutes a farmers' market have varied based on location and regulations. Some define farmers' markets as recurring food markets where farmers and producers bring their produce for sale direct to the public (Bullock *et al.*, 2000; Brown, 2002; Smithers, *et al.*, 2008). Burns and Johnson (1996) defined farmers' markets as a common facility or area where multiple farmers and growers gather on a regular, recurring basis to sell a variety of fresh fruit and vegetables and other farm products directly to consumers. The United States Department of Agriculture (USDA) defines a farmers' market as a common area where several farmers gather on a recurring basis to sell fresh produce and other farm products directly to consumers (USDA, 2015).

Farmers' markets are more loosely regulated than permanent food service operations, creating gaps in training and oversight. Due to the lack of regulations, there may be increased opportunities for foodborne illness outbreaks from these temporary establishments (Seo and Behnke, 2011). The rise in popularity of farmers' markets is accompanied by a parallel rise in concerns about how best to keep local consumers safe from the same pathogens responsible for nationwide outbreaks of commercially produced foods.

The growth of farmers' markets

In 1976, Public Law 94-463, Farmer-to-Consumer Direct Marketing Act of 1976 was passed which helped provide farmers with more direct support and allowed them to grow (Brown, 2002). This public law allowed county extension agents to work with farmers and local activists to organize farmers' markets by making direct marketing a legitimate activity of Cooperative Extension Service (Brown, 2002). Farmers' markets in the United States developed at a rapid pace after its passage from about 340 in 1970 to over 3,000 in 2001 and over 8,000 in 2015 (Brown, 2002; USDA, 2015).

In 1993, due to the growth and increased popularity of farmers' markets, the Wholesale and Alternative Markets Program of USDA's Agricultural Marketing Service began to assemble a comprehensive list of America's retail farmers' markets every year. In 2015, there were 8,476 registered farmers' markets in the United States (USDA, 2015). Markets have grown mainly due to changing consumer interest and the changing economies of agriculture (Brown, 2002). The popularity of local farmers' markets has been so rapid a recent national survey reports that 2% of U.S. food shoppers say farmers' markets are their primary food-shopping venue (Tropp et al., 2008). The USDA ERS reports that small farms rely heavily on direct-to-consumer channels to sell their goods, with 73% of direct sales of food coming from small and medium-sized farms (Low & Vogel, 2011). However, as of 2007, in the United States, direct-to-consumer sales are still only 0.4% of total agricultural sales, but still a rise from 10 years prior when it was 0.3% (Martinez et al., 2010).

The farmers who sell at farmers' markets do so because it is the most suitable market for their scale of production (Andreatta & Wickliffe, 2002; Brown, 2002; Bullock et al., 2000;

Smithers et al., 2008). Farmers and vendors are able to receive their income immediately as opposed to the lengthier returns of the industrial food system (Andreatta & Wickliffe, 2002). They are able to sell directly to consumers allowing for a decrease in marketing costs, such as insurance and advertising that farmers would face in a large production venue (Andreatta & Wickliffe, 2002). Farmers utilize centrally located farmers' markets to sell their products to patrons and encourage their return to a market (Andreatta & Wickliffe, 2002). As patrons continue to increase their willingness to visit different food retail venues in search of specialty food products, farmers selling at farmers' markets can continue to depend on the farmers' market sector (Tropp *et al.*, 2008).

Public/consumer opinion of farmers' markets

Incentive for purchasing food from farmers' markets. Abel *et al.* (1999) reported that freshness of produce is the number one reason patrons shop at and purchase product at farmers' markets in the United States. Other perceived benefits related to purchasing and consuming locally produced food are environmental, social, economic, personal health, food security, and food safety (Pearson *et al.*, 2011). Environmental benefits may be created through adopting more sustainable production systems that reduce transportation distance, minimizing the carbon footprint of the supply chain (Pearson *et al.*, 2011). However, some life cycle analyses have suggested the carbon footprint from some local foods is higher than the industrially-produced alternative because they do not benefit from mass production and transportation (Edwards-Jones *et al.*, 2009). Perceived social benefits of adopting local food systems and farmers' markets is a greater trust and connectedness that can be developed between and within consumer and farmers (Pearson *et al.*, 2011; Pretty, 2001). The economic benefits of purchasing local foods at farmers' markets can include contributing to the local economy by giving revenue to local farmers and

businesses at the market which can also contribute to adding employment in the local community (Pearson *et al.*, 2011). Furthermore, perceived personal health benefits of purchasing food from farmers' markets may include the increase in diversity of the food system. Consumers may also believe that local food purchased from farmers' markets provide food security for their community (Pearson *et al.*, 2011).

The aforementioned benefits and attributes are similar to reported reasons for specifically shopping at local farmers' markets: high food quality (freshness, appearance, and taste), supporting local agriculture, social appeal, an enjoyable atmosphere, organic chemical- and pesticide-free foods, and food safety (Abel *et al.*, 1999; Byker *et al.*, 2012; Chang *et al.*, 2011). Surveys of UK patrons (n=48) revealed that farmers' market patrons purchase based on trust, quality, and morality, tied in to the notion of "localness" (Holloway and Kneafsey, 2000).

The increase in patrons buying locally-grown foods has also been attributed to concerns about the local and national economies as a result of the 2008 recession and a rapidly expanding promotional effort by local food producers and merchandizers. Price and convenience are only important to some consumers, likely due to differences in the features of each market (Byker *et al.*, 2012).

Perception of risk associated with purchasing locally grown food from farmers' markets. Patrons perceive less risk when buying food products directly from farmers because they feel that they are making an informed decision (Smithers *et al.*, 2008) or that the farmers have a stake in the community (Green *et al.*, 2003). Within the local food movement, it is perceived that locally sourced produce grown on a small-scale farm is inherently safer and carries less risk than commercially grown products (Smithers *et al.*, 2008). In the conventional

food market, fresh produce travels an estimated 1,500 miles before consumption by consumers (Pirog *et al.*, 2001). Consumer perception of the current agricultural and food system has led to dissatisfaction with the globalized nature and increased support for a more localized food system (Andreatta & Wickliffe, 2002). However, regardless of scale, the same risks apply to how fresh produce is grown and handled. More Americans feel that food from local and regional sources were safe (74% and 73%, respectively) compared to national (56%) and global (15%) sources (Pirog & Rasmussen, 2008). Considering the increasing popularity of farmers' markets and the increasing number of produce outbreaks, a focus on safety of food products sold at farmers' markets can protect farmers, patrons, and local economies (Otto and Varner, 2005).

An early ethnographic account of a Midwestern urban farmers' market included no mention of food safety (McGrath *et al.*, 1993). However, more recent literature shows consumers do consider food safety when purchasing food at farmers' markets. It was found that food safety was a motive behind purchasing foods at farmers' markets in a study conducted in Maine in 2007 as well as Michigan consumers in 2009 (Conner *et al.*, 2010; Hunt, 2007; Kezis *et al.*, 1998). Additionally, nearly 50% of individuals (n=1,052) who participated in a web-based survey indicated that locally-grown foods were superior to other foods in terms of food safety, as well as quality and freshness (Onozaka *et al.*, 2010). Farmers' market consumers in Arkansas believed that organic foods were safer than the conventional items, but "fewer harmful bacteria" was the least motivating factor when compared to better taste, nutritional quality, and environmental friendliness (Rainey *et al.*, 2011, p. 148). In 2011, researchers at the University of Arkansas conducted a survey with 305 consumers regarding their belief system on farmers' market foods (Crandall *et al.*, 2011). They found that few respondents (2-6%) were concerned about "harmful bacteria" in their food, regardless of education projects and media outreach.

Lastly, the statement “Recent events have made me very concerned about the safety of the food I eat” was repeatedly chosen in a survey of both farmers’ market shoppers and non-shoppers (n=336) in San Luis Obispo, California, but it lacked statistical significance and was not determined to be a critical attribute.

Regulations associated with farmers’ markets

The regulations set for farmers' market vendors to sell food products at a farmers' market are different for each state, differing even between counties within states, and sometimes between each market. Given the wide variety of types of food products (from meat and fish to jams and cheeses to fruits and vegetables) sold in the markets, it can be difficult to understand which government entity’s food guidelines are supposed to be followed as the type of food often determines the regulatory agency. According to the 2006 USDA National Farmers’ Market Manager Survey, over two thirds of managers report that their market rules and bylaws were created by either the market manager or a vendor-operated board of directors (Tropp, 2008). Government is less involved, with 14% of managers reporting state government regulation and only 20% reporting city, county, or municipal government’s regulation (Tropp, 2008). States vary drastically in terms of rules and regulations in place for farmers' market operations and vendors. Regulations vary, for example, related to which entity (State Health Department or Department of Agriculture) is the primary regulator at markets. For example, if a food product is processed or prepared at the market, the vendor falls under jurisdiction of the Department of Health and Human Services Division of Public Health due to food service retail requirements; but farmers or producers that process at home and bring product to the market fall under the jurisdiction of the State Department of Agriculture and Consumer Services. Within each state, each farmers' market may provide extra guidelines specific for the individual market. Guidelines

can include information on production location, product diversity, farm visits, management, inspection, and fees.

Federal regulations pertaining to farmers' markets. There are a few federal regulations that apply to farmers' markets. Prepared foods and meats fall under similar guidelines in that they are considered processed previous to market sales, rather than raw agricultural commodities. The kitchens where foods are prepared must be inspected, as per 21 CFR Part 110, prior to sale of the goods in the markets (U.S. GPO, 2011). This particular part of the Administrative Code not only sets the regulations for the kitchens, but also for the specificities for high-sugar foods (jams, jellies) but also for the low-acid canned foods (soups, beans). Low-acid canned foods are illegal to be sold in farmers' markets across the United States due to risk associated with botulism toxin production, however acidified foods (pickles, chutney) are permitted under 21 CFR Parts 108 and 114. Only low-risk packaged foods (baked goods, pickles, jams) can be manufactured in a home kitchen; the kitchen must still pass the Home Processing Inspection of the State Department of Agriculture and Consumer Services.

Under the Current Good Manufacturing Practices (CGMPs) of the 21 CFR Part 110, agencies are expected make unannounced inspections to check on potential food safety violations in facilities, including goods produced in a home (U.S. GOP, 2011). The aforementioned "raw agricultural commodities" must be cleaned and prepared prior to arrival in the market (i.e., washed, bagged, and trimmed), as per 21 CFR Part 110. Federal law also deals with sanitation of facilities and cleanliness of personnel, but it is up to the state (and farmers' market by-laws) to specify the level of precaution that must be taken previous to sale.

Food Safety Modernization Act. The FDA Food Safety Modernization Act (FSMA) was signed into law January 2011, shifting the agency's focus from foodborne illness reaction measures to prevention measures. To date, two final rules have been published as a result of FSMA, including, 1) Preventive Controls for Human Food, and 2) Preventive Controls for Animal Food (FDA, 2015). While these new rules outline more rigorous food safety requirements, farmers' markets may be considered a retail food establishment and are exempt from the preventive controls rules. To further support the implementation of FSMA, the FDA is in the process of finalizing two more rules that may affect farmers' markets, including Produce Safety and Sanitary Transportation,. The proposed produce safety rule addresses key areas such as agricultural water quality and testing standards, manure-use procedures, and worker training and health and hygiene requirements. However, farms or "farm mixed-type" facilities with an average annual monetary value of produce sales of \$25,000 or less will be exempt from the rule. Depending on the size of the vendors' operation, it is likely that many farmers' market vendors will be exempt from this produce safety rule, but they will be required to provide documentation of completion of food safety training/education. The FDA, together with Cornell University and USDA AMS has established a jointly funded Produce Safety Alliance that will develop and disseminate science- and risk-based training and education programs to provide produce farms with fundamental food safety knowledge (FDA, 2015). It is likely that training created through this alliance may suffice for fulfilling the training requirements of exempt businesses. Businesses that acquire greater than \$25,000 but less than \$250,000 in annual produce sales will have four years to comply after final rule publication. Furthermore, the publication of the sanitary transportation rule has a deadline of March 31, 2016. The sanitary transportation rule will establish food safety requirements for vehicles and transportation equipment, transportation

operations, sanitary transportation training, record keeping, and information exchange requirements to include knowledge of prior cargo to prevent cross contamination. All shippers, receivers, or carriers engaged in food transportation operations that have less than \$500,000 in total annual sales will be exempt from the sanitary transportation rule. With this exemption, again, depending on the size of the vendors' operation, it is likely that many farmers' market vendors will be exempt from this sanitary transportation rule. Farmers' markets do not apply to the scope of the remaining food safety rules.

Farmers' market vendor food safety knowledge

Gaps in the breadth of knowledge that market vendors have related to food safety. Additionally, poor food safety has been documented, but the research is limited. Surveys have been conducted in Wales, United Kingdom and in four states within the United States (Florida, Virginia, Georgia and South Carolina). Worsfold and colleagues (2004) studied food handler hygiene and safety behaviors at farmers' markets in southeast Wales by asking farmers' market vendors (n=50) to self-report behavior, interviewing patrons, and observing the quality/quantity of facilities available at farmers' markets. The questionnaire asked vendors about product range, outline of production process, hygiene training, perceptions of hygiene standards, perception of risk, perceptions of risk management/Hazard Analysis and Critical Control Points (HACCP), food safety guidance, monitoring and inspection. Even though the vendors had training in food safety, they rated their hygiene standards highly; yet, few had any food safety risk management procedures in place (Worsfold *et al*, 2004).

Self-completed surveys of 47 farmers' market vendors across two farmers' markets in Florida were collected as part of a study to better understand the need and areas for educational development (Simonne et al., 2006). The survey focused on certain key areas, including: type of

product sold at farmers' markets, source of food safety information, perception of importance of food safety issues and training for farm operator/vendor. Even though only 32% of the vendors had received food safety training, more than 50% of the vendors self-identified as very confident about their food safety practices (Simonne *et al.*, 2006). Another survey assessing food safety knowledge of 21 farmers' market vendors and managers was conducted in British Columbia, Canada. It was found that neither experience, geographic location, nor food safety training affected the scores of the knowledge assessment (McIntyre *et al.*, 2014). Few vendors and market managers were able to identify and assess potentially hazardous foods.

Another survey evaluated food safety practices used by farmers on small to medium-sized farms as well as managers of farmers' markets in Georgia, Virginia, and South Carolina. Data was collected from 226 farmers and 45 market managers. Over 42% of market managers had no food safety standards in place for the market. Only 2 to 11% ask farmers specific questions about conditions on the farm that could affect product safety. Moreover, less than 25% of managers sanitized market surfaces and only 11% always cleaned market containers between uses. Over 75% of markets did not offer a sanitation training to workers or vendors. These results indicate that some practices may put consumers at risk of foodborne illness and there is a need for training for both farmers and market managers (Harrison *et al.*, 2013).

Farmers' market vendor food safety behavior and practices

Although vendors self-reported having food safety knowledge and following good food handling practices, observed food safety behaviors do not always reflect the self-reported results. Smartphone technology was used to record direct observations of food safety practices at an Indiana farmers' market (Behnke *et al.*, 2012). Eighteen employees engaging in 900 sequential food-handling transactions revealed that safe food handling practices were

infrequently performed, which could lead to an increased risk of foodborne illness (Behnke et al., 2012). The greater the number of simultaneous work roles an employee is engaged in associated with a greater number of violations. However, adding more food handlers to a booth did not ensure that work roles were properly segregated. Having numerous employees in the operation does not ensure that they have clearly separated roles or that they engage in correct food safety behaviors. This study demonstrates the importance of clearly defined work roles for employees and education to improve understanding of cross contamination to improving food safety at farmers' markets (Behnke et al., 2012).

Choi and Almanza (2012) compared health inspection scores and violations from farmers' markets and other temporary food service establishment and compared them to restaurants. They compared 29 farmers' markets to 120 full-service restaurants. Farmers' markets had significantly fewer average numbers of food safety violations than full-service independent restaurants (Choi & Almanza, 2012). However, permanent food service establishments have longer inspections and more categories to inspect and, therefore, a greater potential for violations (Choi & Almanza, 2012). Repeat violations were not considered, which could be an important indicator of the enforcement of food safety practices (Choi & Almanza, 2012).

Observational data collection methods have identified temperature abuse and poor hygiene at farmers' markets in Ontario. Specifically, one market observed found that 47 % of the observed vendors did not have adequate refrigeration resulting in cheese storage in temperatures exceeding 41 °F (Teng *et al.*, 2004). Additionally, vendors from markets in British Columbia were selling products including eggs, frozen fish and baked goods with whipped

cream topping without adequate refrigeration (McIntyre *et al.*, 2014). Multiple studies reported poor food handler hygiene practices associated with an overall lack of hand-washing facilities at the markets (Behnke *et al.*, 2012; McIntyre *et al.*, 2014). The results of these studies highlight the lack of infrastructure at farmers' markets, creating an environment that has limited access to tools needed to practice proper hygiene and sanitation.

Microbial analysis of farmers' market products

Regardless of food outlet or supply chain scope, microorganisms can contaminate foods, and improper handling can lead to increased population of pathogens, which may result in a foodborne illness. Fresh fruits and vegetables, meat and dairy products, including those sold at farmers' markets, can be the source of foodborne illness. Major foodborne pathogenic bacteria of concern include *Shigella*, *Salmonella*, *Escherichia coli*, *Campylobacter*, *Listeria monocytogenes*, and *Giardia*, as well as the spore-forming pathogenic bacteria, *Clostridium botulinum* (Beuchat, 1996).

A limited number of microbiological surveys have been conducted with food commodities from farmers' markets. In 1992, 1,564 fresh samples of 10 vegetable types were tested for thermotolerant *Campylobacter*. Of the 1,564 vegetable samples, 533 samples were collected from an outdoor farmers' market and 1,031 samples were collected from a supermarket (Park *et al.*, 1992). While *Campylobacter* was not detected on the supermarket vegetable samples, it was detected on six types of vegetables from the outdoor farmers' market. The *Campylobacter* species present on the farmers' market samples were identified as *Campylobacter jejuni* (88%), *C. lari* (8%), and *C. coli* (4%). Vegetable samples that tested positive were spinach (3.3%), lettuce (3.1%), radishes (2.7%), green onions (2.5%), parsley

(2.4%), and potatoes (1.6%). Results from this study suggest that produce sold at farmers' markets may be produced and/or stored under less sanitary conditions than those sold at retail markets (Park *et al.*, 1992). Another study in 2007, analyzed samples of lettuce, spinach, tomatoes, carrots, green onions, and strawberries from 36 farmers' and public markets in two urban centers in Alberta, Canada. The produce samples were tested for the presence of *Salmonella*, *E. coli* O157:H7, and *Campylobacter*. While generic *E. coli* was isolated from 8.2% (55 of 673) of the samples (lettuce, carrots, green onions), the target pathogenic bacteria were not isolated from any samples. These results are similar to microbiological analyses of retail produce, suggesting that there is no difference in the safety of farmers' market produce and retail produce (Bohaychuk *et al.*, 2009). Additionally, green, red, and romaine lettuce from five regional farmers' markets in British Columbia were obtained from 14 vendors and tested for *E. coli* in the summer of 2012. Phylogroup indicators suggestive of fecal contamination were found in two of the produce groups, but the researchers were unable to identify where in the supply chain contamination occurred (Wood *et al.*, 2015).

Scheinberg *et al.* (2013) compared the prevalence of *Campylobacter* and *Salmonella* on whole chickens from supermarkets and farmers' markets. *Salmonella* was isolated from 28 out of 100 (28%) and *Campylobacter* was isolated from 90 out of 100 (90%) whole bird products obtained from farmers' markets (Scheinberg *et al.*, 2013). While, organic chicken (bearing the USDA certified organic label) obtained from supermarkets tested positive for *Campylobacter* and *Salmonella* in 10 out of 50 (20%) and 14 out of 50 (28%) samples, respectively. In comparison, conventionally-raised (no organic certification) chicken tested positive for *Campylobacter* and *Salmonella* in 4 out of 50 (8%) and 26 out of 50 (52%) of samples, respectively. In addition to microbial analysis, a needs-assessment was conducted to assess

knowledge and attitudes of poultry vendors. Twenty out of 21 (95%) vendors who participated in the survey believed poultry products sold through the farmers' market sector were safer than products sold through commercial shopping centers (Scheinberg et al., 2013).

Foodborne illness outbreaks linked to farmers' markets

The U.S. Centers for Disease Control and Prevention (CDC) estimates that each year approximately one in six Americans get sick, 128,000 are hospitalized, and 3,000 die from foodborne illness (Scallan *et al.*, 2011). Between 1998 and 2008, more illnesses were attributed to leafy greens than any other commodity with greater than two million illnesses between those years (Painter, 2013).

While food safety concerns can be a reason consumers choose to shop in a farmers' market (Dodds et al., 2014; Feagan et al., 2004), foods produced on a small scale still face the same risks as foods produced on an industrial scale (French *et al.*, 2011). Instances of foodborne outbreaks caused by products sold at farmers' markets are explained in the following sections, with key details summarized in Table 1.

***Escherichia coli* O157:H7 outbreak associated with Oregon-produced strawberries (2011).** In mid-July of 2011, the Oregon Health Department started receiving reports of a foodborne illness outbreak. Fifteen individuals became ill between July 10th and July 29th (Office of the Commissioner, 2011). Four individuals were hospitalized, two people suffered kidney failure, and one elderly woman died due to kidney failure, a complication associated with severe symptoms of *E. coli* O157:H7. Through interviews with those who had become sick, the Health Department was able to establish a connection between the *E. coli* O157:H7 cases and consumption of strawberries purchased through multiple farmstands (Office of the

Commissioner, 2011). Early in the investigation, officials encouraged patrons to avoid eating strawberries from any farmers' markets in an attempt to reduce further illnesses (Office of the Commissioner, 2011). This caused major profit losses for vendors selling strawberries and other vendors in the farmers' markets of Oregon. However, it was quickly determined that each farmstand had purchased strawberries from Jaquith Strawberry Farm and resold to patrons (Oregon Health Authority, 2011).

Upon investigation of Jaquith Strawberry Farm, 10 % of the environmental samples collected tested positive for *E. coli* O157:H7. The outbreak strain was found in samples from fields in three separate locations. Strawberries from Jaquith Strawberry Farm were confirmed as the vehicle of contamination through laboratory testing procedures. *E. coli* O157:H7, matching the human isolates was later isolated from deer feces found in the vicinity of the strawberry fields. Deer were suspected to be the source of contamination (Produce Traceability News, 2011; Oregon Health Authority, 2011).

***Salmonella enterica* serovar Newport Outbreak in Iowa guacamole (2010).** In the summer of 2010, 44 cases of *Salmonella* Newport were linked to products sold at two Iowa farmers' markets (Iowa Department of Public Health, 2010). Through epidemiological interview questionnaires and laboratory testing of implicated food products, it was determined that guacamole-based products produced by La Reyna Supermarket & Taqueria were identified as the vehicle of contamination. The restaurant sold guacamole and red and green salsa, along with pork, chicken, and vegetable tamales, at the Iowa farmers' markets.

According to Iowa health officials, Linn County Public Health inspected the restaurant stand at the farmers' market during the time period the contaminated guacamole-based products

were being sold. The health officials found that some of the ice used for cooling the guacamole products was melted, increasing the risk for temperature abuse of the products. Officials identified risky food safety factors that could contribute to contamination including lack of proper sanitation practices, cross-contamination opportunities, and improper washing of avocados at the restaurant during preparation. Additionally, improper holding temperatures at the market could contribute to bacterial proliferation as the temperature for that day was above 80°F, which is an optimal growth temperature for *Salmonella*. (Iowa Department of Public Health, 2010).

***E. coli* O157:H7 Outbreak in Alberta unpasteurized Gouda cheese (2002).** In 2002, thirteen individuals were infected by *E. coli* O157:H7 in Edmonton, Alberta, Canada, resulting in illnesses and two cases of hemolytic uremic syndrome (Honish et al., 2005). The illnesses were traced back to unpasteurized Gouda cheese from a local dairy, with the human isolate and cheese isolate matching by pulsed field gel electrophoresis (PFGE) pattern (Honish et al., 2005). The implicated cheese was found to be contaminated with *E. coli* O157:H7 104 days after production, despite having met regulated microbiological and aging requirements. Of the 13 individuals who became ill, five purchased the cheese at a local farmers' market, two received the cheese as a gift, and one purchased the cheese directly from the dairy (Honish et al., 2005). While the food products were sold by a small number of vendors, multiple people consumed the product, potentially exposing a relatively large number of people to unsafe product.

***E. coli* O157:H7 Outbreak in Colorado produce samples, 2000.** In September of 2000, an outbreak of *E. coli* O157:H7 was linked to produce samples offered at a Fort Collins, Colorado farmers' market. Factors that could have led to this outbreak include lack of hygiene and sanitation by a food handler, cross- contamination, and temperature abuse during storage.

The outbreak involved 14 people including two elementary school-aged children who required dialysis. Further information on the outbreak is not readily available but the outbreak initiated the production of a brochure focusing on safe food samples at farmers' markets (Colorado Department of Public Health and Environment, 2000; Bridges, 2000). Further information on the outbreak is not readily available.

***S. enterica* outbreak in Ontario, Canada soft cheese, 1994.** In September of 1994, a woman notified the Waterloo Regional Community Health Department after her and her aunt consumed a soft, spreadable breakfast cheese at a local farmers' market and became ill (Ellis et al., 1998). The two ladies suffered symptoms including diarrhea and thought that the source of contamination may have been the cheese product. One of the women received medical attention and *Salmonella* Berta was identified through the culture of her stool sample (Ellis et al., 1998).

The implicated cheese product tested positive for *S. Berta* and *E. coli* (Ellis et al., 1998). The cheese was produced at a licensed local dairy facility using unpasteurized milk in an unregulated manner (Ellis et al., 1998). The skim milk curds were stored at room temperature for 2-3 days without extensive temperature monitoring (Ellis et al., 1998). The farmers used the same buckets used for ripening the cheese to soak raw chicken carcasses and it was likely that the buckets were not disinfected properly prior to the cheese production. The farmers disclosed that two of them had become sick, as did another family member (Ellis et al., 1998). The potential for cross-contamination and improper handwashing and hygiene practices were also identified as potential risk factors. Through investigations, 82 cases of *S. Berta* (35 confirmed, 44 suspected, 3 secondary) were associated with this particular outbreak (Ellis et al., 1998).

It is possible that the lack of inspections or institutional evaluation of the vendors allows for the failure to follow the regulations and even market-designed by-laws. The lack of enforcement of proper food safety practices and behaviors could contribute to foodborne illness outbreaks originated from temporary food service establishments, such as farmers' markets. These outbreaks are examples of contamination issues that can occur in small-scale farming affecting many farmers' markets. Small-scale growers must also implement proper food safety behaviors and practices to ensure risk reduction actions are performed on the farm to help reduce contamination likelihood.

Risk management and food safety training for farmers' markets

Food safety risk analyses can help identify potential contamination opportunities in a farmers' market setting. Food safety training geared towards farmers' markets can help market managers and vendors better identify and address the food safety risks present at a farmers' market. A study conducted by Park *et al.*, (2010) evaluated a food safety training method for food handlers in restaurant operations. In this study, employees were given a questionnaire for food safety knowledge and an on-site observational inspection was performed before and after the training was administered. Food safety knowledge showed a significant improvement after the training; however, food safety practices and sanitation performance remained unchanged. Another food safety training utilizing theoretical and practical (hands-on) approaches for training was evaluated based on microbiological counts of food contact surfaces, food tools, food equipment surfaces and hand washing in canteens and cafes of one university campus. Microbial counts were significantly decreased after training was implemented. The researchers associated the success of the food safety training to the use of combined theoretical and practical (hands-on)

training (Soares *et al.*, 2013). However it is important to note that this study was conducted in a setting more controlled than an outdoor market.

Food safety info-sheets as a communication tool were found to increase numbers of hand-washing attempts, and significantly reduce indirect cross-contamination events when used for eight food service operations (Chapman *et al.*, 2010). Previous research indicates that the most influential food safety training programs utilizes a combination of theoretical, practical (hands-on), and info-sheets as teaching tools to influence positive behavior change (Soares *et al.*, 2013).

Some barriers can be identified through risk analysis, including those defined by Chapman and colleagues (2005). The process of risk analysis consists of risk assessment, risk management, and risk communication with research involved at every step (Martin, 2007). Risk assessment is made up of four main components: hazard identification; characterization of any adverse effects associated with biological, chemical, and physical agents; evaluation of the degree of risk likely to occur; and risk characterization. The use of risk management to produce a food safety plan for farmers' markets can help with reducing the potential risk of foodborne illness but must also be communicated to patrons and have documentation as well as practices to support these efforts (Powell *et al.*, 2001).

In a review of risk communication research and its applicability for managing food-related risks, Soby and colleagues (1993) developed the concept of the risk management cycle. In this model, public and other stakeholder concerns are actively sought at each stage of the management process. In 1997, this idea was further converted into an integrative framework to help risk managers such as government officials, private sector businesses, and individual

members of the public to make good risk management decisions. Risk analysis and risk communication can be a useful tool to aid in reducing risky food safety behaviors and practices at farmers' markets.

Conclusion

Although there is a perception that locally grown food is inherently safer; generally, locally grown food, including those sold at farmers' markets, is not more or less safe than commercially produced products. There is a need for food safety training tailored for farmers' markets to positively influence food safety behaviors and mitigate contamination. Past foodborne illness outbreaks originating from farmers' markets should be reviewed to prevent repeating the same food safety mistakes in the future.

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CHAPTER 2

Identification of Risky Food Safety Practices at Southwest Virginia Farmers' Markets

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ABSTRACT

There have been multiple outbreaks associated with food purchased from farmers' markets. Many farmers' markets do not have an established food safety plan to promote proper food safety practices. The purpose of this study was to identify risky food safety practices at Southwest Virginia farmers' markets using an observational data collection method. Three of the observed market vendors and market managers received food safety training in comparison, vendors and market managers were observed at two markets where food safety training was not implemented. While market managers and vendors in three of the five markets observed had formal food safety training, numerous risky food safety behaviors were still observed including temperature abuse, cross contamination opportunities, and poor personal hygiene and sanitation. The results of this study highlight the need for food safety interventions at farmers' markets.

INTRODUCTION

According to United States Department of Agriculture Economic Research Service (USDA ERS), direct-to-consumer marketing of foods increased to \$1.2 billion in sales in 2008, compared to \$551 million in 1997 (20). Farmers' markets are a growing sector among the direct-to-consumer outlets for foods. The number of farmers' markets in the U.S. has increased significantly over the last decade, from 3,706 in 2004 to 8,268 in 2014 (38). The increase in farmers' markets and popularity of buying local foods represent consumers' demand for the services and products that farmers' markets provide (1).

Farmers' markets offer a unique opportunity for growers to sell agricultural products directly to the consumer, often with higher profit margins (13). However, these products are not without risk of being contaminated with foodborne pathogens. A foodborne outbreak caused from consumption of food purchased at a farmer's market could quickly bankrupt the alleged vendor as the average monetary award to a plaintiff who was hospitalized from a foodborne illness was \$141,199 in 1998 (5). It is likely that the monetary award would be much higher today.

Of the commodities sold at the markets, fresh produce constitutes 82 % of the total foods for sale (1). Produce accounted for 46 % of the 4,589 foodborne illness outbreaks linked to a specific commodity between 1998 and 2008 (6, 24). More illnesses were attributed to leafy greens than any other commodity with greater than two million illnesses between 1998 and 2008 (24). The growing number of produce-related foodborne outbreaks coupled with the growing number of farmers' markets selling fresh produce highlights the need for a food safety focus within these markets to protect farmers, patrons and local economies (23).

There is a perception within the local food movement that locally grown produce is safer and carries less risk than products grown elsewhere, as it does not travel long distances or come from a large industrial-sized farm (26, 31). However, regardless of scale, fresh produce hazards and risks are similar. Foodborne illness outbreaks have been linked to traditional local food systems including roadside stands and farmers' markets (4, 8, 11, 16, 22).

There are many risk factors that increase the likelihood of contamination at a farmers' market. Cut produce increases risk of contamination by creating wounds that allow for harmful bacteria to enter internal tissues and grow (33). Additionally, produce sold in outdoor markets can be handled and stored with less control over sanitation, worker hygiene and temperature control when compared to supermarkets (31, 39).

The purpose of this study was to identify risky food safety behaviors practiced at Southwest Virginia farmers' markets through the use of a secret shopper system, and determine if there is a difference between those markets that have received food safety training and those that have not. The lack of formal food safety training of farmers' market vendors and market managers warrants investigation to identify risky food safety behaviors practiced at farmers' markets (29). Concealed direct observations of farmers' markets in the form of a secret shopper model can be used to observe vendors and market managers without their knowledge and help reduce the Hawthorne effect and thus gather more accurate observational behavioral data (2, 9, 14, 17). Concealed direct observations provide an accurate account of food safety behaviors practiced in a given time period by allowing researchers to capture behaviors directly rather than relying on self-reporting in which food handlers often overestimate the frequency in which proper food safety practices are applied (2, 9, 10, 17).

MATERIALS AND METHODS

Farmers' market site and vendor selection

Three farmers' market sites with market managers and vendors who have received food safety training and two markets with managers and vendors who have not received any training were selected for observational data collection in Southwest Virginia, using a convenience sample. Convenience samples were used due to the proximity of the farmers' markets and budget restraints. The USDA definition of a farmers' market was used to define a farmers' market unit: a multi-stall market at which farmer-producers sell agricultural products directly to the general public at a central or fixed location (37). Each vendor selling raw produce was observed. Two markets consisting of vendors who have had food safety training were visited three times and the remaining trained market was visited four times. One non-trained market was visited four times and the other non-trained market was visited twice. Due to time limitations, each produce vendor was observed for an average of 15 minutes each per visit with an average of two visits per vendor.

Food safety training

To address the food safety education needs of small growers, specifically farmers' market vendors, a two hour training based on Good Agricultural Practices (GAPs) principles was delivered through local extension agents. The audience for the training were farmers' market vendors selling produce and managers in their respective locations.

Development of observational instrument

The observational instrument used to identify risky food safety behaviors was modified from Smathers and colleagues (30). An advisory committee with multiple food safety experts

from Virginia Tech and North Carolina State University helped to define specific risky food safety behaviors targeted for observation in this study. The instrument was designed to focus on behaviors and infrastructure impacting three of the five U.S. Centers for Disease Control & Prevention (CDC) identified common risk factors for foodborne illness: (1) temperature abuse, (2) lack of hygiene and sanitation by food handlers and (3) cross contamination. The observational instrument addressed sixteen risky food safety behaviors associated with food handling (Table 1).

In addition to observation of food handling practices, markets were also observed for overall infrastructure that may contribute to risk, including the absence of a protective covering or tent, the presence of animals/pets, lack of access to electricity, lack of availability of trash receptacles, and the availability of public hand-washing stations with free-flowing water and soap (Table 1).

Observational instrument

The observational criteria were designed so that observations of the pre-determined risk factors could be recorded via a smartphone. The use of a smartphone application allowed for concealed data collection and reduction of the Hawthorne effect (2). The observational instrument was configured in the Qualtrics (Provo, UT; <http://www.qualtrics.com/>) smart phone application which was loaded on to an Android platform. The presence of each behavior or contributing infrastructure could be recorded using a multiple choice answer (yes, no, N/A) or an open-ended answer (text entry). Utilizing Qualtrics software permitted data collection using any smartphone.

Data collection

Observations of farmers' markets were performed between May and October 2014 at five Southwest Virginia farmers' markets which were selected based on location of the market (Southwest Virginia) and vendors food safety training history. Each individual vendor was observed for 15 minutes during each observational period with an average of two observational periods per vendor. Observations were recorded instantly with the smartphone app. Vendor and market anonymity was maintained via coding of data to prevent any connection of data to vendor or market. Observational data collection was approved by the Institutional Review Board of Virginia Tech (IRB 13-562).

Data analysis

Data analysis was performed using JMP Pro version 10.0.2 for Windows (Cary, NC; http://www.jmp.com/en_us/software/jmp-pro.html). Statistical analysis and significance testing were assessed using Chi-square tests or Fisher's Exact Test to compare risky food handling practices observed at farmers' markets who have received food safety training versus those who have not received any formal training. Fisher's Exact Test was utilized for sample sizes less than five as the Chi-square test is less reliable for smaller sample sizes. Fisher's Exact Test was utilized to compute statistics associated with offering samples. P value ≤ 0.05 was considered significant.

RESULTS

Farmers' market demographics

Forty-two produce vendors were observed across five Southwest Virginia farmers' markets during the months of May through October 2014. Vendors were observed from three

markets that have received training delivered through Virginia Cooperative Extension (VCE; n=32) and from two markets that did not receive any food safety training and have no current relationship with VCE (n=10 vendors). All vendors observed sold one or more of the following produce commodities: berries (blackberries, blueberries, and strawberries), cucumbers, herbs (basil, cilantro, parsley, sage, and thyme), cut and whole leafy greens (cabbage, chard, kale, and lettuce mixes), green onions, peppers (banana, green, jalapeño, serrano, and yellow), tomatoes, yellow squash, and zucchini.

Observed foodborne illness risk factors associated with temperature abuse

The foodborne illness risk factors observed associated with food handling at the market are shown in Tables 2 and 3. Of the 32 trained and ten non-trained vendors, 17 (53.1 %) and five (50 %) sold pre-cut produce, respectively. Of those, five (29.4 %) and two (40 %) used some form of temperature control. Methods of temperature control that were used included bags of ice placed at the bottom of produce containers and produce immersion within a pool of iced water as a form of temperature control to keep the pre-cut leafy greens at a lower temperature. No vendors were observed using a thermometer to monitor and record temperatures. Vendors offering samples were also observed practicing risky food safety behaviors. Of the 32 total trained vendors, four (12.5 %) offered samples. Three out of the four offered samples requiring temperature control for safety including cut tomatoes and mushrooms. Two of the three vendors (66.7 %) used bags of ice to lower the temperature of the environment surrounding the samples. However, there was no thermometer-use observed to monitor the temperature of samples offered and no temperature recording. None of the non-trained vendors were observed offering any samples.

Observed foodborne illness risk factors associated with cross contamination

Eight (25.0 %) of the trained and one (10.0 %) of the non-trained vendors had designated employees to handle monetary transactions and separate employees handling food sales to prevent cross contamination when handling money and food.

Most vendors (72.0 and 90.0 % trained and non-trained respectively) kept produce stored on display tables at least three feet off the ground, nine (28.1 %) trained vendors and one (10.0 %) non-trained vendor stored produce at ground-level in open cardboard boxes. Twelve (37.5 %) trained and four (40.0 %) non-trained vendors were observed using a table to display food products that was porous, such as wood, and could not be easily cleaned. Similarly, 15 (46.9 %) trained and four (40.0 %) non-trained vendors were observed using produce bins that could not be easily cleaned such as wooden baskets and cardboard boxes.

Observed Foodborne illness risk factors associated with poor personal hygiene

None of the vendors (n=42) had a hand-washing station, were observed using gloves, or had hand sanitizer present at their stall. One (33.3 %) trained (n=3) and one (50.0 %) non-trained (n=2) market provided a proper hand-washing station including running water, soap and paper towels. The hand-washing station at the trained market was located in a bathroom facility on the outer perimeter of the markets. The hand-washing station at the non-trained market was a stand-alone station located outside of a portable bathroom facility. Additionally, another trained market had a public hand-washing facility (not associated with the market) across the street from the market.

Chi squared and Fisher's Exact Tests revealed no significant differences in the amount of food safety risky behaviors observed between market managers and vendors who have had food safety training versus those who have not had any formal food safety training.

Food safety risk at market level

The food safety risk factors observed at the market level is shown in Table 4. While all vendors had protective covering, two (66.7%) and one (50.0%) of trained and non-trained markets, respectively, provided permanent covering for vendors. Vendors who were not provided with permanent covering brought their own temporary covering in the form of a portable tent. All three of the trained markets (100.0%) and one (50.0%) of the non-trained markets allowed pets at the market and vendors and patrons were observed with pets. Only one (33.3%) of the trained markets had access to electricity, which allowed vendors to utilize a miniature refrigerator for storage of temperature-sensitive products such as milk. One (33.3%) of trained and one (50.0 %) of non-trained markets had trash receptacles present for vendors and patrons to dispose of trash, which could potentially serve as a contamination source.

Although vendors and market managers in three of the five farmers' markets observed in this study have had food safety training, numerous risky food safety behaviors were observed. Vendors were observed lacking temperature control of pre-cut produce, creating opportunities for cross contamination and demonstrating a lack of proper hygiene and sanitation practices. These findings are not uncommon among other observational studies of food safety practices at farmers' markets and other food service venues. The lack of facilities and infrastructure at a farmers' market compared to retail grocery stores creates opportunities for preventable hygiene and food contamination concerns (2, 9, 15, 17, 21, 28, 34).

DISCUSSION

Foodborne illness risk factors associated with temperature abuse

Temperature abuse can allow harmful bacteria to proliferate, contributing to foodborne illness (3). In this study temperature abuse was observed in 68.2 % of vendors when cut

produce was not kept in a temperature controlled environment. FDA food code identifies cut leafy greens, cut melons and cut tomatoes as needing temperature control because these foods are capable of supporting the growth of various infectious microorganisms or toxins (12).

Previous studies have highlighted the effects of temperature abuse, reporting a 2.0 log CFU/g increase in *E. coli* O157:H7 populations on lettuce when held at 12°C for 3 days (18). It has also been proven that the growth of *E. coli* O157:H7 can outpace that of spoilage bacteria and the appearance of quality deterioration, resulting in unsafe product without visual aversion (19).

Similarly, temperature abuse of cheese products has been reported at farmers' markets, where 47 % of the observed vendors did not have adequate refrigeration resulting in cheese storage in temperatures exceeding 41°F (34). Temperature abuse has also been observed in farmers' markets in British Columbia when vendors selling products including eggs, frozen fish and baked goods with whipped cream topping did not use adequate refrigeration (21).

Foodborne illness risk factors associated with poor personal hygiene

Proper hand-washing practices can reduce the risk of foodborne illness and other infections (15). While two markets observed in this study provided a public hand-washing facility with soap and running water within the market for vendors and patrons, none of the vendors were observed practicing proper hand-washing during the observational period . Multiple studies reported poor food handler hygiene practices associated with an overall lack of hand-washing facilities at the markets (2, 21). The results of these studies highlight the lack of infrastructure at farmers' markets, creating an environment that has limited access to tools needed to practice proper hygiene and sanitation.

Foodborne illness risk factors associated with cross contamination

Paper money has the potential to be contaminated with bacteria. Heterotrophic aerobic bacteria (98.4 %), coliforms (87.3 %), and Staphylococci (79.4 %) were isolated from paper and polymer currency (27). McIntyre and colleagues reported 90.9 % of observed vendors handle money and food without practicing proper hand-washing (21). Another study observing 18 farmer's market vendors found that touching money without proper hand-washing was the most common unsanitary practice (2).

While the improper use of gloves can become a source of contamination for food handlers, proper glove use can substantially reduce opportunities for food contamination (36). Similarly, while proper hand-washing with soap and running water is the most effective method for removing potentially harmful bacteria from hands, hand sanitizer solutions offer an alternative option when hand-washing stations are not available, such as at a farmers' market (35). Although both proper glove-use and the use of hand sanitizer solutions have the potential to reduce bacterial populations when done properly, none of the vendors or market managers observed in this study used gloves or hand sanitizer.

Food safety training

Market managers and vendors in three of the five farmers' markets observed in this study have had food safety training. However, there were no significant differences observed between market manager and vendor practices that have had training compared to those who have not had any training. These results illustrate that food safety education and training does not necessarily correlate to behavior change.

A study conducted by Park *et al.*, (25) evaluated a food safety training method for food handlers in restaurant operations. In this study, employees were given a questionnaire for food safety knowledge and an on-site observational inspection was performed before and after the

training was administered. Food safety knowledge showed a significant improvement after the training; however, food safety practices and sanitation performance remained unchanged.

Another food safety training utilizing theoretical and practical (hands-on) approaches for training was evaluated based on microbiological counts of food contact surfaces, food tools, food equipment surfaces and hand washing in canteens and cafes of one university campus. It was found that microbial counts were significantly decreased after training was implemented. The researchers associated the success of the food safety training to the use of combined theoretical and practical (hands-on) training (32). However it is important to note that this study was conducted in a setting more controlled than an outdoor market.

Furthermore, Chapman and colleagues (7) utilized food safety infosheets as a communication tool to influence proper food safety behaviors. It was found through video observation that food handlers in eight food service operations demonstrated a significant increase in mean hand-washing attempts, and a significant reduction in indirect cross-contamination events. Previous research indicates that the most influential food safety training programs utilize theoretical, practical (hands-on), and infosheets as teaching tools to influence positive behavior change (32). Because there were no significant differences in food safety behaviors observed in this study between market managers and vendors who have had food safety training and those who have not had training, this highlights the need for the development of more food safety training programs specific for farmers' markets that utilize a diverse range of training tools.

CONCLUSIONS

The results of this study highlight the need for food safety interventions at farmers' markets. While market managers and vendors in three of the five markets observed have had

formal food safety training, numerous risky food safety behaviors were still observed. This study highlights the need for facility and infrastructure development to improve food safety behaviors as well as food safety training that utilizes various training tools to positively influence food safety behavior.

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TABLE 1. Observational instrument used to identify risky food safety behaviors practiced by markets and their produce vendors.

Observational Criteria
Sale of Pre-Cut Produce
Use of Temperature Control for Pre-Cut Produce
Use of Thermometer to Measure Temperature of Pre-Cut Produce
Temperature Recording of Pre-Cut Produce
Sale of Temperature-Sensitive Samples
Use of Temperature Control for Temperature-Sensitive Samples
Use of Thermometer to Measure Temperature of Temperature-Sensitive Samples
Temperature Recording of Temperature-Sensitive Samples
Access to Electricity*
Handling Money and Produce Without Proper Hand-Washing
Glove Use
Proper Glove Use
Product Storage on Ground
Can the Table be Easily Cleaned
Can Produce Bins be Easily Cleaned
Use of a Protective Covering
Are Animals Allowed in the Market*
Are Trash Receptacles Available*
Presence of Hand Sanitizer
Availability of a Hand-Washing Station at Vendor Site
Proper Hand-Washing
Availability of Hand-Washing Station in Another Location at the Market*

*Indicates an observation of the entire market infrastructure, not specific vendor.

TABLE 2. Percentage of observed risky food safety behaviors associated with food handling.

	Percentage of Vendors	
	Yes	No
Sale of Pre-Cut Produce	52.4	47.6
Use of Temperature Control for Pre-Cut Produce ^b	31.8	68.2
Use of Thermometer to Measure Temperature of Pre-Cut Produce ^b	0.0	100
Temperature Recording of Pre-Cut Produce ^b	0.0	100
Sale of Temperature-Sensitive Samples	7.1	92.9
Use of Temperature Control for Temperature-Sensitive Samples ^c	66.7	33.3
Use of Thermometer to Measure Temperature-Sensitive Samples ^c	0.0	100
Temperature Recording of Temperature-Sensitive Samples ^c	0.0	100
Handling Money and Produce Without Proper Hand-Washing	78.6	21.4
Proper Glove Use	0.0	100
Product Storage on Ground	23.8	76.2
Can the Table be Easily Cleaned	61.2	38.1
Can Produce Bins be Easily Cleaned	54.8	45.2
Use of a Protective Covering	100	0.0
Presence of Hand Sanitizer	0.0	100
Availability of a Hand-Washing Station ^a	0.0	100

^a These results reflect the presence of a hand-washing station at an individual vendor's site, not the market as a whole.

^b Percentage calculated from market vendors that sold pre-cut produce

^c Percentage calculated from market vendors that sold temperature-sensitive samples

TABLE 3. Percentage of observed risky food safety behaviors associated with food handling from food safety trained and non-trained vendors.

	Percentage of Trained Vendors, n=32		Percentage of Non-Trained Vendors, n=10		Chi-Squared or Fisher's Exact Test Comparison ^a
	Yes	No	Yes	No	P-value
Sale of Pre-Cut Produce	53.1	46.9	50	50	0.8629
Use of Temperature Control for Pre-Cut Produce ^b	29.4	70.6	40	60	0.6593
Use of Thermometer to Measure Temperature of Pre-Cut Produce ^b	0	100	0	100	X
Temperature Recording of Pre-Cut Produce ^b	0	100	0	100	X
Sale of Temperature-Sensitive Samples	12.5	87.5	0	100	X
Use of Temperature Control for Temperature-Sensitive Samples ^c	66.7	33.3	N/A	N/A	X
Use of Thermometer to Measure Temperature-Sensitive Samples ^c	0	100	N/A	N/A	X
Temperature Recording of Temperature-Sensitive Samples ^c	0	100	N/A	N/A	X
Handling Money and Produce Without Proper Hand-Washing	75	25	90	10	0.2828
Proper Glove Use	0	100	0	100	X
Product Storage on Ground	28.1	71.9	10	90	0.2088
Can the Table be Easily Cleaned	62.5	37.5	60	40	0.8872
Can Produce Bins be Easily Cleaned	53.1	46.9	60	40	0.7021
Use of a Protective Covering	100	0	100	0	X
Presence of Hand Sanitizer	0	100	0	100	X
Availability of a Hand-Washing Station ^d	0	100	0	100	X

^a For all statistical comparisons, $\alpha = 0.05$. Chi-Squared was used for all test comparisons unless $n < 5$, then Fisher's Exact Test was used

^b Percentage calculated from market vendors that sold pre-cut produce

^c Percentage calculated from market vendors that sold temperature-sensitive samples

^d These results reflect the presence of a hand-washing station at an individual vendor's site, not the market as a whole.

TABLE 4. Percentage of factors observed to contribute to overall market food safety risk.

Observational Criteria	Percentage of Trained Markets ^a		Percentage of Non-Trained Markets ^b	
	Yes	No	Yes	No
Access to Electricity	33.3	66.7	0	100
Are Animals Allowed in the Market	100	0	50	50
Availability of Trash Receptacles	33.3	66.7	50	50
Availability of Proper Hand-Washing Stations	66.7 ^c	33.3	50.0	50.0

^a n = 3

^b n = 2

^c One of the markets had a hand-washing station open to the public that was adjacent to the market, not within the market.

CHAPTER 3

A Microbial Assessment of Raw Produce from Southwest Virginia Farmers' Markets and Retail

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ABSTRACT

There is a lack of food safety regulations surrounding farmers' markets creating an environment in which proper food safety practices may not be enforced. The absence of proper food safety practices may increase contamination opportunities. The purpose of this study was to assess the microbial quality of fresh produce sold at Southwest Virginia farmers' markets and from a retail grocery store. Total aerobic bacteria and coliforms were enumerated and selective enrichment with PCR confirmation was performed for detection of generic *Escherichia coli*, *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella enterica*, and *Staphylococcus aureus*. A greater quantity of total aerobic bacteria was isolated from farmers' market leafy greens, onions and tomatoes when compared to a retail grocery store ($p=0.0011$, $p=0.0395$, and $p<0.0001$, respectively). There were no differences in the amount of coliforms found in farmers' market produce compared to retail produce. Additionally, one or more target pathogens were isolated from 28 different farmers' market vegetable samples and 16 retail grocery store samples. The microbial counts and identification of pathogens in produce samples in this study emphasizes the need for a pathogen reduction focus on fresh produce not only at farmers' markets, but also with growers and other retail outlets.

INTRODUCTION

Outbreaks have originated from local food sources including roadside stands and farmers' markets. For example, an outbreak of *E. coli* O157:H7 was linked to produce samples offered at a farmer's market in Fort Collins, Colorado resulting in 14 illnesses, including 2 children requiring dialysis (Colorado Department of Public Health and Environment, 2000; Bridges, 2000). Another outbreak of *E. coli* O157:H7 was linked to eating fresh strawberries produced by Jaquith Strawberry Farm in Oregon in 2011. The farm sold berries to buyers who then distributed them to roadside stands and farmers' markets. Furthermore, a *Salmonella* outbreak in Iowa was traced back to consumption of guacamole and salsa at a farmers' market in 2010 (Chapman, 2010; Iowa Department of Health, 2010). The rise in popularity of farmers' markets is accompanied by a parallel rise in concerns about how best to keep local consumers safe. The number of farmers' markets selling fresh produce combined with the prevalence of produce-related foodborne illness outbreaks emphasizes the need for a food safety focus within these markets (Otto and Varner, 2005).

Produce sold in outdoor markets are handled and stored with less control over sanitation, worker hygiene and temperature control when compared to supermarkets (Smathers *et al.*, 2012; Worsfold *et al.*, 2004). Farmers' markets are exempt from the proposed produce safety regulations of the Food Safety and Modernization Act (FSMA). Under the regulations, farms are considered exempt if they sell less than \$500,000 in food sales annually and sell most of their food directly to consumers, restaurants, and stores within the state or within 275 miles or less from the farm (FDA, 2011). The absence of regulation surrounding these direct-to-consumer food entities may create an environment in which many farmers' market vendors have little to no formal training in food safety (Beecher, 2013, Seo and Behnke, 2011). Because farmers'

markets are more loosely regulated than permanent food service operations, there are gaps in training requirements and oversight; there may also be increased opportunities for foodborne illness outbreaks from these temporary establishments (Seo and Behnke, 2011).

The purpose of this study was to assess the microbial quality of fresh produce sold at Southwest Virginia farmers' markets and from a retail grocery store and identify any differences in enumeration of total aerobic bacteria and coliforms and detection of target pathogens.

MATERIALS AND METHODS

Produce sampling. Raw produce samples were collected from one retail grocery store and five different farmers' markets across Southwest Virginia between May and October, 2014. Produce included: berries (blackberries, blueberries, raspberries, and strawberries), cucurbitaceae (cucumbers, squash, and zucchini), herbs (basil, cilantro, parsley, sage, and thyme), whole and pre-cut leafy greens (cabbage, chard, kale, lettuce, and spinach), green onions, peppers (banana, green, jalapeño, red, serrano, and yellow), and off-vine tomatoes. From each vendor, three samples of each representative product were purchased for analysis at the time of each market sampling. Each market was sampled an average of three times and each individual vendor was sampled an average of two times. Each produce sample was individually bagged (Sampling bags, Nasco, Whirlpak, Sandy Springs, GA) and stored in a cooler containing ice packs that was disinfected before each use with 70% ethanol during transportation back to the lab within two hours of purchase. Produce was stored in a 4 °C walk-in cooler for ≤ 48 hours before analysis. Additionally, produce was purchased from a retail grocery store each week in accordance with the various produce commodities that were purchased from the farmers' market that particular week in effort to make a direct comparison between the produce commodities collected from

farmers' markets that week and from the retail grocery store. Produce was purchased from the grocery store and placed in plastic bags and transported back to the lab within one hour. Produce samples were stored in a 4 °C walk-in cooler for \leq 48 hours prior to analysis.

Sample preparation. To begin analysis, each produce sample was mixed and a random 25 g subsample was combined with 225ml of broth in a filtered stomacher bag (Nasco, Whirlpak, Sandy Springs, GA) and homogenized for 120s at 230rpm using a JumboMix 3500 VW (Interscience, Saint Now, France). The type of broth used for each subsample was dependent on the target bacteria to be isolated. For quantification of total aerobic bacteria (TAB) and coliforms, 25g subsamples were homogenized in 225ml 0.1% buffered peptone water (Oxoid, Thermo Scientific, Franklin Lakes, NJ). Once homogenized, the samples were immediately serially diluted and enumerated in duplicate using 3M Petrifilm Aerobic Count Plates and Coliform Count Plates according to manufacturer's instructions (3M, Saint Paul, MN). To test for presence/absence of pathogenic bacteria and generic *E. coli*, samples were homogenized in enrichment broth and incubated for 24h at 37°C; however, to test for the presence of *L. monocytogenes*, samples were incubated for 48h at 30°C. Brain-heart infusion (BHI), *Listeria* enrichment broth (LEB), lactose broth and tryptone soya broth (TSB) was used to enrich for generic *E. coli* and *E. coli* O157:H7, *L. monocytogenes*, *Salmonella* spp., and *S. aureus*, respectively. All enrichment broths were purchased from Oxoid, Thermo Scientific, Franklin Lakes, NJ. Following incubation, sample homogenates were stored in a -20°C freezer for \leq 6 months prior to DNA extraction and PCR detection.

Total aerobic bacteria (TAB) and coliforms. Quantification of TAB and coliforms was performed as described above and plated onto 3M Petrifilm Aerobic Count Plates and Coliform

Count Plates in duplicate (3M, Saint Paul, MN). Inoculated Petrifilm was incubated at 37°C for 48h. Colony counts were expressed as log CFU per gram.

Nucleic acid based detection of generic *E. coli* and target pathogens. DNA was extracted from the non-enriched homogenate obtained from each item as described above. The resulting homogenate was pelleted and 80 mg of cell pellet was extracted using the Zymo Research Fecal DNA Kit (Zymo Research Corporation, Irvine, CA) via manufacturer's instructions. *E. coli* was detected utilizing a uniplex PCR reaction following previously published methods targeting the amino-terminal end of the *uidA* gene (Maheux *et al.*, 2009). The reaction was performed using a Bio-Rad IQ5 thermal cycler (Bio-Rad, Hercules, CA) in PCR master mixtures (FideliTaq PCR Master Mix, Affymetrix, Santa Clara, CA) containing Taq DNA polymerase, 3mM magnesium and 0.4mM nucleotide concentrations with a final volume of 25µl with 2µl DNA template and 1.5µM concentration of each primer, *uidA*-F/R following previously published methods.

The reaction parameters consisted of an initial denaturation at 95°C for 3 min, followed by 30 cycles of 95°C for 30s, 60°C for 30s, and 72°C for 30s, and a final extension time of 5 min at 72°C. The amplified products were separated by electrophoresis on a 2% agarose gel at 90 V for 60 min. The gels were stained with 0.5µg/ml ethidium bromide solution and visualized using an ultraviolet transilluminator (Gel Doc XR system, Bio-Rad, Hercules, CA). Each positive PCR reaction was performed in duplicate. *E. coli* ATCC 25922 was used as a positive control strain in this study and a negative control lacking DNA was used for every PCR and electrophoresis reaction. Two replicates were performed for each reaction.

To test for the presence/absence of pathogenic bacteria, samples that were previously homogenized in BHI broth, LEB, lactose broth, and TSB were thawed at room temperature and homogenized a second time for 120s at 230rpm in the JumboMix 3500 VW. Next, DNA was extracted from each homogenate using Zymo Research Fecal DNA Kit (Zymo Research Corporation, Irvine, CA) via manufacturer's instructions. Previously published multiplex PCR methods were used to simultaneously test for the presence of *E. coli* O157:H7, *L. monocytogenes*, *Salmonella* spp., *S. aureus*, and bacterial DNA (Lee *et al.*, 2014). The oligonucleotide primers used in this study are shown in Table 1. The target genes selected are presented in Table 1.

The multiplex PCR was performed (Bio-Rad IQ5 Thermal Cycler) in reaction mixtures (AccuPower® Gold Multiplex PCR PreMix; Bio-Rad, Hercules, CA) containing 10mM Tris-HCl, 1.5mM MgCl₂, 250µM dNTP with a final volume of 20µl of 2 U *Top* DNA polymerase, 2 µl of DNA template, and varying concentrations of each primer. The optimized concentrations of the five primer pairs in the multiplex were 0.3µM for 16S-F/R; 0.8µM for hly-F/R; 1µM for rfbE-F/R, and nuc-F/R; and 1.8µM for invA-F/R.

The reaction parameters consisted of an initial denaturation at 95°C for 5 min, followed by 35 cycles of 95°C for 50s, 58°C for 1 min, and 72°C for 50s, and a final extension time of 5 min at 72°C. The amplified products were separated by electrophoresis on a 2% agarose gel at 90 V for 60 min. The gels were stained with 0.5µg/ml ethidium bromide solution and visualized using an ultraviolet transilluminator (Gel Doc XR system, Bio-Rad, Hercules, CA). Each positive PCR reaction was conducted in duplicate. Positive control strains were used for each target bacteria and a negative control lacking DNA was used for every multiplex PCR and electrophoresis reaction.

Statistical analysis. Data analysis was performed using JMP Pro version 10.0.2 for Windows (Cary, NC; http://www.jmp.com/en_us/software/jmp-pro.html). Statistical analysis and significance testing were assessed using Analysis of Variance (ANOVA) to compare the quantity of total aerobic bacteria and coliforms from samples collected from farmers' markets and a retail grocery store. Statistical analysis and significance testing were assessed using Chi-square test or Fisher's exact test to compare the proportion of pathogen and/or *E. coli* positive samples from farmers' markets compared to a retail grocery store. Fisher's exact test was utilized for comparisons with sample sizes equal to or less than five as the Chi-square test is less reliable for smaller sample sizes. P value of ≤ 0.05 was considered significant for this study.

RESULTS AND DISCUSSION

Produce sampling. Each market (n=5) visited had between 1 and 13 produce vendors (mean=8). Produce was purchased from a total of 42 different vendors between May – October, 2014. During that time, samples were also purchased from a retail grocery store during 13 separate visits. Due to time constraints and availability of produce at farmers' markets, an unequal sample size was collected for each commodity (e.g. tomatoes were more abundant at the markets (n=88), while berries were not as common (n=19)).

Total aerobic bacteria (TAB). Leafy greens, onions, and tomatoes purchased from farmers' markets had a 1.8, 1.2, and 2.1 log CFU/g increase, respectively, in TAB concentrations compared to the same retail commodities (p=0.0011, p=0.0395, and p<0.0001, respectively).

The level of TAB found on produce samples in this study were similar to other studies which report an average of 5 to 6 log CFU/g (Johnston *et al.*, 2005; Park and Sanders, 1991; Soendjojo, 2012; and Wood *et al.*, 2015). Lettuce and spinach sampled from farmers' markets in

Indiana had higher levels of bacteria with a mean of 6.1 log CFU/g compared to grocery stores with a mean of 5.4 log CFU/g (Soendjojo, 2012). Romaine lettuce sampled from five regional farmers' markets in British Columbia was also found to have a similar TAB count of 6.3 log CFU/g (Wood *et al.*, 2015). The higher level of TAB found on leafy greens and tomatoes purchased from farmers' markets may be due to the absence of a disinfectant wash. Most commercially produced leafy greens and tomatoes are subjected to a chlorine (or other sanitizing solution) wash to reduce microbial populations on the surface of the produce during postharvest handling (Banach *et al.*, 2015; Gil *et al.*, 2009; Haute *et al.*, 2013).

Coliforms. In this study, produce samples collected from farmers' markets and retail contained an average coliform level of 3.0 log CFU/g (Figure 2). Between 18.2% and 91.1% of each produce commodity collected from farmers' markets was coliform-positive, with leafy greens having the highest percentage of coliform-positive samples followed by leafy greens. Between 12.5% and 100% of produce commodities collected from retail were coliform-positive, with cucurbitaceae and peppers having the highest percentage of coliform-positive samples.

Leafy greens generally had a high concentration of coliforms with an average of 3.6 log CFU/g with 91.1% and 40.0% of farmers' market and retail samples, respectively, being coliform-positive. Wood and colleagues analyzed fresh green, red and romaine (n=68) lettuce samples from farmers' markets in British Columbia and found a lower concentration (1.9 log CFU/g coliforms) (Wood *et al.*, 2015). It is not surprising to see differences which could be due to farming practices including type of irrigation (surface water, well water, etc.), type of fertilizer used (raw manure, compost, etc.), environmental conditions (temperature, humidity, etc.), or coliform detection methods among other factors. The different types of leafy greens sampled between the two studies could also contribute to the differences observed in coliform

concentration. This study sampled cabbage, chard, kale, lettuce, and spinach samples compared to the green, red, and romaine lettuce samples analyzed by Wood and colleagues.

While the United States does not have an established bacterial limit for coliforms in produce, coliforms are commonly used as indicators of pathogen presence (Consumers Union, 2010). Other countries have varying established maximum levels of fecal coliforms in ready-to-eat salads including 100 CFU/g and 1,000 CFU/g limits for Brazil and France, respectively. Israel has an established limit of 100 CFU/g total coliforms acceptable in salad vegetables (Consumers Union, 2010). Figure 2 reflects the levels of total coliforms found in produce samples in this study in which there was an average of 3.6 log CFU/g total coliforms for leafy greens.

Detection of generic *E. coli*. Generic *E. coli* present on the samples was not quantified, instead, molecular methods were used to detect the presence/absence of generic *E. coli*. *E. coli* was identified in 28.5% of farmers' market samples (n=77) and 31.6% retail samples (n=43). Significantly more leafy greens purchased from farmers' markets tested positive for the presence of *E. coli* compared to leafy greens purchased from a retail store (p=0.0263). Farmers' market leafy greens also contained a higher level of coliform-positive samples (91.1%) compared to retail (40.0%) (p<0.0001). The higher levels of *E. coli*-positive and coliform-positive farmers' market leafy greens may be due to differences in farming practices (fertilizer used, irrigation water source, harvesting practices, etc.) and the absence of a disinfectant wash (Haute et al).

Other studies have reported between 8.2 to 27.1 % *E. coli*-positive produce samples from farmers' markets (Bohaychuk *et al.*, 2009; Pan *et al.*, 2015; Wood *et al.*, 2015). In 2008, lettuce (n=128), spinach (n=59), tomatoes (n=120), carrots (n=206), green onions (n=129), and

strawberries (n=31) were collected from markets in Canada and tested for the presence of *E. coli*. *E. coli* was isolated from 8.2 % of samples including lettuce, spinach, carrots, and green onions with spinach having 27.1 % *E. coli*-positives and carrots having 4.4 % *E. coli* positives (Bohaychuk *et al.*, 2009). Furthermore, 62% of lettuce and 6.4% of tomato samples obtained from farmers' markets in Seattle, WA were *E. coli*-positive (Leang, 2013). The differences in the levels of *E. coli*-positive samples could be due to many factors including the type of commodity sampled, climate, farming practices, and detection methods. This study found 45% of leafy greens sampled from farmers' markets tested positive for *E. coli*, 28% of tomatoes, 30.8 % of green onions, and 54.5% of berries.

Detection of pathogenic bacteria. Pathogenic bacteria were detected in a limited number of samples collected throughout the sampling period. *S. aureus* was not identified in any produce samples tested. *Salmonella* spp. was identified in the greatest number of samples, 8.1% farmers' market samples (n=22) and 10.3% retail samples (n=14) (Table 3). *Salmonella* spp. was identified most frequently from farmers' market leafy green samples (n=6), followed by farmers' market peppers (n=4) and retail cucumbers (n=4).

E. coli O157:H7 was identified in one green pepper sample purchased from a retail grocery store (0.7%), but not from any other samples. Retail pepper samples also contained a high level of coliform-positive samples (85.7%). *L. monocytogenes* was identified in 2.2% of farmers' market samples (n=6) and 0.7% of retail samples (n=1) (Table 3). All *L. monocytogenes*-positive samples were also positive for generic *E. coli*. *L. monocytogenes* was identified most frequently from farmers' market leafy greens (n=3), which correlates with a high percentage of coliform-positive samples (91.1%), the highest frequency of *Salmonella* spp.-positive samples (n=6) and the highest frequency of *E. coli*-positive samples (n=20).

While farmers' market and retail produce contained an average of 66.2 and 54.6% coliform-positive samples, respectively, only a fraction of those samples tested positive for pathogenic bacteria. These results suggest that the presence of coliforms may not be a good indicator of pathogen presence. Previous studies have found a lack of correlation between the presence of coliforms and pathogens in fresh produce (Anonymous, 2000). This study further proves that the absence of correlation between coliforms and the presence of bacterial pathogens in fresh produce makes coliforms an unreliable indicator for the presence of pathogens.

A higher level of pathogen-positive samples was found in this study as compared to similar studies. During the summer months of 2011, samples of salad (n=142), fresh-cut fruit (n=64), and sprouts (n=27) were collected from the Swiss Market and analyzed for the presence of *Salmonella* spp. and *L. monocytogenes*. No *Salmonella* spp. was isolated from any of the samples and *L. monocytogenes* was only isolated from 3.5% of salad samples (Althaus *et al.*, 2012). Leafy greens, herbs, and cantaloupe (n=398) were collected through production and the packing shed and only 0, 0, and 0.7% of samples tested positive for *L. monocytogenes*, *E. coli* O157:H7, and *Salmonella*, respectively (Johnston *et al.*, 2005). Furthermore, another study collected lettuce, spinach, tomatoes, carrots, green onions, and strawberries from farmers' markets in Alberta, Canada and none of the samples tested positive for *Salmonella* spp. or *E. coli* O157:H7 (Bohaychuk *et al.*, 2009).

The multi-plex PCR methods established by Lee *et al.*, 2014 used in this study was sufficient to detect $< 10^1$ CFU/g levels of pathogen(s), which is more sensitive than previously described multi-plex methods (Germini *et al.*, 2009; Kim *et al.*, 2007). The lower detection limit of this method could allow for a more accurate detection of pathogen DNA which would cause this study to report higher levels of pathogen presence than other studies. Although this study

has a low detection limit, a limitation of utilizing molecular methods is the detection of pathogen DNA from dead pathogen cells that are not infectious.

CONCLUSIONS

This study provided baseline information on the levels of TAB and coliforms as well as occurrence of *E. coli*, *E. coli* O157:H7, *L. monocytogenes*, *Salmonella* spp., and *S. aureus* present in produce. The growing popularity of farmers' markets and the limited number of microbiological studies conducted to assess the safety of produce sold at the markets warranted investigation.

There were few significant differences in the microbial quality of farmers' market produce compared to retail produce. This research suggests that there is no difference in the safety of farmers' market produce as compared to retail produce. Although the safety of produce purchased from farmers' markets was not significantly different from produce purchased from retail, the identification of pathogens in produce from both locations emphasizes the need for a pathogen reduction focus on fresh produce with both farmers' markets and retail outlets.

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TABLE 1. Primer pairs selected for multi-plex and uni-plex PCR.

Bacterium	Sequence (5' to 3')	Target Gene	Amplicon (bp)
<i>E. coli</i> O157:H7	AACGGTTGCTCTTCATTTAG GAGACCATCCAATAAGTGTG	<i>rfbE</i>	678
Bacterial DNA	CCTACGGGAGGCAGCAGT CGTTTACGGCGTGGACTA	16S rRNA	475
<i>S. enterica</i>	AATTATCGCCACCACGTTTCGGGCAA TCGCACCGTCAAAGGAACC	<i>invA</i>	278
<i>L. monocytogenes</i>	CGCAACAAACTGAAGCAAAG TTGGCGGCACATTTGTCAC	<i>hly</i>	210
<i>S. aureus</i>	AAATTACATAAAGAACCTGCGAC GCACTTGCTTCAGGACCATA	<i>nuc</i>	164

TABLE 2. Sample sizes of produce commodities purchased from farmers' markets and retail.

Produce Commodity	Farmers' Markets Sample Sizes	Retail Sample Sizes
Berries	11	8
Cucurbitaceae	87	49
Herbs	14	12
Leafy greens	45	20
Onions	13	9
Peppers	36	14
Tomato	64	24

TABLE 3. Microbial assessment of produce purchased from A) farmers' markets and B) retail

A)

Produce Commodity	N	% Coliform Positive	% Generic <i>E. coli</i> Positive	% <i>Se</i>^a Positive	% <i>Lm</i>^b positive	% O157:H7^c Positive
Berries	11	18.2	54.5	-	-	-
Cucurbitaceae	87	88.5	18.4	4.6	1.1	-
Herbs	14	78.6	21.4	21.4	-	-
Leafy greens	45	91.1	44.4	13.3	6.7	-
Onions	13	76.9	30.8	23.1	2.8	-
Peppers	36	55.5	27.8	11.1	-	-
Tomatoes	64	54.7	28.1	3.1	1.6	-

^a*Salmonella enterica*; ^b*Listeria monocytogenes*; ^c*Escherichia coli* O157:H7

B)

Produce Commodity	N	% Coliform Positive	% Generic <i>E. coli</i> Positive	% <i>Se</i>^a Positive	% <i>Lm</i>^b positive	% O157:H7^c Positive
Berries	8	12.5	25.0	-	-	-
Cucurbitaceae	49	85.7	42.9	14.3	-	-
Herbs	12	50.0	33.3	16.7	8.3	-
Leafy greens	20	40.0	15.0	5.0	-	-
Onions	9	66.7	33.3	33.3	-	-
Peppers	14	85.7	28.6	-	-	7.1
Tomatoes	24	41.7	25.0	4.2	-	-

^a*Salmonella enterica*; ^b*Listeria monocytogenes*; ^c*Escherichia coli* O157:H7

TABLE 4. Produce samples from farmers' markets and retail contaminated with target bacteria.

Bacterium	Farmers Market^a (n=270)		Retail^a (n=136)		Total (n= 406)	
	# positive	% positive	# positive	% positive	# positive	% positive
<i>E. coli</i> O157:H7	0	0	1	0.7	1	0.2
<i>L. monocytogenes</i>	6	2.2	1	0.7	7	1.7
<i>Salmonella</i> spp.	22	8.1	14	10.3	36	8.9
<i>S. aureus</i>	0	0	0	0	0	0
<i>E. coli</i>	77	28.5	43	31.6	120	29.6

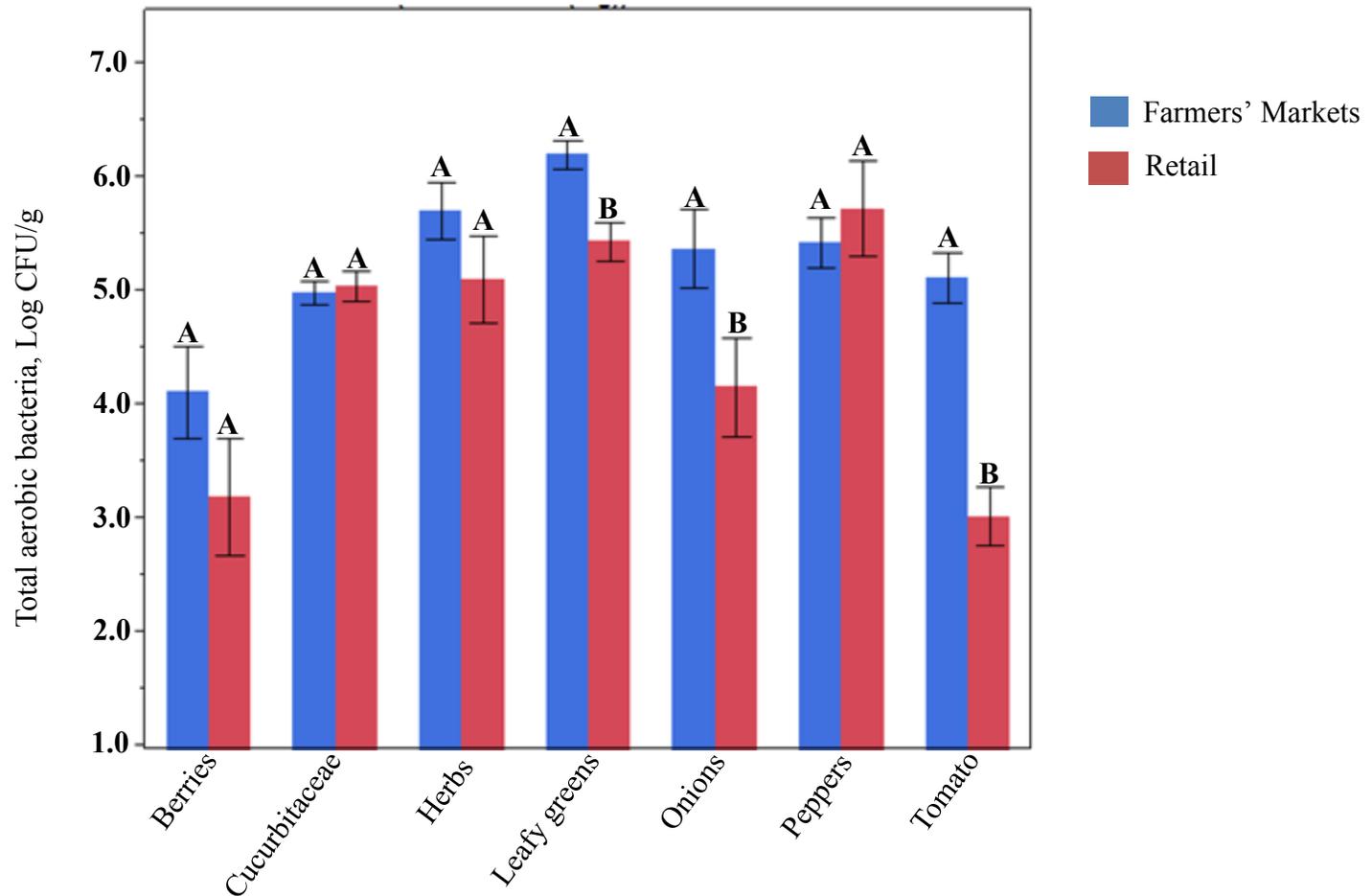


FIGURE 1. Mean total aerobic bacteria in produce samples from farmers' markets and retail. The sample size of each commodity was: Berries (Farmers' market=11; Retail=8), Cucurbitaceae (Farmers' market=87; Retail=49), Herbs (Farmers' market=14; Retail=12), Leafy greens (Farmers' market=45; Retail=20), Onions (Farmers' market=13; Retail=9), Peppers (Farmers' market=36; Retail=14), and Tomatoes (Farmers' market=64; Retail=24). Total number of samples (n=406).

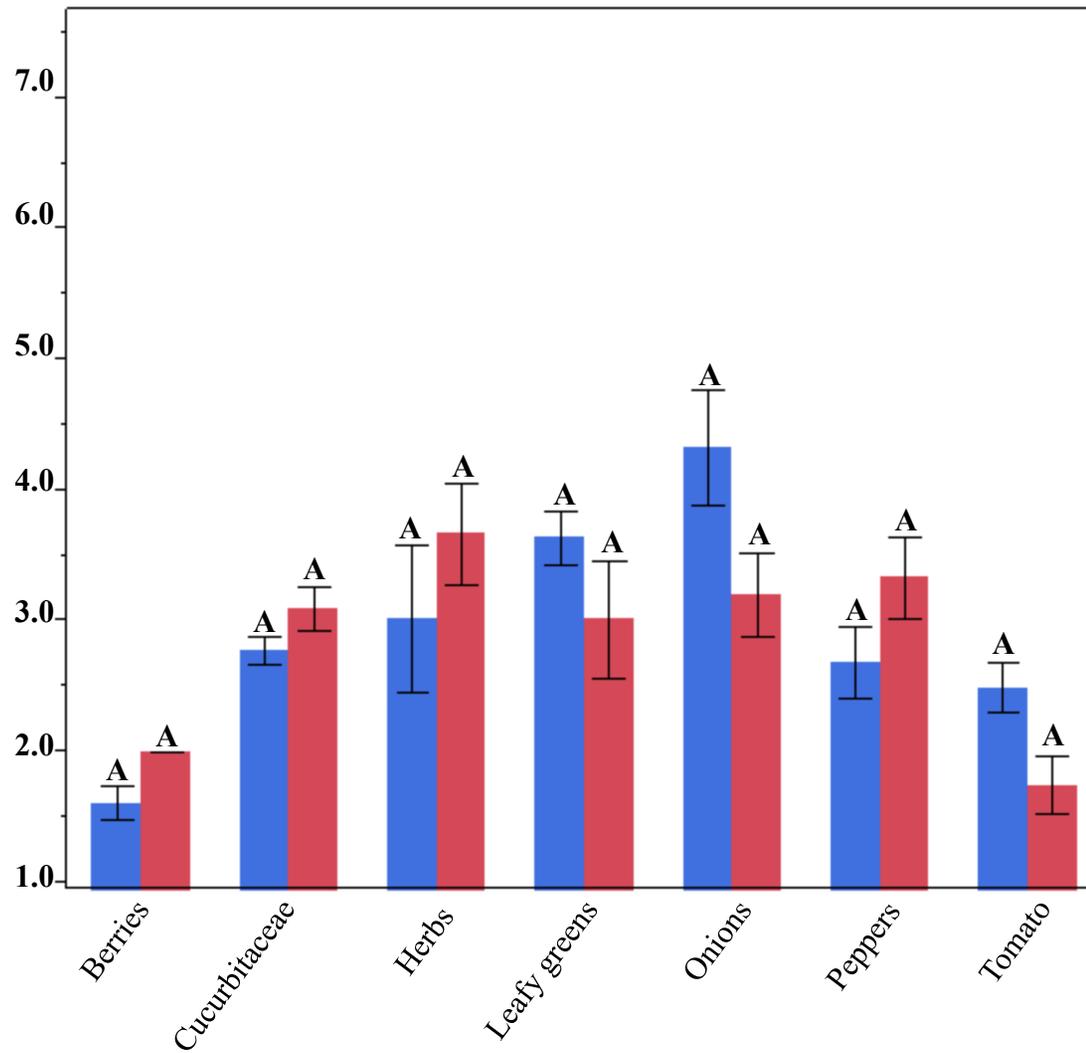


FIGURE 2. Mean coliforms in produce samples purchased from farmers' markets and retail. The sample size of each commodity was: Berries (Farmers' market=11; Retail=8), Cucurbitaceae (Farmers' market=87; Retail=49), Herbs (Farmers' market=14; Retail=12), Leafy greens (Farmers' market=45; Retail=20), Onions (Farmers' market=13; Retail=9), Peppers (Farmers' market=36; Retail=14), and Tomatoes (Farmers' market=64; Retail=24). Total number of samples (n=406).

CHAPTER 4

Development and Evaluation of a Food Safety Management Plan Template for Farmers' Markets

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ABSTRACT

Many farmers' markets lack established food safety management plans. The development and implementation of proper food safety plans may reduce risk of contamination. The purpose of this study was to develop and evaluate a food safety management plan (FSMP) template tailored specifically to farmers' markets. The intended use of the plan is for market managers to use it to create a plan to reduce food safety risks at the market. The FSMP was developed to address the top five risk factors contributing to foodborne illness as identified by the Centers for Disease Control and Prevention (CDC). The FSMP was evaluated for practicality and feasibility through interviews with market managers in North Carolina and Virginia (n=6). Most market managers (66.7% agreed that the FSMP was practical for their market while only 33.3% agreed that they could implement the plan immediately. Revisions suggested to the FSMP will be made and it will be made available in Virginia and North Carolina in spring 2016.

INTRODUCTION

Patrons perceive less risk when buying food products directly from farmers because they feel that they are making an informed decision (Smithers *et al.*, 2008) or that the farmers have a stake in the community (Green *et al.*, 2003). In the conventional food market, food travels an average of 1,300 miles for processed foods and 1,500 miles for produce before consumption by consumers (Pirog *et al.*, 2001). Regardless of farm scale and distance traveled, contamination risks still apply to how fresh produce is grown and handled. The local food movement also reflects consumer interest in supporting local farmers and better understanding of the origin of their food (Martinez, 2010). Considering the increasing popularity of farmers' markets and the occurrence of produce outbreaks, a food safety focus at farmers' markets can protect farmers, patrons, and local economies (Otto and Varner, 2005).

It is common practice for food processing facilities that sell retail foods to have a hazard analysis and critical control points (HACCP) plan in place to help mitigate food safety risks. While there are limited food safety requirements for farmers' markets, the use of a FSMP to establish proper food safety policies at the market may foster increased food safety awareness. While farmers' market vendors and market managers often have little to no food safety training, in recent surveys they self-report practicing proper hygiene standards with limited food safety risk management procedures in place (Simonne *et al.*, 2006; Worsfold *et al.*, 2004). Even farmers' market vendors who have had food safety training have been observed taking unnecessary food safety risks. An observational study of Southwest Virginia farmers' markets found that less than 30% of vendors (n=32) who had received food safety training were practicing proper temperature control for pre-cut produce. Moreover, only 66.7 % of the markets had hand-washing stations available to vendors and patrons (Pollard *et al.*, Chapter 3).

Farmers' markets are more loosely regulated than permanent food service operations, creating gaps in food safety training and oversight. There may be increased opportunities for foodborne illness outbreaks from these temporary establishments due to lack of regulations surrounding these facilities (Seo and Behnke, 2011).

There are currently no requirements for farmers markets to have a written food safety plan, but such a plan may help market managers elucidate correct procedures and assist in enforcing vendors to follow suggested protocol. To our knowledge no food safety management plan templates have been developed specifically for farmers' markets. The purpose of this study was to develop and evaluate a food safety management plan template for feasibility and practicality. The plan can be tailored for individual farmers' markets to influence positive food safety practices and behaviors in farmers' markets across the nation.

FSMP development. The FSMP addressed each of the five risk factors for foodborne illness as outlined by the CDC. There is data that supports these risk factors and how controlling them can reduce foodborne illness. The FDA food code identifies cut leafy greens, cut melons and cut tomatoes as needing temperature control because these foods are capable of supporting the growth of various infectious microorganisms or toxins (FDA, 2009). Temperature abuse can allow harmful bacteria to proliferate, contributing to foodborne illness (Brackett, 1999). Previous studies have highlighted the effects of temperature abuse, reporting a 2.0 log CFU/g increase in *E. coli* O157:H7 populations on lettuce when held at 12°C for 3 days (Luo *et al.*, 2010). Growth of *E. coli* O157:H7 can outpace that of spoilage bacteria and the appearance of quality deterioration, resulting in unsafe product without visual aversion (Luo *et al.*, 2009). The temperature policy that market managers can build for their market with the use of the FSMP

may help reduce risk of foodborne illness associated with improper hot/cold holding and cooking temperatures.

Additionally, cross contamination prevention strategies and policies are addressed in the FSMP in the form of handwashing policies, proper glove-use policies, separation of raw and ready-to-eat (RTE) foods, cleaning and sanitizing procedures, pet policies, transportation policies, and food display and storage bin policies. Proper handwashing procedures can reduce the risk of foodborne illness and other infections (Green *et al.*, 2003). Multiple studies have reported poor food handler hygiene practices associated with an overall lack of hand-washing facilities at farmers' markets (Behnke *et al.*, 2012; McIntyre *et al.*, 2014). Establishing proper hand-washing policies and procedures as well as facility requirements may help reduce the risk of contamination associated with poor hygiene practices. In addition to proper hand-washing policies and procedures, the FSMP encourages market managers to build a sick policy to prevent ill vendors from selling food at the market. Food handlers carrying pathogens (such as hepatitis A, *Salmonella*, and *Escherichia coli* O157:H7) have been implicated in outbreaks of foodborne illness (Green and Selman, 2005; Greig *et al.*, 2007). Utilizing the FSMP to prevent ill vendors from selling food at the market may reduce the risk of cross contamination.

Improper glove-use may also become a source of contamination. Many farmers' markets do not have hand-washing facilities and may turn to glove use to reduce cross contamination. The FSMP allows market managers to input a proper glove-use policy as proper glove use has been proven to substantially reduce opportunities for food contamination (Todd *et al.*, 2010).

Utilizing the FSMP to create policies to mitigate risks associated with cross contamination may help reduce the risk of contamination while also educating vendors on proper

food safety practices and behaviors. Although the goal of the FSMP was not to serve as a food safety educational tool, during the process of using the template to build the market's FSMP market managers and vendors may be made aware of risky food safety behaviors that they were not previously identify as a risk.

The FSMP further addresses risk reduction strategies associated with cross contamination by probing market managers to input policies regarding proper food containers, cleaning and sanitizing policies and cleanliness of vehicle(s) used to transport food to the market.

Lastly, on-farm food safety practices are briefly addressed in the last section of the FSMP template. Factors such as irrigation sources and manure-use can affect the microbial quality of produce (Harrison *et al.*, 2013). The final section of the FSMP requires market managers to establish an irrigation and manure-use policy to encourage good agricultural practices (GAPs). The market managers may also indicate requirements for an on-farm hygiene and sanitation plan as well as farm inspection requirements.

MATERIALS AND METHODS

Farmers' market FSMP development and design. The farmers' market FSMP was developed with input from food safety experts and market managers. CDC's top five risk factors contributing to foodborne illness including improper hot/cold holding temperatures, improper cooking temperatures, cross contamination, poor food handler health and hygiene, and obtaining food from unsafe sources were used to outline the risk reduction focus areas within the plan. Input from market managers and food safety experts helped develop a farmers' market FSMP template that can be tailored by individual market managers to meet the needs of their market. The FSMP was designed to allow market managers to answer specific questions relating to their

market's food safety policy and, in the process, create a food safety plan for the market.

Intended use. The farmers' market FSMP was developed as a template for market managers to use to develop a food safety plan tailored specific to their market. The FSMP addresses five key areas, including: 1) temperature abuse, 2) improper cooking temperatures, 3) cross contamination, 4) proper food handler health and hygiene, and 5) obtaining food from unsafe sources. Each area addresses specific food safety risks allowing market managers to input parameters specific to their market. The developed FSMP template consists of 21 key areas centered on CDC's top five foodborne illness risk factors (Appendix 1). A significant portion of the FSMP is focused on temperature abuse by helping market managers build their policies regarding temperature control of temperature control for safety (TCS) foods and policies regarding cooking foods to the proper temperature. Another large portion of the FSMP addresses risks related to cross contamination. The FSMP addresses key cross contamination avenues such as separation of raw meats from RTE foods, hand-washing, cleaning and sanitation of food contact surfaces, and pet policies. On-farm food safety procedures are also prompted in the FSMP in the form of irrigation quality and manure use policies and on-farm inspections. Market managers are also prompted to create a sick policy for vendors at the market.

Data collection. After development of the FSMP, market managers in the Triangle and Triad regions of North Carolina were given the food safety plan and asked questions designed to evaluate the plan for practicality and feasibility (Table 1). Market managers were selected using the North Carolina online farmers' market directory. There are a total of 221 farmers' markets in the state of North Carolina. A convenience sample of 11 counties was chosen to include all counties within a 40 mile radius of Raleigh, North Carolina, which reduced the sample size to 44. To choose which markets to include in the final sample, markets that only operated on the

weekends were eliminated. For six markets, no information could be found for the market manager and as a result they were eliminated from the final sample, leaving an overall market sample size of 16. Five market managers agreed to participate in the interview. Additionally, one market manager from Virginia was included in the study due to her previous involvement with Cooperative Extension food safety efforts and interest in the topic. The market managers were provided with the FSMP and allowed to review the document before giving feedback by answering evaluation questions during an in-person interview outlined in Table 1. Market manager interviews were approved by the Institutional Review Board of North Carolina State University (IRB 5988).

RESULTS AND DISCUSSION

FSMP evaluation. Six market managers from North Carolina and Virginia evaluated the FSMP for practicality and feasibility. Most market managers (66.7%) agreed that the FSMP was practical for their market and 33.3% agreed that they could implement the plan immediately. The biggest concern about the plan is the amount of information and policy development required. Many market managers (50%) expressed concern that the FSMP was too involved and required too much effort for the vendors to comply with all the food safety policies. Additionally, 83.3% of market managers indicated that they would need help with implementation of the FSMP and 66.7% indicated they would seek help from cooperative extension agents/specialists in order to make it work (Table 1 and 2).

One market manager expressed concern over providing hand-washing stations citing the requirement of the stations to be impractical. Another market manager did not see the value in

the FSMP and thought that vendors already did enough to meet food safety requirements such as implementing GAPs on the farm.

While most market managers perceived the FSMP to be practical for their needs, they expressed concern over implementation and most agreed that they would need help to fully utilize this plan. Feedback from the market managers will be used to revise the FSMP to make it more feasible for market managers to implement. It may be useful to develop educational tools to help market managers utilize this template to build their own FSMP. Additionally, getting extension agents/specialists involved in helping market managers develop some of the policies needed to build the FSMP may help with implementation.

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TABLE 1. Quotations from FSMP evaluation from farmers’ market managers.

FSMP evaluation questions	Answers from select market managers	
Is the food safety plan provided practical?	The plan is very extensive and all aspects will not be applicable to all vendors.	This is a fantastic resource. We have been doing a lot of this already but there are some additional items addressed in this plan that we have gaps in.
What, if anything, makes it impractical?	Too much for the farmers to focus on. They do things on their farm already, like GAPs, that’s enough.	Difficult to regulate.
Could you implement this plan right now?	No, we will need buy-in from the vendors, they have all the power.	Would need help with enforcement and implementation.
If you cannot implement the plan right now, what would you need to get it started?	Need to educate farmers on why this is important/necessary. Need support from vendors.	Hand-outs and infosheets would help make people aware of the details of the plan and why it is needed.
Would you need help to implement the plan?	Yes, would seek help from Cooperative extension agents/specialists	Yes, help would be needed and ample time.

TABLE 2. Results from FSMP evaluation from market managers.

FSMP evaluation	Evaluation from Market Managers ^a	
	Yes	No
Is the food safety plan provided practical?	4	2
Could you implement this plan right now?	2	4
Would you need additional help to implement this plan?	5	1
Would you seek help from Cooperative Extension agents/specialists?	4	2

^a n=6

Farmers' market food safety management plan template

This food safety management plan (FSMP) is designed to create a framework that farmer's market vendors and managers can use to mitigate risks associated with pathogen contamination of foods at the market.

The Center for Disease Control and Prevention (CDC) estimates that 1 in 6 Americans get sick, 128,000 are hospitalized, and 3,000 die of foodborne disease each year. CDC has listed the top five risk factors contributing to foodborne illness, including:

- 1) Improper hot/cold holding temperatures of potentially hazardous foods (temperature abuse)
- 2) Improper cooking temperatures
- 3) Contaminated utensils and equipment (cross contamination)
- 4) Poor food handler health and hygiene
- 5) Obtaining food from unsafe sources

The FSMP will include sections addressing each of the five top risk factors contributing to foodborne illness.

Part I: Improper hot/cold holding

Risk: Temperature control for safety (TCS) foods held in the danger zone of 41-135 °F can foster the growth of harmful pathogenic bacteria.

1.1) At this market, vendors are required to keep foods needing to be kept cold (at or below 41 °F) by taking the following action(s):

- a) Use of a refrigerator set at or below 41 °F with temperature monitoring with a calibrated thermometer and record keeping
- b) Use of a cooler with potable ice and temperature monitoring with a calibrated thermometer and record keeping
- c) Use of a cooler with potable ice and temperature monitoring with a calibrated thermometer. No record keeping.
- d) Use of a cooler with potable ice. No temperature monitoring or record keeping.
- e) Use of a cooler with non-potable ice. No temperature monitoring or record keeping.
- f) No temperature monitoring, must sell or throw out within 6 hours (cold food).
- g) No requirements.

1.2) At this market, vendors are required to take the following action(s) to reduce risk associated with improper hot holding of foods:

- a) Use hot holding equipment to keep food at or above 135 °F. Monitor the temperature of the food with a calibrated thermometer once every hour by properly checking the temperature of the food recording the temperature measurements.

- b) Use hot holding equipment to keep food at or above 135 °F. Monitor the temperature of the food once every hour by properly checking the temperature of the food with a calibrated thermometer. No record keeping.
- c) Use hot holding equipment to keep food hot. No active temperature monitoring or record keeping.
- d) No temperature monitoring; must sell or throw out food within 4 hours.
- e) No requirements.

1.3) Please check all procedures below that are to be followed when offering samples to customers:

- Vendors must use single-use gloves when prepping and serving RTE foods (refer to section 3: cross contamination).
- Single service items for customers, such as toothpicks, must be used when possible (refer to section 3: cross contamination).
- Samples must be kept covered to protect from flies, dust and other possible air contaminants (refer to section 3: cross contamination).
- Samples must be held at proper temperatures to prevent microbial growth.
- Temperature must be monitored and recorded for hot and cold held foods
- TCS foods are required to be held either at or below 41 °F at all times.
- TCS foods must be labeled with the time it was prepared and must be disposed of after two hours, or one hour if the surrounding temperature exceeds 90 °F.
- This market does not have a policy concerning samples.

Part II: Cooking Temperatures

Risk: If foods are not cooked to the proper temperature, harmful pathogenic bacteria can survive the insufficient cooking process.

2.1) Please select the steps listed below that are used to ensure foods are cooked to the proper temperature:

- Foods are to be cooked to the proper temperature according to USDA guidelines.
- Vendors are to properly measure the temperature of the food with a calibrated thermometer while cooking and while (hot) holding food.
- Vendors are to keep a record of temperature measurements in a temperature log book during on site cooking of food.
- No temperature monitoring program is in place at this market.

Part III: Reducing Cross-Contamination

Risk: Contamination of food with pathogenic bacteria can occur if/when food comes into contact with contaminated objects including equipment, people, food contact surfaces, etc.

At this market, vendors are required to take the following action(s) to reduce risk associated with cross contamination:

3.1) Please check below this market's proper hand-washing policy:

- Vendors have been trained in proper hand-washing procedures
- Vendors have not been trained in proper hand-washing procedures
- Hand-washing signs are posted throughout the market informing vendors and patrons of where a public hand-washing station is located.

- This market does not have any hand-washing stations available to the public.

3.2) Please check all the activities that, after performed, require food handlers to wash their hands before touching food:

- Before, during and after preparing food.
- After using the restroom.
- After coughing, sneezing or blowing your nose.
- After handling money.
- After handling trash.
- After handling/petting pets or other animals.
- Whenever hands come into contact with bodily fluids (i.e. runny nose, watery eyes, saliva, etc.)
- Food handlers are not required to wash their hands.
- Food handlers (vendors) have been trained on when to wash their hands.

3.2) Check all that apply for this market's proper glove-use policy:

- Hands must be washed before putting on gloves.
- Gloves must be replaced when they are torn.
- Gloves must be replaced before beginning a different task, such as handling raw meat and RTE foods.
- Gloves must be changed every four hours during continual use.
- After handling raw meat and before handling cooked or RTE food.
- Single-use gloves cannot be washed and re-used.
- Vendors have been trained on this market's proper glove-use policy.

- This market does not have a proper glove-use policy.

3.3) It is important to keep raw meats separated from ready-to-eat (RTE) foods to prevent cross-contamination. Please choose how raw meats are to be stored in this market (check all that apply).

- Raw meats are to be stored in an area completely separated from RTE foods.
- Raw meats are to be stored in an enclosed container separate from RTE foods.
- Raw meats are to be stored in a temperature controlled environment.
- Vendors have been trained on this market's raw meat storage policy.
- This market does not have a raw meat storage policy.

3.4) Please check how often food contact surfaces should be cleaned and sanitized:

- Food contact surfaces must be cleaned before every use.
- Food contact surfaces must be cleaned after every use.
- Vendors have been trained on this market's food contact cleaning and sanitation policy.
- This market does not have a food contact cleaning and sanitizing policy.

3.5) Check all that apply that describe the market's food contact cleaning and sanitizing procedures.

- Detergents are to be used routinely to wash food contact surfaces per manufacturer's instructions.
- Chemical sanitizers may be used with proper consideration of concentration, temperature, and contact time per manufacturer's instructions.

- All chemical sanitizers must be approved by the FDA for use on food contact surfaces.
- All vendors are trained on proper cleaning and sanitizing procedures.
- This market does not have a food contact cleaning and sanitizing policy.

3.6) Please choose this market's pet policy here:

- No pets of any kind are allowed on the market premises.
- Pets are allowed in the market.
- Only certain kinds of pets are allowed in the market. Please list:

- Other:

- Vendors are aware of the market's pet policy.
- This market does not have a pet policy.

3.7) Check all that apply regarding policies addressing transporting food to the market:

- Vehicles used to transport food to the market must be cleaned regularly to prevent contamination during transport.
- Vehicles used to transport animals or animal products, carcasses, manure, or pesticides must not be used to transport food to the market until the vehicle has been cleaned and disinfected.
- Food products that require temperature control must be transported in coolers with ice or freezer packs to keep temperature at or below 41 °F (refer to section 1: Improper hot/cold holding).

- Vendors have been trained in the policy regarding vehicles used to transport food to the market.
- This market does not have a policy to address transportation of food to the market.

3.8) Containers/bins used to transport food to the market or store/display food at the market may be:

- Single-use cardboard boxes
- Easily-cleaned multiple-use containers such as plastic bins.
- Wooden baskets.
- Wooden bins that are lined with clean cloth or a single-use bag.
- Vendors have been trained in the policy regarding food storage/display bins.
- This market does not have a policy regarding food storage/display bins.

3.9) Food must be stored:

- At least three feet off the ground.
- This market does not have any food storage requirements related to distance off the ground.

Part IV: Food Handler Health and Hygiene

Risk: Sick vendors/food handlers can serve as a source of contamination for foods and should not handle foods while sick. Food handlers can also contaminate foods if proper hygiene (i.e. handwashing) is not performed.

4.1) Hand-washing stations are:

- Available to the public within the market.
- Available to the public in a neighboring building.
- Required at stations in which vendors are selling food prepared on site (vendors must build their own).
- Other:

There are no handwashing stations at this market

4.2) Hand-washing stations must be equipped with (check all that apply):

- Running water
- Soap
- Paper towels
- Trash receptacle
- Receptacle for dirty water (grey water)
- No policy

4.3) Food handler – sick worker policy:

- This market does have a sick policy.
- Vendors are trained on the market's sick policy.
- This market does not have a sick policy.

4.4) First aid kits at the market:

- First aid kits are at the market in a designated location.

- There are no first aid kits at the market.

Part V: Obtaining Food from Unsafe Sources

Risk: Obtaining food that has been prepared and/or grown in unsanitary conditions can lead to contamination.

5.1) Please check when and how often the market manager will visit each vendor's farm and/or kitchen (if selling items made in the vendor's kitchen) for inspection:

- Once before the vendor is approved to sell at the market.
- Every season before each vendor is approved to sell at the market.
- Random short-notice visits throughout each growing season.
- The market manager does not visit the vendor's farm.
- The market manager does not visit the vendor's kitchen (only applies to vendors who are selling food prepared in their kitchen).
- Other: _____

5.2) Please check the market's water use policy here regarding water quality used on the farm (check all that apply):

- Water must be tested for fecal coliform bacteria once a year if well water is used.
- Water must be tested for fecal coliform bacteria quarterly if surface water is used.
- The vendor must keep records of water test results.
- This market does not have a water use policy.

5.3) Please check the market's manure use policy here regarding manure usage on the farm (check all that apply):

- If compost is used, compost must reach internal temperatures between 131 and 170 °F for the appropriate amount of time approved by the USDA and EPA.
- Vendors must keep records of temperature measurements.
- Raw manure may not be used for fertilization.
- If raw manure is used, vendors must wait 120 days before harvesting crops where the edible portion comes in contact with the soil (i.e. potatoes, carrots, beets, lettuce, etc.).
- If raw manure is used, vendors must wait 90 days before harvesting any crop where the edible portion does not come in contact with the soil after incorporation of the raw manure (i.e. tomatoes, peppers, okra, etc.).
- Separate tools must be used for composted manure and raw manure or tools must be properly cleaned and sanitized in between uses to prevent cross contamination.
- Composted manure and raw manure must be stored in separate areas to prevent cross contamination.
- Vendors are trained on the market's manure policy.
- This market does not have a manure policy.

5.4) Please check all that apply for the market's on-farm hygiene and sanitation plan:

- Ill food handlers are prevented from harvesting and having contact with food items.
- All food handlers are trained on proper hygiene procedures such as hand-washing, including when hands should be washed and proper hand-washing procedures.

- Food handlers must be trained on proper glove use during harvesting and/or packing.
- Food handlers must be provided access to hand-washing and toilet facilities when on-farm.
- Food handlers must be trained on basic first aid procedures.
- This market does not require on-farm hygiene and sanitation plans.

CHAPTER 5

Conclusions and Future Directions

This research revealed that regardless of previous food safety training, numerous risky food safety practices were observed at farmers' markets including temperature abuse, cross contamination opportunities, and poor personal hygiene and sanitation. It was found that while 66.7% of vendors used some form of temperature control for temperature-sensitive products, none of the vendors used a thermometer to monitor the temperatures over time. It was also found that 40% of farmers' markets observed in the study did not provide a hand-washing station for vendors or patrons. These results highlight the need for a food safety focus at farmers' markets to encourage proper food safety practices and behaviors.

Additionally, the microbial quality of farmers' market and retail produce was assessed by quantifying total aerobic bacteria and coliforms as well as testing for the presence or absence of generic *E. coli* and foodborne pathogens, *E. coli* O157:H7, *L. monocytogenes*, *S. enterica*, and *S. aureus*. It was found that farmers' market leafy greens, onions and tomatoes had a significantly greater quantity of total aerobic bacteria when compared to a retail grocery store. *S. enterica* was identified in 8.1% of farmers' market samples and 10.3 %of retail samples. Generic *E. coli* was identified in 28.5% and 31.6% of farmers' market and retail samples, respectively. Although the safety of produce purchased from farmers' markets was not significantly different from produce purchased from retail, the identification of pathogens in produce from both locations emphasizes the need for a pathogen reduction focus on fresh produce with both farmers' markets and retail outlets.

To help address food safety needs at farmers' markets, a farmers' market food safety management plan (FSMP) template was developed to help market managers build their own food safety plan for their market. The plan addressed concerns around temperature abuse, cross contamination, personal hygiene and sanitation, cooking foods to the proper temperature and obtaining food from safe sources. While most market managers perceived the FSMP to be practical for their needs, they expressed concern over implementation and most agreed that they would need help to fully utilize this plan.

There are opportunities for this research to be expanded upon in the future. The FSMP can be revised based on feedback and evaluations from market managers. It would help to train local extension agents on how to best utilize and help market managers to implement the FSMP at their market to promote proper food safety practices. It would be useful to pilot the use of the FSMP in the farmers' markets that were observed in the previous study to determine if vendor food safety practices will improve with the implementation of the FSMP. It would also be useful to conduct another microbial assessment study to compare markets who implement the FSMP and market who do not have a food safety plan.

The microbial assessment could be expanded to include quantification of generic *E. coli*, which may give a better indication of the sanitary quality of the produce instead of presence/absence data. It may also be useful to use plating techniques to select for live pathogenic cells only, as opposed to molecular tools that allow for the detection of live and dead cells. It would also be interesting and useful to gather information concerning the presence antibiotic resistant bacteria on samples collected from farmers' markets. Antibiotic-resistant (AR) bacteria are becoming a concern in the public health realm and that field of research would benefit from gathering more data on the presence of AR bacteria in a farmers' market sector.

The farmers' market community would also benefit from continual development of the FSMP and resources to help implement the plan, such as local extension agents. If the plan is proven to be effective at improving food safety practices at markets, it is possible that other markets across the country could benefit from such a plan. Efforts could be placed on the improvement of the current FSMP as well as the development of tools to help market managers fully utilize and implement the plan. Launching the FSMP online could promote use of the plan by markets that would not have access to the plan otherwise, thereby promoting proper food safety practices at farmers' markets across the country.

APPENDIX A

Vendor Observation Instrument

Foods Available:

Check: Place a check mark beside the product name being careful to note whether the product is sold whole or cut.

Table 1. Produce sold by vendors at Southwest Virginia farmers’ markets.

Produce	Whole	Cut	Notes
Acidified foods			
Apples			
Green Beans			
Lima Beans			
Blueberries			
Broccoli			
Cabbage			
Corn			
Cucumbers			
Grapes			
Lettuce			
Melons			
Okra			
Peaches			
Pears			
Peppers			
Potatoes			
Spinach			
Sprouts			
Squash			
Strawberries			
Tomatoes			
Zucchini			

TABLE 2. Vendor observational instrument

	Observational Questions	No	Yes	Comments
1	Is more than one person working the station?			
2	Do the employees appear clean and healthy (i.e. clean hands, no exposed wounds, etc.)?			
3	Are there any signs/certificates displaying good food safety practices?			
4	Are one-use gloves used? Are they used correctly?			
5	Does the vendor have hand sanitizer?			
6	Does the vendor have a hand washing station?			
7	Does the vendor use their hand washing station? Correctly?			
8	Are there any products directly on the ground?			
9	Does the vendor's table appear clean (no dirt or debris)?			
10	Is the table covered? Is it covered with something that is easily cleaned?			
11	Are the products displayed in bins/containers that are easily cleaned?			
12	Are the containers lined?			
13	Are the products stored in bins that are easily cleaned?			
14	Does the vendor have samples?			

15	Are the samples covered on ice (if needed)?			
16	Are the samples prepared on site?			
17	Is a thermometer visible? Are temperatures being recorded (that you can see)?			
18	Is there any (other) visible food safety record keeping that you can see?			
19	Does the same person handle product and money?			
20	Does the vehicle used to transport the products to the market appear clean?			

APPENDIX B

Market Observation Instrument

TABLE 1. Market observational instrument.

Questions	Comments
How many vendors are selling in the market?	
How many vendors are selling produce?	
Are the vendors under a protective covering?	
Are live animals allowed in the market area? Do vendors or patrons have animals with them?	
Does the market have access to electricity?	
Are there any free-standing hand washing stations? If yes, how many?	
Is free-flowing water available?	
Is soap provided?	
Are one use towels provided?	
Are there trash receptacles?	

APPENDIX C

Institutional Review Board application for collection of observational data



Institutional Review Board Research Protocol

Once complete, upload this form as a Word document to the IRB Protocol Management System:
<https://secure.research.vt.edu/irb>

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST?

(<http://www.irb.vt.edu/pages/researchers.htm#conflict>)

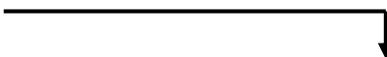
No

Yes, explain:

1.2 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

No, go to question 1.3

Yes, answer questions within table



IF YES

Provide the name of the institution [for institutions located overseas, please also provide

name of country]: North Carolina State University
<p>Indicate the status of this research project with the other institution's IRB:</p> <p><input type="checkbox"/> Pending approval</p> <p><input checked="" type="checkbox"/> Approved</p> <p><input type="checkbox"/> Other institution does not have a human subject protections review board</p> <p><input type="checkbox"/> Other, explain:</p>
<p>Will the collaborating institution(s) be engaged in the research?</p> <p>(http://www.hhs.gov/ohrp/policy/engage08.html)</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p>
<p>Will Virginia Tech's IRB review all human subject research activities involved with this project?</p> <p><input type="checkbox"/> No, provide the name of the primary institution:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><i>Note: primary institution = primary recipient of the grant or main coordinating center</i></p>

1.3 IS THIS RESEARCH FUNDED?

No, go to question 1.4

Yes, answer questions within table 

IF YES

Provide the name of the sponsor [if NIH, specify department]:

Is this project receiving federal funds?

No

Yes

If yes,

Does the grant application, OSP proposal, or “statement of work” related to this project include activities involving human subjects that are not covered within this IRB application?

No, all human subject activities are covered in this IRB application

Yes, however these activities will be covered in future VT IRB applications, these activities include:

Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows:

Yes, however these activities have been or will be reviewed by another institution’s IRB, the name of this institution is as follows:

Other, explain:

Is Virginia Tech the primary awardee or the coordinating center of this grant?

No, provide the name of the primary institution:

Yes

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY?

For example – government / industry proprietary or confidential trade secret information

No

Yes, describe:

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT AGENT OUTSIDE THE U.S.?

No

Yes

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

The purpose of this project is to collect observational and microbiological data from farmers' markets that will be used as the foundation for the creation of education curriculum targeted at enhancing food safety knowledge and prompting behavior change that will result in a reduction of foodborne illness occurrences.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

Through the completion of this project, the results are to be used for publication, dissertation, and the aid in the development of farmers' market food safety educational materials.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

The subject pool will consist of produce vendors at four southwest Virginia farmers' markets. The approximate number of subjects will be 60.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

No, go to question 3.3

Yes, answer questions within table 

IF YES	
Are these records private or public?	
<input type="checkbox"/>	Public
<input type="checkbox"/>	Private, describe the researcher's privilege to the records:
Will student, faculty, and/or staff records or contact information be requested from the University?	
<input type="checkbox"/>	No
<input type="checkbox"/>	Yes, visit the following link for further information:

<http://www.policies.vt.edu/index.php> (policy no. 2010)

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Will talk to local extension agents and farmers' market managers to gain permission to observe the specified farmers' markets. The extension agents and market managers will be told that the study is to help identify risky behavior pertaining to food safety in effort to enhance food safety knowledge and the safe production of foods. There will be no advertisement for recruitment purposes.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

We want to determine the current food safety practices and behaviors at local farmer's markets. This will allow us to create the best future training for this population.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link:

<http://www.irb.vt.edu/pages/consent.htm>

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in

recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

- Verbal consent will be obtained from participants
- Written/signed consent will be obtained from participants
- Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

We will explain what the study is about to the market managers and give them an information sheet describing the project. After the market managers have read the information sheet we will ask for verbal consent to observe the farmers' markets.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Stephanie Pollard

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

At the farmers' markets or prior via email or phone conversation

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

Before the observational study begins

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

Will explain the information sheet to the market managers prior to beginning the study, and will debrief the market managers on key findings after the observation period and answer all questions.

Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

I will obtain permission from market manager to be at the farmer's markets and observe the vendors and facility.

Will explain the information sheet to the market managers thoroughly before collecting any data.

Will observe the markets on pre-determined days for a 3 hour period once a month for three months.

Will debrief the market managers with key findings and answer all questions.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

I will take notes and record data on observational rubric

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITIES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the “Policy for Online Research Data Collection Activities Involving Human Subjects” at <http://www.irb.vt.edu/documents/onlinepolicy.pdf>

No, go to question 6.1

Yes, answer questions within table 

IF YES	
Identify the service / program that will be used:	
<input type="checkbox"/>	www.survey.vt.edu , go to question 6.1
<input type="checkbox"/>	Blackboard, go to question 6.1
<input type="checkbox"/>	Center for Survey Research, go to question 6.1
<input type="checkbox"/>	Other
IF OTHER:	
Name of service / program:	
URL:	
This service is...	
<input type="checkbox"/>	Included on the list found at: http://www.irb.vt.edu/pages/validated.htm
<input type="checkbox"/>	Approved by VT IT Security
<input type="checkbox"/>	An external service with proper SSL or similar encryption (https://)

on the login (if applicable) and all other data collection pages.

- None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

There are no more than minimal risks

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

There is minimal risk - an information sheet will be explained to market managers and participation is voluntary. Market managers will be allowed to ask questions as needed to clarify as much as possible before and after the research.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

Through the completion of this project and the implementation of the food safety curriculum generated, the risk of local food producers contributing to a foodborne outbreak will be greatly reduced, which will, in turn, contribute to the economic viability of the local food system as a whole.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

No

Yes

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR MENTALLY DISABLED PERSONS?

No, go to question 7.3

Yes, answer questions within table 

IF YES	
This research involves:	
<input type="checkbox"/> Prisoners	
<input type="checkbox"/> Pregnant women	<input type="checkbox"/> Fetuses <input type="checkbox"/> Human in vitro fertilization
<input type="checkbox"/> Mentally disabled persons	

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (<http://www.irb.vt.edu/pages/categories.htm>), it will not need to go to the Full Board.

No

Yes

IF YOU ANSWERED “YES” TO **ANY ONE** OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT’S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: <http://www.irb.vt.edu/pages/deadlines.htm>

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link:
<http://www.irb.vt.edu/pages/confidentiality.htm>

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

No

Yes, to whom will identifying data be released?

8.2 WILL ANY STUDY FILES CONTAIN PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select “Yes.”

No, go to question 8.3

Yes, answer questions within table 

IF YES
<p>Describe if/how the study will utilize study codes:</p>
<p>If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] be stored and who will have access?</p> <p><i>Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.</i></p>
<p><i>The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.</i></p>

8.3 WHERE WILL DATA BE STORED?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

In a locked file cabinet

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

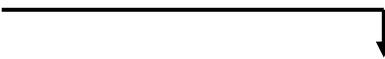
The research team members

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

Observational data will be destroyed - shredded

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

No, go to question 9.1

Yes, answer questions within table 

IF YES
<p>Does the study plan to obtain a Certificate of Confidentiality?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form)</p> <p><i>For more information about Certificates of Confidentiality, visit the following link:</i> http://www.irb.vt.edu/pages/coc.htm</p>

Section 9: Compensation

For more information about compensating subjects, visit the following link:
<http://www.irb.vt.edu/pages/compensation.htm>

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

No, go to question 10.1

Yes, answer questions within table 

IF YES

What is the amount of compensation?

Will compensation be prorated?

Yes, please describe:

No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link:
<http://www.irb.vt.edu/pages/recordings.htm>

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

No, go to question 11.1

Yes, answer questions within table



IF YES
<p>This project involves:</p> <p><input type="checkbox"/> Audio recordings only</p> <p><input type="checkbox"/> Video recordings only</p> <p><input type="checkbox"/> Both video and audio recordings</p>
<p>Provide compelling justification for the use of audio/video recording:</p>
<p>How will data within the recordings be retrieved / transcribed?</p>
<p>How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?</p>
<p>Who will have access to the recordings?</p>
<p>Who will transcribe the recordings?</p>
<p>When will the recordings be erased / destroyed?</p>

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

No, go to question 12.1

Yes, answer questions within table 

IF YES
<p>Does this study involve conducting research with students of the researcher?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation:</p> <p><i>Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.</i></p>
<p>Will the study need to access student records (e.g., SAT, GPA, or GRE scores)?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes</p>

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

No, go to question 11.3

Yes, answer questions within table 

IF YES

Will study procedures be completed during school hours?

No

Yes

If yes,

Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:

Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:

Is the school's approval letter(s) attached to this submission?

Yes

No, project involves Montgomery County Public Schools (MCPS)

No, explain why:

You will need to obtain school approval (if involving MCPS, click here: <http://www.irb.vt.edu/pages/mcps.htm>). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

No, go to question 12.1

Yes, answer questions within table



IF YES

Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded:

Included

Actively excluded, describe how the study will ensure that minors will not be included:

Will extra credit be offered to subjects?

No

Yes

If yes,

What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

Include a description of the extra credit (e.g., amount) to be provided within question 9.1 ("IF YES" table)

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

No, go to question 13.1

Yes, answer questions within table 

IF YES
<p>Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, thoroughly explain how the study will react to such reports:</p> <p><i>Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.</i></p>
<p>Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)?</p> <p><input type="checkbox"/> No, both parents/guardians will provide their permission, if possible.</p> <p><input type="checkbox"/> No, only one parent/guardian will provide permission.</p> <p><input type="checkbox"/> Yes, describe below how your research meets all of the following criteria (A-D):</p> <p style="padding-left: 40px;">Criteria A - The research involves no more than minimal risk to the subjects:</p> <p style="padding-left: 40px;">Criteria B - The waiver will not adversely affect the rights and welfare of the subjects:</p> <p style="padding-left: 40px;">Criteria C - The research could not practicably be carried out without the waiver:</p> <p style="padding-left: 40px;">Criteria D - (Optional) Parents will be provided with additional pertinent information after</p> <p style="padding-left: 80px;">participation:</p>
Is it possible that minor research participants will reach the legal age of consent (18 in

Virginia) while enrolled in this study?

No

Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors' previously provided assent and parents' permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects' data? If yes, explain how:

For more information about minors reaching legal age during enrollment, visit the following link: <http://www.irb.vt.edu/pages/assent.htm>

*The procedure for obtaining assent from minors and permission from the minor's guardian(s) must be described in **Section 4** (Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at <http://www.irb.vt.edu/pages/deception.htm>

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

No, go to question 14.1

Yes, answer questions within table



IF YES

Describe the deception: The market managers will be aware of the observational study taking place, however, the individual vendors at the farmers' markets will

not.

Why is the use of deception necessary for this project? Deception is necessary to prevent the vendors from changing his/her normal behavior. If the vendors knew I was observing their actions related to food safety, they would likely change their behavior to incorporate more food safety practices.

Describe the debriefing process: I will explain to the market managers why the use of deception was necessary for this study and answer any questions he/she might have. I will also explain the data that was collected and ask for permission to use the data and obtain consent to do so. If the market manager doesn't allow me to use the data the information will be destroyed.

Provide an explanation of how the study meets all the following criteria (A-D) for an alteration of consent:

Criteria A - The research involves no more than minimal risk to the subjects: **I will only be observing the farmer's market vendors in their usual work environment without their knowledge - the market managers will know.**

Criteria B - The alteration will not adversely affect the rights and welfare of the subjects: **I will have consent from the market managers to observe the market and the data collected will remain anonymous.**

Criteria C - The research could not practicably be carried out without the alteration: **Without the use of deception, the farmer's market vendors would likely alter their actions and create data that did not accurately depict the events.**

Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception): **The subjects will be debriefed at the end of the study and will learn why the deception was necessary. I will also answer any questions they might have.**

By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.

The IRB requests that the researcher use the title "Information Sheet" instead of "Consent

Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

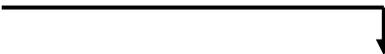
Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

No, you are finished with the application

Yes, answer questions within table



IF YES
From where does the existing data originate?
Provide a detailed description of the existing data that will be collected or studied/analyzed:
Is the source of the data public? <input type="checkbox"/> No, continue with the next question <input type="checkbox"/> Yes, you are finished with this application

Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:

- **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or
- **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc
or
- **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

No, collected/analyzed data will be completely de-identified

Yes,

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

-----END-----

APPENDIX D

Information sheet pertaining to observational data collection

VIRGINIA TECH

Information Sheet for Participants in Research Projects Involving Human Subjects

Investigators: Dr. Renee Boyer, Ms. Stephanie Pollard

Extension Agents: Ms. Joell Eifert, Ms. Dawn Barnes

I. Purpose of the Research/Project:

The purpose of this research project is to gain an understanding of food safety practices and behaviors at farmers' markets. The goal of this project is to collect observational data from farmers' markets that will be used as the foundation for the creation of education curriculum targeted at enhancing food safety knowledge and prompting behavior change that will result in a reduction of foodborne illness occurrences linked to farmers' markets.

II. Procedures:

Farmer's market facilities and vendors will be observed once a month for three months for approximately three hours at a time. The market vendors will be unaware of the observation taking place.

III. Risks:

There are no risks associated with this research.

IV. Benefits:

The observational data collected will help in the development of training programs and educational curriculum to enhance food safety knowledge and practices at farmers' markets.

V. Extent of Anonymity and Confidentiality:

The observational data collected is for research purposes only. This information will be kept confidential and anonymous. Neither you nor the vendors at your respective markets will be identified nor will the researchers release your individual results of the study to anyone other than the research team working on the project. "It is possible that the Institutional Review Board (IRB) may view this study's collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research."

VI. Compensation

By taking part in this research you will receive no direct compensation.

VII. Freedom to Withdraw

You are free to withdraw your market(s) from this study at any time without penalty.

There may be circumstances under which the investigator may determine that you should not continue as a subject.

VIII. Subject's Responsibilities:

You voluntarily agree to allow your respective market(s) to take part in this study. You are to keep the observational study private from the vendors so that they will complete their job as normal.

Should you have any pertinent questions about this research or its conduct, and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects, you may contact:

Renee R. Boyer

Associate Professor
103 Food Science Bldg.
22 Duck Pond Road
Blacksburg, VA 24061
rrboyer@vt.edu
540-231-4330

Stephanie Pollard

Graduate Research Assistant
103 Food Science Bldg.
22 Duck Pond Road
Blacksburg, VA 24061
spollard@vt.edu

APPENDIX E



Office of Research Compliance
Institutional Review Board
North End Center, Suite 4120, Virginia Tech
300 Turner Street NW
Blacksburg, Virginia 24061
540/231-4606 Fax 540/231-0959
email irb@vt.edu
website <http://www.irb.vt.edu>

MEMORANDUM

DATE: February 27, 2015
TO: Renee Raiden Boyer, Stephanie Kay Pollard, Monica Anne Ponder
FROM: Virginia Tech Institutional Review Board (FWA00000572, expires April 25, 2018)
PROTOCOL TITLE: Farmers' Market Food Safety
IRB NUMBER: 13-562

Effective June 20, 2013, the Virginia Tech Institutional Review Board (IRB) Chair, David M Moore, approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

<http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Exempt, under 45 CFR 46.110 category(ies) 2**
Protocol Approval Date: **June 20, 2013**
Protocol Expiration Date: **N/A**
Continuing Review Due Date*: **N/A**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

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